DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–2010–0034]

RIN 1218–AB70

Occupational Exposure to Respirable Crystalline Silica

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes to amend its existing standards for occupational exposure to respirable crystalline silica. The basis for issuance of this proposal is a preliminary determination by the Assistant Secretary of Labor for Occupational Safety and Health that employees exposed to respirable crystalline silica face a significant risk to their health at the current permissible exposure limits and that promulgating these proposed standards will substantially reduce that risk.

This document proposes a new permissible exposure limit, calculated as an 8-hour time-weighted average, of 50 micrograms of respirable crystalline silica per cubic meter of air (50 μg/m^3). OSHA also proposes other ancillary provisions for employee protection such as preferred methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. OSHA is proposing two separate regulatory texts—one for general industry and maritime, and the other for construction—in order to tailor requirements to the circumstances found in these sectors.

DATES: *Written comments.* Written comments, including comments on the information collection determination described in Section IX of the preamble (OMB Review under the Paperwork Reduction Act of 1995), must be submitted (postmarked, sent, or received) by December 11, 2013.

Informal public hearings. The Agency plans to hold informal public hearings beginning on March 4, 2014, in Washington, DC. OSHA expects the hearings to last from 9:30 a.m. to 5:30 p.m., local time; a schedule will be released prior to the start of the hearings. The exact daily schedule may be amended at the discretion of the presiding administrative law judge (ALJ). If necessary, the hearings will continue at the same time on subsequent days. Peer reviewers of OSHA's Health Effects Literature Review and Preliminary Quantitative Risk Assessment will be present in Washington, DC to hear testimony on the second day of the hearing, March 5, 2014; *see* Section XV for more information on the peer review process.

Notice of intention to appear at the hearings. Interested persons who intend to present testimony or question witnesses at the hearings must submit (transmit, send, postmark, deliver) a notice of their intention to do so by November 12, 2013. The notice of intent must indicate if the submitter requests to present testimony in the presence of the peer reviewers.

Hearing testimony and documentary evidence. Interested persons who request more than 10 minutes to present testimony, or who intend to submit documentary evidence, at the hearings must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence by December 11, 2013. *See* Section XV below for details on the format and how to file a notice of intention to appear, submit documentary evidence at the hearing, and request an appropriate amount of time to present testimony.

ADDRESSES: *Written comments.* You may submit comments, identified by Docket No. OSHA–2010–0034, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions on-line for making electronic submissions.

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: You must submit your comments to the OSHA Docket Office, Docket No. OSHA–2010–0034, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger, or courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., E.T.

Instructions: All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA–2010–0034). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.,* consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific and technical analyses, OSHA requests that you disclose: (1) The nature of any financial relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party prior to its submission. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

Informal public hearings. The Washington, DC hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Notice of intention to appear, hearing testimony and documentary evidence. You may submit (transmit, send, postmark, deliver) your notice of intention to appear, hearing testimony, and documentary evidence, identified by docket number (OSHA–2010–0034), by any of the following methods:

Electronically: http://www.regulations.gov. Follow the instructions online for electronic submission of materials, including attachments.

Fax: If your written submission does not exceed 10 pages, including attachments, you may fax it to the OSHA Docket Office at (202) 693–1648.

Regular mail, express delivery, hand delivery, and messenger and courier service: Submit your materials to the OSHA Docket Office, Docket No. OSHA–2010–0034, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (TTY number (877) 889–5627). Deliveries (express mail, hand delivery, and messenger and courier service) are accepted during the Department of Labor's and OSHA Docket Office's normal hours of operation, 8:15 a.m. to 4:45 p.m., ET.

Instructions: All submissions must include the Agency name and docket number for this rulemaking (Docket No. OSHA–2010–0034). All submissions, including any personal information, are placed in the public docket without change and may be available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting certain personal information, such as social security numbers and birthdates. Because of security-related procedures, the use of regular mail may cause a significant delay in the receipt of your submissions. For information about security-related procedures for submitting materials by express delivery, hand delivery, messenger, or courier service, please contact the OSHA Docket Office. For additional information on submitting notices of intention to appear, hearing testimony or documentary evidence, *see* Section XV of this preamble, Public Participation.

Docket: To read or download comments, notices of intention to appear, and materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA–2010–0034 at *http://www.regulations.gov* or to the OSHA Docket Office at the address above. All comments and submissions are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All comments and submissions are available for inspection and, where permissible, copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://regulations.gov.* Copies also are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1888. This document, as well as news releases and other relevant information, is also available at OSHA's Web site at *http://www.osha.gov.*

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999. For technical inquiries, contact William Perry or David O'Connor, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1950 or fax (202) 693–1678. For hearing inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

SUPPLEMENTARY INFORMATION:

The preamble to the proposed standard on occupational exposure to respirable crystalline silica follows this outline:

OSHA currently enforces permissible exposure limits (PELs) for respirable crystalline silica in general industry, construction, and shipyards. These PELs were adopted in 1971, shortly after the Agency was created, and have not been updated since then. The PEL for quartz (the most common form of crystalline silica) in general industry is a formula that is approximately equivalent to 100 micrograms per cubic meter of air (μg/m³) as an 8-hour time-weighted average. The PEL for quartz in construction and shipyards is a formula based on a now-obsolete particle count sampling method that is approximately equivalent to 250 μg/m³. The current PELs for two other forms of crystalline silica (cristobalite and tridymite) are one-half of the values for quartz in general industry. OSHA is proposing a new PEL for respirable crystalline silica (quartz, cristobalite, and tridymite) of 50 μg/m³ in all industry sectors covered by the rule. OSHA is also proposing other elements of a comprehensive health standard, including requirements for exposure assessment, preferred methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping.

OSHA's proposal is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. *See* Section II of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases, including chronic obstructive pulmonary disease (COPD).

As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in Section VIII of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA directed Inforum—a not-for-profit corporation (based at the University of Maryland) well recognized for its macroeconomic modeling—to run its LIFT (Long-term Interindustry Forecasting Tool) model of the U.S. economy to estimate the industry and aggregate employment effects of the proposed silica rule. Inforum developed estimates of the employment impacts over the ten-year period from 2014–2023 by feeding OSHA's year-by-year and industry-by-industry estimates of the compliance costs of the proposed rule into its LIFT model. Based on the resulting Inforum estimates of employment impacts, OSHA has preliminarily concluded that the proposed rule would have a negligible—albeit slightly positive—net impact on aggregate U.S. employment.

OSHA believes that a new PEL, expressed as a gravimetric measurement of respirable crystalline silica, will improve compliance because the PEL is simple and relatively easy to understand. In comparison, the existing PELs require application of a formula to account for the crystalline silica content of the dust sampled and, in the case of the construction and shipyard PELs, a conversion from particle count to mg/m³ as well. OSHA also expects that the approach to methods of compliance for construction operations included in this proposal will improve compliance with the standard. This approach, which specifies exposure control methods for selected construction operations, gives employers a simple option to identify the control measures that are appropriate for these operations. Alternately, employers could conduct exposure assessments to determine if worker exposures are in compliance with the PEL. In either case, the proposed rule would provide a basis for ensuring that appropriate measures are in place to limit worker exposures.

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires that OSHA either certify that a rule would not have a significant economic impact on a substantial number of small firms or prepare a regulatory flexibility analysis and hold a Small Business Advocacy Review (SBAR) Panel prior to proposing the rule. OSHA has determined that a regulatory flexibility analysis is needed and has provided this analysis in Section VIII.G of this preamble. OSHA also previously held a SBAR Panel for this rule. The recommendations of the Panel and OSHA's response to them are summarized in Section VIII.G of this preamble.

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget, and the remainder of this section summarizes the key findings of the analysis with respect to costs and benefits of the rule and then presents several possible alternatives to the rule.

Table SI–1—which, like all the tables in this section, is derived from material presented in Section VIII of this preamble—provides a summary of OSHA's best estimate of the costs and benefits of the proposed rule using a discount rate of 3 percent. As shown, the proposed rule is estimated to prevent 688 fatalities and 1,585 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $637 million annually. Also as shown in Table SI–1, the discounted monetized benefits of the proposed rule are estimated to be $5.3 billion annually, and the proposed rule is estimated to generate net benefits of $4.6 billion annually. These estimates are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed silica rule. The courts have ruled that OSHA may not use benefit-cost analysis or a criterion of maximizing net benefits as a basis for setting OSHA health standards.[1]

[1] *Am. Textile Mfrs. Inst., Inc.* v. *Nat'l Cotton Council of Am.*, 452 U.S. 490, 513 (1981); *Pub. Citizen Health Research Group* v. *U.S. Dep't of Labor,* 557 F.3d 165, 177 (3d Cir. 2009); *Friends of the Boundary Waters Wilderness* v. *Robertson,* 978 F.2d 1484, 1487 (8th Cir. 1992).

Table SI-1: Annualized Benefits, Costs and Net Benefits of OSHA's Proposed Silica Standard of 50 μg/m³

Discount Rate		**3%**
Annualized Costs		
Engineering Controls (includes Abrasive Blasting)		$329,994,068
Respirators		$90,573,449
Exposure Assessment		$72,504,999
Medical Surveillance		$76,233,932
Training		$48,779,433
Regulated Area or Access Control		$19,243,500
Total Annualized Costs (point estimate)		**$637,329,380**
Annual Benefits: Number of Cases Prevented		
Fatal Lung Cancers (midpoint estimate)	162	
Fatal Silicosis & other Non-Malignant Respiratory Diseases	375	
Fatal Renal Disease	151	
Silica-Related Mortality	688	$3,268,102,481
Silicosis Morbidity	1,585	$1,986,214,921
Monetized Annual Benefits (midpoint estimate)		**$5,254,317,401**
Net Benefits		**$4,616,988,022**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Both the costs and benefits of Table SI–1 reflect the incremental costs and benefits associated with achieving full compliance with the proposed rule. They do not include (a) costs and benefits associated with current compliance that have already been achieved with regard to the new requirements, or (b) costs and benefits associated with achieving compliance with existing requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements. They also do not include costs or benefits associated with relatively rare, extremely high exposures that can lead to acute silicosis.

Subsequent to completion of the PEA, OSHA identified an industry, hydraulic fracturing, that would be impacted by the proposed standard. Hydraulic fracturing, sometimes called ''fracking,'' is a process used to extract natural gas and oil deposits from shale and other tight geologic formations. A recent cooperative study by the National Institute for Occupational Safety and Health (NIOSH) and industry partners identified overexposures to silica among workers conducting hydraulic fracturing operations. An industry focus group has been working with OSHA and NIOSH to disseminate information about this hazard, share best practices, and develop engineering controls to limit worker exposures to silica. OSHA finds that there are now sufficient data to provide the main elements of the economic analysis for this rapidly growing industry and has done so in Appendix A to the PEA.

Based on recent data from the U.S. Census Bureau and industry sources, OSHA estimates that roughly 25,000 workers in 444 establishments (operated by 200 business entities) in hydraulic fracturing would be affected by the proposed standard. Annual benefits of the proposed 50 μg/m³ PEL include approximately 12 avoided fatalities—2.9 avoided lung cancers (mid-point estimate), 6.3 prevented non-cancer respiratory illnesses, and 2.3 prevented cases of renal failure—and 40.8 avoided cases of silicosis morbidity. Monetized benefits are expected to range from $75.1 million at a seven percent discount rate to $105.4 million at a three percent discount rate to undiscounted benefits of $140.3 million. OSHA estimates that under the proposed standard, annualized compliance costs for the hydraulic fracturing industry will total $28.6 million at a discount rate of 7 percent or $26.4 million at a discount rate of 3 percent.

In addition to the proposed rule itself, this preamble discusses several regulatory alternatives to the proposed OSHA silica standard. These are presented below as well as in Section VIII of this preamble. OSHA believes that this presentation of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to respirable crystalline silica. The second is tied to the Agency's statutory requirement, which underlies the proposed rule, to reduce significant risk to the extent feasible. If, based on evidence presented during notice and comment, OSHA is unable to justify its preliminary findings of significant risk and feasibility as presented in this preamble to the proposed rule, the Agency must then consider regulatory alternatives that do satisfy its statutory obligations.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m³; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

In addition, OSHA would like to draw attention to one possible modification to the proposed rule, involving methods of compliance, that the Agency would not consider to be a legitimate regulatory alternative: To permit the use of respiratory protection as an alternative to engineering and work practice controls as a primary means to achieve the PEL.

As described in Section XVI of the preamble, Summary and Explanation of the Proposed Standards, OSHA is proposing to require primary reliance on engineering controls and work practices because reliance on these methods is consistent with long-established good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with the Agency's traditional adherence to a hierarchy of preferred controls. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see AFL–CIO* v. *Marshall,* 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers* v. *Marshall,* 647 F.2d 1189 (D.C. Cir. 1980), *cert. denied,* 453 U.S. 913 (1981) (lead standard); *ASARCO* v. *OSHA,* 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel* v. *OSHA,* 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen* v. *U.S. Dep't of Labor,* 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

Engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored, allow for predictable performance levels, and can efficiently remove a toxic substance from the workplace. Once removed, the toxic substance no longer poses a threat to employees. The effectiveness of engineering controls does not generally depend on human behavior to the same extent as personal protective equipment does, and the operation of equipment is not as vulnerable to human error as is personal protective equipment.

Respirators are another important means of protecting workers. However, to be effective, respirators must be individually selected; fitted and periodically refitted; conscientiously and properly worn; regularly maintained; and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any of these conditions can reduce or eliminate the protection that respirators provide to some or all of the employees who wear them.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators impose substantial physiological burdens on some employees. Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees. These concerns about the burdens placed on workers by the use of respirators are the basis for the requirement that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace. Although experience in industry shows that most healthy workers do not have physiological problems wearing properly chosen and fitted respirators, common health problems can sometime preclude an employee from wearing a respirator. Safety problems created by respirators that limit vision and communication must also be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult and fatiguing.

Because respirators are less reliable than engineering and work practice controls and may create additional problems, OSHA believes that primary reliance on respirators to protect workers is generally inappropriate when feasible engineering and work practice controls are available. All OSHA substance-specific health standards have recognized and required employers to observe the hierarchy of controls, favoring engineering and work practice controls over respirators. OSHA's PELs, including the current PELs for respirable crystalline silica, also incorporate this hierarchy of controls. In addition, the industry consensus standards for crystalline silica (ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities) incorporate the hierarchy of controls.

It is important to note that the very concept of technological feasibility for OSHA standards is grounded in the hierarchy of controls. As indicated in Section II of this preamble, Pertinent Legal Authority, the courts have clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. [*See United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980)]

Allowing use of respirators instead of engineering and work practice controls would be at odds with this framework for evaluating the technological feasibility of a PEL.

Alternative PELs

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industry sectors covered by the rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³).

Tables SI–2 and SI–3 present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m³ and for the regulatory alternatives of a PEL of 100 μg/m³ and a PEL of 25 μg/m³ (Regulatory Alternatives #1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m³ to the proposed PEL of 50 μg/m³ and then of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Table

SI–2 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table SI–3 breaks out costs and benefits by major industry sector.

Table SI-2: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Table SI-3: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

As Tables SI–2 and SI–3 show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its preliminary findings that the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables SI–2 and SI–3 also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA preliminarily determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables SI–2 and SI–3, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other than the PEL), including requirements for exposure assessment, medical surveillance, training, and regulated areas or access control. As shown in Table SI–2, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in this preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) Help ensure that the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table SI–4. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Table SI-4: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	—	—	—
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	—	—	—
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Under Regulatory Alternative #3, the action level would be raised from 25 μg/ m^3 to 50 μg/m^3 while keeping the PEL at 50 μg/m^3. As a result, exposure monitoring requirements would be triggered only if workers were exposed above the proposed PEL of 50 μg/m³. As shown in Table SI–4, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table SI–4, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table SI–4, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table SI–4, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed construction standard, employers would be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under that regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

OSHA will strongly consider alternatives that would reduce the economic impact of the rule and provide additional flexibility for firms coming into compliance with the requirements of the rule. The Agency solicits comment and suggestions from stakeholders, particularly small business representatives, on options for phasing in requirements for engineering controls, medical surveillance, and other provisions of the rule (*e.g.,* over 1, 2, 3, or more years). These options will be considered for specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

Although OSHA did not explicitly develop or quantitatively analyze the multitude of potential regulatory alternatives involving longer-term or more complex phase-ins of the standard, the Agency is soliciting comments on this issue. Such a particularized, multi-year phase-in could have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. Second, a differential phase-in for smaller firms would aid very small firms by allowing them to gain from the control experience of larger firms. Finally, a phase-in would be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard.

OSHA analyzed one regulatory alternative (Regulatory Alternative #9) involving the timing of the standard which would arise if, contrary to OSHA's preliminary findings, a PEL of 50 μg/m³ with an action level of 25 μg/m³ were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 μg/m³ and an action level of 25 μg/m³ to take effect in five years, but at the same time issue an interim PEL of 100 μg/m³ and an action level of 50 μg/m³ to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 μg/m³ with an action level of 50 μg/m³ and those estimated for a PEL of 50 μg/m³ with an action level of 25 μg/m³, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

I. Issues

OSHA requests comment on all relevant issues, including health effects, risk assessment, significance of risk, technological and economic feasibility, and the provisions of the proposed regulatory text. In addition, OSHA requests comments on all of the issues raised by the Small Business Regulatory Fairness Enforcement Act (SBREFA) Panel, as summarized in Table VIII–H–4 in Section VIII.H of this preamble.

OSHA is including Section I on issues at the beginning of the document to assist readers as they review the proposal and consider any comments they may want to submit. However, to fully understand the questions in this section and provide substantive input in response to them, the parts of the preamble that address these issues in detail should be read and reviewed. These include: Section V, Health Effects Summary; Section VI, Summary of the Preliminary Quantitative Risk Assessment; Section VII, Significance of Risk; Section VIII, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis; and Section XVI, Summary and Explanation of the Standards. In addition, OSHA invites comment on additional technical questions and discussions of economic issues presented in the Preliminary Economic Analysis (PEA) of the proposed standards. Section XIX is the text of the standards and is the final authority on what is required in them.

OSHA requests that comments be organized, to the extent possible, around the following issues and numbered questions. Comment on particular provisions should contain a heading setting forth the section and the paragraph in the standard that the comment is addressing. Comments addressing more than one section or paragraph will have correspondingly more headings.

Submitting comments in an organized manner and with clear reference to the issue raised will enable all participants to easily see what issues the commenter addressed and how they were addressed. This is particularly important in a rulemaking such as silica, which has multiple adverse health effects and affects many diverse processes and industries. Many commenters, especially small businesses, are likely to confine their interest (and comments) to the issues that affect them, and they will benefit from being able to quickly identify comments on these issues in others' submissions. Of course, the Agency welcomes comments concerning this proposal that fall outside the issues raised in this section. However, OSHA is especially interested in responses, supported by evidence and reasons, to the following questions:

Health Effects

1. OSHA has described a variety of studies addressing the major adverse health effects that have been associated with exposure to respirable crystalline silica. Has OSHA adequately identified and documented all critical health impairments associated with occupational exposure to respirable crystalline silica? If not, what adverse health effects should be added? Are there any additional studies, other data, or information that would affect the information discussed or significantly change the determination of material health impairment? Submit any relevant information, data, or additional studies (or the citations), and explain your reasoning for recommending the inclusion of any studies you suggest.

2. Using currently available epidemiologic and experimental studies, OSHA has made a preliminary determination that respirable crystalline silica presents risks of lung cancer, silicosis, and non-malignant respiratory disease (NMRD) as well as autoimmune and renal disease risks to exposed workers. Is this determination correct? Are there additional studies or other data OSHA should consider in evaluating any of these adverse health risks? If so, submit the studies (or citations) and other data and include your reasons for finding them germane to determining adverse health effects of exposure to crystalline silica.

Risk Assessment

3. OSHA has relied upon risk models using cumulative respirable crystalline silica exposure to estimate the lifetime risk of death from occupational lung cancer, silicosis, and NMRD among exposed workers. Additionally, OSHA has estimated the lifetime risk of silicosis morbidity among exposed workers. Is cumulative exposure the correct metric for exposure for each of these models? If not, what exposure measure should be used?

4. Some of the literature OSHA reviewed indicated that the risk of contracting accelerated silicosis and lung cancer may be non-linear at very high exposures and may be described by an exposure dose rate health effect model. OSHA used the more conservative model of cumulative exposure that is more protective to the worker. Are there additional data to support or rebut any of these models used by OSHA? Are there other models that OSHA should consider for estimating lung cancer, silicosis, or NMRD risk? If so, describe the models and the rationale for their use.

5. Are there additional studies or sources of data that OSHA should have included in its qualitative and quantitative risk assessments? What are these studies and have they been peer-reviewed, or are they soon to be peer-reviewed? What is the rationale for recommending the studies or data?

6. Steenland et al. (2001a) pooled data from 10 cohort studies to conduct an analysis of lung cancer mortality among silica-exposed workers. Can you provide quantitative lung cancer risk estimates from other data sources? Have or will the data you submit be peer-reviewed? OSHA is particularly interested in quantitative risk analyses that can be conducted using the industrial sand worker studies by McDonald, Hughes, and Rando (2001) and the pooled center-based case-control study conducted by Cassidy et al. (2007).

7. OSHA has made a preliminary determination that the available data are not sufficient or suitable for quantitative analysis of the risk of autoimmune disease, stomach cancer, and other cancer and non-cancer health effects. Do you have, or are you aware of, studies, data, and rationale that would be suitable for a quantitative risk assessment for these adverse health effects? Submit the studies (or citations), data, and rationale.

Profile of Affected Industries

8. In its PEA of the proposed rule, summarized in Section VIII of this preamble, OSHA presents a profile of the affected worker population. The profile includes estimates of the number of affected workers by industry sector or operation and job category, and the distribution of exposures by job category. If your company has potential worker exposures to respirable crystalline silica, is your industry among those listed by North American Industry Classification System (NAICS) code as affected industries? Are there additional data that will enable the Agency to refine its profile of the worker population exposed to respirable crystalline silica? If so, provide or reference such data and explain how OSHA should use these data to revise the profile.

Technological and Economic Feasibility of the Proposed PEL

9. What are the job categories in which employees are potentially exposed to respirable crystalline silica in your company or industry? For each job category, provide a brief description of the operation and describe the job activities that may lead to respirable crystalline silica exposure. How many employees are exposed, or have the potential for exposure, to respirable crystalline silica in each job category in your company or industry? What are the frequency, duration, and levels of exposures to respirable crystalline silica in each job category in your company or industry? Where responders are able to provide exposure data, OSHA requests that, where available, exposure data be personal samples with clear descriptions of the length of the sample, analytical method, and controls in place. Exposure data that provide information concerning the controls in place are more valuable than exposure data without such information.

10. Please describe work environments or processes that may expose workers to cristobalite. Please provide supporting evidence, or explain the basis of your knowledge.

11. Have there been technological changes within your industry that have influenced the magnitude, frequency, or duration of exposure to respirable crystalline silica or the means by which employers attempt to control such exposures? Describe in detail these technological changes and their effects on respirable crystalline silica exposures and methods of control.

12. Has there been a trend within your industry or an effort in your firm to reduce or eliminate respirable crystalline silica from production processes, products, and services? If so, please describe the methods used and provide an estimate of the percentage reduction in respirable crystalline silica, and the extent to which respirable crystalline silica is still necessary in specific processes within product lines or production activities. If you have substituted another substance(s) for crystalline silica, identify the substance(s) and any adverse health effects associated with exposure to the substitute substances, and the cost impact of substitution (cost of materials, productivity impact). OSHA also

requests that responders describe any health hazards or technical, economic, or other deterrents to substitution.

13. Has your industry or firm used outsourcing or subcontracting, or concentrated high exposure tasks in-house, in order to expose fewer workers to respirable crystalline silica? An example would be subcontracting for the removal of hardened concrete from concrete mixing trucks, a task done typically 2–4 times a year, to a specialty subcontractor. What methods have you used to reduce the number of workers exposed to respirable crystalline silica and how were they implemented? Describe any trends related to concentration of high exposure tasks and provide any supporting information.

14. Does any job category or employee in your workplace have exposures to respirable crystalline silica that air monitoring data do not adequately portray due to the short duration, intermittent or non-routine nature, or other unique characteristics of the exposure? Explain your response and indicate peak levels, duration, and frequency of exposures for employees in these job categories.

15. OSHA requests the following information regarding engineering and work practice controls to control exposure to crystalline silica in your workplace or industry:

a. Describe the operations and tasks in which the proposed PEL is being achieved most of the time by means of engineering and work practice controls.

b. What engineering and work practice controls have been implemented in these operations and tasks?

c. For all operations and tasks in facilities where respirable crystalline silica is used, what engineering and work practice controls have been implemented to control respirable crystalline silica? If you have installed engineering controls or adopted work practices to reduce exposure to respirable crystalline silica, describe the exposure reduction achieved and the cost of these controls.

d. Where current work practices include the use of regulated areas and hygiene facilities, provide data on the implementation of these controls, including data on the costs of installation, operation, and maintenance associated with these controls.

e. Describe additional engineering and work practice controls that could be implemented in each operation where exposure levels are currently above the proposed PEL to further reduce exposure levels.

f. When these additional controls are implemented, to what levels can exposure be expected to be reduced, or what percent reduction is expected to be achieved?

g. What amount of time is needed to develop, install, and implement these additional controls? Will the added controls affect productivity? If so, how?

h. Are there any processes or operations for which it is not reasonably possible to implement engineering and work practice controls within one year to achieve the proposed PEL? If so, how much additional time would be necessary?

16. OSHA requests information on whether there are any specific conditions or job tasks involving exposure to respirable crystalline silica where engineering and work practice controls are not available or are not capable of reducing exposure levels to or below the proposed PEL most of the time. Provide data and evidence to support your response.

17. OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. OSHA has further made a preliminary determination that the proposed rule is technologically feasible. OSHA solicits comments on the reasonableness of these preliminary determinations.

Compliance Costs

18. In its PEA (summarized in Section VIII.3 of this preamble), OSHA developed its estimate of the costs of the proposed rule. The Agency requests comment on the methodological and analytical assumptions applied in the cost analysis. Of particular importance are the unit cost estimates provided in tables and text in Chapter V of the PEA for all major provisions of the proposed rule. OSHA requests the following information regarding unit and total compliance costs:

a. If you have installed engineering controls or adopted work practices to reduce exposure to respirable crystalline silica, describe these controls and their costs. If you have substituted another substance(s) for crystalline silica, what has been the cost impact of substitution (cost of materials, productivity impact)?

b. OSHA has proposed to limit the prohibition on dry sweeping to situations where this activity could contribute to exposure that exceeds the PEL and estimated the costs for the use of wet methods to control dust. OSHA requests comment on the use of wet methods as a substitute for dry sweeping and whether the prohibition on dry sweeping is feasible and cost-effective.

c. In its PEA, OSHA presents estimated baseline levels of use of personal protective equipment (PPE) and the incremental PPE costs associated with the proposed rule. Are OSHA's estimated PPE compliance rates reasonable? Are OSHA's estimates of PPE costs, and the assumptions underlying these estimates, consistent with current industry practice? If not, provide data and evidence describing current industry PPE practices.

d. Do you currently conduct exposure monitoring for respirable crystalline silica? Are OSHA's estimates of exposure assessment costs reasonable? Would your company require outside consultants to perform exposure monitoring?

e. Are OSHA's estimates for medical surveillance costs—including direct medical costs, the opportunity cost of worker time for offsite travel and for the health screening, and recordkeeping costs—reasonable?

f. In its PEA, OSHA presents estimated baseline levels of training and information concerning respirable crystalline silica-related hazards and the incremental costs associated with the additional requirements for training and information in the proposed rule. OSHA requests information on information and training programs addressing respirable crystalline silica that are currently being implemented by employers and any necessary additions to those programs that are anticipated in response to the proposed rule. Are OSHA's baseline estimates and unit costs for training reasonable and consistent with current industry practice?

g. Are OSHA's estimated costs for regulated areas and written access control plans reasonable?

h. The cost estimates in the PEA take the much higher labor turnover rates in construction into account when calculating costs. For the proposed rule, OSHA used the most recent BLS turnover rate of 64 percent for construction (versus a turnover rate of 27.2 percent for general industry). OSHA believes that the estimates in the PEA capture the effect of high turnover rates in construction and solicits comments on this issue.

i. Has OSHA omitted any costs that would be incurred to comply with the proposed rule?

Effects on Small Entities

19. OSHA has considered the effects on small entities raised during its SBREFA process and addressed these concerns in Chapter VIII of the PEA. Are there additional difficulties small

entities may encounter when attempting to comply with requirements of the proposed rule? Can any of the proposal's requirements be deleted or simplified for small entities, while still providing equivalent protection of the health of employees? Would allowing additional time for small entities to comply make a difference in their ability to comply? How much additional time would be necessary?

Economic Impacts

20. OSHA, in its PEA, has estimated compliance costs per affected entity and the likely impacts on revenues and profits. OSHA requests that affected employers provide comment on OSHA's estimate of revenue, profit, and the impacts of costs for their industry or application group. The Agency also requests that employers provide data on their revenues, profits, and the impacts of cost, if available. Are there special circumstances—such as unique cost factors, foreign competition, or pricing constraints—that OSHA needs to consider when evaluating economic impacts for particular applications and industry groups?

21. OSHA seeks comment as to whether establishments will be able to finance first-year compliance costs from cash flow, and under what circumstances a phase-in approach will assist firms in complying with the proposed rule.

22. The Agency invites comment on potential employment impacts of the proposed silica rule, and on Inforum's estimates of the employment impacts of the proposed silica rule on the U.S. economy.

Outreach and Compliance Assistance

23. If the proposed rule is promulgated, OSHA will provide outreach materials on the provisions of the standards in order to encourage and assist employers in complying. Are there particular materials that would make compliance easier for your company or industry? What materials would be especially useful for small entities? Submit recommendations or samples.

Benefits and Net Benefits

24. OSHA requests comments on any aspect of its estimation of benefits and net benefits from the proposed rule, including the following:

a. The use of willingness-to-pay measures and estimates based on compensating wage differentials.

b. The data and methods used in the benefits calculations.

c. The choice of discount rate for annualizing the monetized benefits of the proposed rule.

d. Increasing the monetary value of a statistical life over time resulting from an increase in real per capita income and the estimated income elasticity of the value of life.

e. Extending the benefits analysis beyond the 60-year period used in the PEA.

f. The magnitude of non-quantified health benefits arising from the proposed rule and methods for better measuring these effects. An example would be diagnosing latent tuberculosis (TB) in the silica-exposed population and thereby reducing the risk of TB being spread to the population at large.

Overlapping and Duplicative Regulations

25. Do any federal regulations duplicate, overlap, or conflict with the proposed respirable crystalline silica rule? If so, provide or cite to these regulations.

Alternatives/Ways to Simplify a New Standard

26. Comment on the alternative to new comprehensive standards (which have ancillary provisions in addition to a permissible exposure limit) that would be simply improved outreach and enforcement of the existing standards (which is only a permissible exposure limit with no ancillary provisions). Do you believe that improved outreach and enforcement of the existing permissible exposure limits would be sufficient to reduce significant risks of material health impairment in workers exposed to respirable crystalline silica? Provide information to support your position.

27. OSHA solicits comments on ways to simplify the proposed rule without compromising worker protection from exposure to respirable crystalline silica. In particular, provide detailed recommendations on ways to simplify the proposed standard for construction. Provide evidence that your recommended simplifications would result in a standard that was effective, to the extent feasible, in reducing significant risks of material health impairment in workers exposed to respirable crystalline silica.

Environmental Impacts

28. Submit data, information, or comments pertaining to possible environmental impacts of adopting this proposal, including any positive or negative environmental effects and any irreversible commitments of natural resources that would be involved. In particular, consideration should be given to the potential direct or indirect impacts of the proposal on water and air pollution, energy use, solid waste disposal, or land use. Would compliance with the silica rule require additional actions to comply with federal, state, or local environmental requirements?

29. Some small entity representatives advised OSHA that the use of water as a control measure is limited at their work sites due to potential water and soil contamination. OSHA believes these limits may only apply in situations where crystalline silica is found with other toxic substances such as during abrasive blasting of metal or painted metal structures, or in locations where state and local requirements are more restrictive than EPA requirements. OSHA seeks comments on this issue, including cites to applicable requirements.

a. Are there limits on the use of water controls in your operations due to environmental regulations? If so, are the limits due to the non-silica components of the waste stream? What are these non-silica components?

b. What metals or other toxic chemicals are in your silica waste streams and what are the procedures and costs to filter out these metals or other toxic chemicals from your waste streams? Provide documentation to support your cost estimates.

Provisions of the Standards

Scope

30. OSHA's Advisory Committee on Construction Safety and Health (ACCSH) has historically advised the Agency to take into consideration the unique nature of construction work environments by either setting separate standards or making accommodations for the differences in work environments in construction as compared to general industry. ASTM, for example, has separate silica standards of practice for general industry and construction, E 1132–06 and E 2625–09, respectively. To account for differences in the workplace environments for these different sectors, OSHA has proposed separate standards for general industry/maritime and construction. Is this approach necessary and appropriate? What other approaches, if any, should the Agency consider? Provide a rationale for your response.

31. OSHA has proposed that the scope of the construction standard include all occupational exposures to respirable crystalline silica in construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926, rather

than restricting the application of the rule to specific construction operations. Should OSHA modify the scope to limit what is covered? What should be included and what should be excluded? Provide a rationale for your position. Submit your proposed language for the scope and application provision.

32. OSHA has not proposed to cover agriculture because the Agency does not have data sufficient to determine the feasibility of the proposed PEL in agricultural operations. Should OSHA cover respirable crystalline silica exposure in agriculture? Provide evidence to support your position. OSHA seeks information on agricultural operations that involve respirable crystalline silica exposures, including information that identifies particular activities or crops (*e.g.,* hand picking fruit and vegetables, shaking branches and trees, harvesting with combines, loading storage silos, planting) associated with exposure, information indicating levels of exposure, and information relating to available control measures and their effectiveness. OSHA also seeks information related to the development of respirable crystalline silica-related adverse health effects and diseases among workers in the agricultural sector.

33. Should OSHA limit coverage of the rule to materials that contain a threshold concentration (*e.g.,* 1%) of crystalline silica? For example, OSHA's Asbestos standard defines ''asbestos-containing material'' as any material containing more than 1% asbestos, for consistency with EPA regulations. OSHA has not proposed a comparable limitation to the definition of respirable crystalline silica. Is this approach appropriate? Provide the rationale for your position.

34. OSHA has proposed to cover shipyards under the general industry standard. Are there any unique circumstances in shipyard employment that would justify development of different provisions or a separate standard for the shipyard industry? What are the circumstances and how would they not be adequately covered by the general industry standard?

Definitions

35. Competent person. OSHA has proposed limited duties for a competent person relating to establishment of an access control plan. The Agency did not propose specific requirements for training of a competent person. Is this approach appropriate? Should OSHA include a competent person provision? If so, should the Agency add to, modify, or delete any of the duties of a competent person as described in the proposed standard? Provide the basis for your recommendations.

36. Has OSHA defined ''respirable crystalline silica'' appropriately? If not, provide the definition that you believe is appropriate. Explain the basis for your response, and provide any data that you believe are relevant.

37. The proposed rule defines ''respirable crystalline silica'' in part as ''airborne particles that contain quartz, cristobalite, and/or tridymite.'' OSHA believes that tridymite is rarely found in nature or in the workplace. Please describe any instances of occupational exposure to tridymite of which you are aware. Please provide supporting evidence, or explain the basis of your knowledge. Should tridymite be included in the scope of this proposed rule? Please provide any evidence to support your position.

PEL and Action Level

38. OSHA has proposed a TWA PEL for respirable crystalline silica of 50 $\mu g/m^3$ for general industry, maritime, and construction. The Agency has made a preliminary determination that this is the lowest level that is technologically feasible. The Agency has also determined that a PEL of 50 $\mu g/m^3$ will substantially reduce, but not eliminate, significant risk of material health impairment. Is this PEL appropriate, given the Agency's obligation to reduce significant risk of material health impairment to the extent feasible? If not, what PEL would be more appropriate? The Agency also solicits comment on maintaining the existing PELs for respirable crystalline silica. Provide evidence to support your response.

39. OSHA has proposed a single PEL for respirable crystalline silica (quartz, cristobalite, and tridymite). Is a single PEL appropriate, or should the Agency maintain separate PELs for the different forms of respirable crystalline silica? Provide the rationale for your position.

40. OSHA has proposed an action level for respirable crystalline silica exposure of 25 $\mu g/m^3$ in general industry, maritime, and construction. Is this an appropriate approach and level, and if not, what approach or level would be more appropriate and why? Should an action level be included in the final rule? Provide the rationale for your position.

41. If an action level is included in the final rule, which provisions, if any, should be triggered by exposure above or below the action level? Provide the basis for your position and include supporting information.

42. If no action level is included in the final rule, which provisions should apply to all workers exposed to respirable crystalline silica? Which provisions should be triggered by the PEL? Are there any other appropriate triggers for the requirements of the rule?

Exposure Assessment

43. OSHA is proposing to allow employers to initially assess employee exposures using air monitoring or objective data. Has OSHA defined ''objective data'' sufficiently for an employer to know what data may be used? If not, submit an alternative definition. Is it appropriate to allow employers to use objective data to perform exposure assessments? Explain why or why not.

44. The proposed rule provides two options for periodic exposure assessment: (1) A fixed schedule option, and (2) a performance option. The performance option provides employers flexibility in the methods used to determine employee exposures, but requires employers to accurately characterize employee exposures. The proposed approach is explained in the Summary and Explanation for paragraph (d) Exposure Assessment. OSHA solicits comments on this proposed exposure assessment provision. Is the wording of the performance option in the regulatory text understandable and does it clearly indicate what would constitute compliance with the provision? If not, suggest alternative language that would clarify the provision, enabling employers to more easily understand what would constitute compliance.

45. Do you conduct initial air monitoring or do you rely on objective data to determine respirable crystalline silica exposures? If objective data, what data do you use? Have you conducted historical exposure monitoring of your workforce that is representative of current process technology and equipment use? Describe any other approaches you have implemented for assessing an employee's initial exposure to respirable crystalline silica.

46. OSHA is proposing specific requirements for laboratories that perform analyses of respirable crystalline silica samples. The rationale is to improve the precision in individual laboratories and reduce the variability of results between laboratories, so that sampling results will be more reliable. Are these proposed requirements appropriate? Will the laboratory requirements add necessary reliability and reduce inter-lab variability, or might they be overly proscriptive? Provide the basis for your response.

47. Has OSHA correctly described the accuracy and precision of existing methods of sampling and analysis for

respirable crystalline silica at the proposed action level and PEL? Can worker exposures be accurately measured at the proposed action level and PEL? Explain the basis for your response, and provide any data that you believe are relevant.

48. OSHA has not addressed the performance of the analytical method with respect to tridymite since we have found little available data. Please comment on the performance of the analytical method with respect to tridymite and provide any data to support your position.

Regulated Areas and Access Control

49. Where exposures exceed the PEL, OSHA has proposed to provide employers with the option of either establishing a regulated area or establishing a written access control plan. For which types of work operations would employers be likely to establish a written access control plan? Will employees be protected by these options? Provide the basis for your position and include supporting information.

50. The Summary and Explanation for paragraph (e) Regulated Areas and Access Control clarifies how the regulated area requirements would apply to multi-employer worksites in the proposed standard. OSHA solicits comments on this issue.

51. OSHA is proposing limited requirements for protective clothing in the silica rule. Is this appropriate? Are you aware of any situations where more or different protective clothing would be needed for silica exposures? If so, what type of protective clothing and equipment should be required? Are there additional provisions related to protective clothing that should be incorporated into this rule that will enhance worker protection? Provide the rationale and data that support your conclusions.

Methods of Compliance

52. In OSHA's cadmium standard (29 CFR 1910.1027(f)(1)(ii),(iii), and (iv)), the Agency established separate engineering control air limits (SECALs) for certain processes in selected industries. SECALs were established where compliance with the PEL by means of engineering and work practice controls was infeasible. For these industries, a SECAL was established at the lowest feasible level that could be achieved by engineering and work practice controls. The PEL was set at a lower level, and could be achieved by any allowable combination of controls, including respiratory protection. In OSHA's chromium (VI) standard (29 CFR 1910.1026), an exception similar to SECALs was made for painting airplanes and airplane parts. Should OSHA follow this approach for respirable crystalline silica in any industries or processes? If so, in what industries or processes, and at what exposure levels, should the SECALs be established? Provide the basis for your position and include supporting information.

53. The proposed standards do not contain a requirement for a written exposure control program. The two ASTM standards for general industry and construction (E 1132–06, section 4.2.6, and E 2626–09, section 4.2.5) state that, where overexposures are persistent (such as in regulated areas or abrasive blasting operations), a written exposure control plan shall establish engineering and administrative controls to bring the area into compliance, if feasible. In addition, the proposed regulatory language developed by the Building and Construction Trades Department, AFL–CIO contains provisions for a written program. The ASTM standards recommend that, where there are regulated areas with persistent exposures or tasks, tools, or operations that tend to cause respirable crystalline silica exposure, the employer will conduct a formal analysis and implement a written control plan (an abatement plan) on how to bring the process into compliance. If that is not feasible, the employer is to indicate the respiratory protection and other protective procedures that will be used to protect employee(s) permanently or until compliance will be achieved. Should OSHA require employers to develop and implement a written exposure control plan and, if so, what should be required to be in the plans?

54. Table 1 in the proposed construction standard specifies engineering and work practice controls and respiratory protection for selected construction operations, and exempts employers who implement these controls from exposure assessment requirements. Is this approach appropriate? Are there other operations that should be included, or listed operations that should not be included? Are the specified control measures effective? Should any other changes be made in Table 1? How should OSHA update Table 1 in the future to account for development of new technologies? Provide data and information to support your position.

55. OSHA requests comments on the degree of specificity used for the engineering and work practice controls for tasks identified in Table 1, including maintenance requirements. Should OSHA require an evaluation or inspection checklist for controls? If so, how frequently should evaluations or inspections be conducted? Provide any examples of such checklists, along with information regarding their frequency of use and effectiveness.

56. In the proposed construction standard, when employees perform an operation listed in Table 1 and the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1 for that operation, the employer is not required to assess the exposure of the employees performing such operations. However, the employer must still ensure compliance with the proposed PEL for that operation. OSHA seeks comment on whether employers fully complying with Table 1 for an operation should still need to comply with the proposed PEL for that operation. Instead, should OSHA treat compliance with Table 1 as automatically meeting the requirements of the proposed PEL?

57. Are the descriptions of the operations (specific task or tool descriptions) and control technologies in Table 1 clear and precise enough so that employers and workers will know what controls they should be using for the listed operations? Identify the specific operation you are addressing and whether your assessment is based on your anecdotal experience or research. For each operation, are the data and other supporting information sufficient to predict the range of expected exposures under the controlled conditions? Identify operations, if any, where you believe the data are not sufficient. Provide the reasoning and data that support your position.

58. In one specific example from Table 1, OSHA has proposed the option of using a wet method for hand-operated grinders, with respirators required only for operations lasting four hours or more. Please comment and provide OSHA with additional information regarding wet grinding and the adequacy of this control strategy. OSHA is also seeking additional information on the second option (commercially available shrouds and dust collection systems) to confirm that this control strategy (including the use of half-mask respirators) will reduce workers' exposure to or below the PEL.

59. For impact drilling operations lasting four hours or less, OSHA is proposing in Table 1 to allow workers to use water delivery systems without the use of respiratory protection, as the Agency believes that this dust suppression method alone will provide

consistent, sufficient protection. Is this control strategy appropriate? Please provide the basis for your position and any supporting evidence or additional information that addresses the appropriateness of this control strategy.

60. In the case of rock drilling, in order to ensure that workers are adequately protected from the higher exposures that they would experience working under shrouds, OSHA is proposing in Table 1 that employers ensure that workers use half-mask respirators when working under shrouds at the point of operation. Is this specification appropriate? Please provide the basis for your position and any supporting evidence or additional information that addresses the appropriateness of this specification.

61. OSHA has specified a control strategy for concrete drilling in Table 1 that includes use of a dust collection system as well as a low-flow water spray. Please provide to OSHA any data that you have that describes the efficacy of these controls. Is the control strategy in Table 1 adequate? Please provide the basis for your position and any supporting evidence or additional information regarding the adequacy of this control strategy.

62. One of the control options in Table 1 in the proposed construction standard for rock-crushing operations is local exhaust ventilation. However, OSHA is aware of difficulties in applying this control to this operation. Is this control strategy appropriate and practical for rock-crushing operations? Please provide any information that you have addressing this issue.

63. OSHA has not proposed to prohibit the use of crystalline silica as an abrasive blasting agent. Abrasive blasting, similar to other operations that involve respirable crystalline silica exposures, must follow the hierarchy of controls, which means, if feasible, that substitution, engineering, or administrative controls or a combination of these controls must be used to minimize or eliminate the exposure hazard. Is this approach appropriate? Provide the basis for your position and any supporting evidence.

64. The technological feasibility study (PEA, Chapter 4) indicates that employers use substitutes for crystalline silica in a variety of operations. If you are aware of substitutes for crystalline silica that are currently being used in any operation not considered in the feasibility study, please provide to OSHA relevant information that contains data supporting the effectiveness, in reducing exposure to crystalline silica, of those substitutes. Provide any information you may have on the health hazards associated with exposure to these substitutes.

65. Information regarding the effectiveness of dust control kits that incorporate local exhaust ventilation in the railroad transportation industry in reducing worker exposure to crystalline silica is not available from the manufacturer. If you have any relevant information on the effectiveness of such kits, please provide it to OSHA.

66. The proposed rule prohibits the use of compressed air and dry brushing and sweeping for cleaning of surfaces and clothing in general industry, maritime, and construction and promotes the use of wet methods and HEPA-filter vacuuming as alternatives. Are there any circumstances in general industry, maritime, or construction work where dry sweeping is the only kind of sweeping that can be done? Have you done dry sweeping and, if so, what has been your experience with it? What methods have you used to minimize dust when dry sweeping? Can exposure levels be kept below the proposed PEL when dry sweeping is conducted? How? Provide exposure data for periods when you conducted dry sweeping. If silica respirable dust samples are not available, provide real time respirable dust or gravimetric respirable dust data. Is water available at most sites to wet down dust prior to sweeping? How effective is the use of water? Does the use of water cause other problems for the worksite? Are there other substitutes that are effective?

67. A 30-day exemption from the requirement to implement engineering and work practice controls was not included in the proposed standard for construction, and has been removed from the proposed standard for general industry and maritime. OSHA requests comment on this issue.

68. The proposed prohibition on employee rotation is explained in the Summary and Explanation for paragraph (f) Methods of Compliance. OSHA solicits comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL.

Medical Surveillance

69. Is medical surveillance being provided for respirable crystalline silica-exposed employees at your worksite? If so:

a. How do you determine which employees receive medical surveillance (*e.g.,* by exposure level or other factors)?

b. Who administers and implements the medical surveillance (*e.g.,* company doctor or nurse, outside doctor or nurse)?

c. What examinations, tests, or evaluations are included in the medical surveillance program? Does your medical surveillance program include testing for latent TB? Do you include pulmonary function testing in your medical surveillance program?

d. What benefits (*e.g.,* health, reduction in absenteeism, or financial) have been achieved from the medical surveillance program?

e. What are the costs of your medical surveillance program? How do your costs compare with OSHA's estimated unit costs for the physical examination and employee time involved in the medical surveillance program? Are OSHA's baseline assumptions and cost estimates for medical surveillance consistent with your experiences providing medical surveillance to your employees?

f. How many employees are included in your medical surveillance program?

g. What NAICS code describes your workplace?

70. Is the content and frequency of proposed examinations appropriate? If not, how should content and frequency be modified?

71. Is the specified content of the physician or other licensed health care professional's (PLHCP) written medical opinion sufficiently detailed to enable the employer to address the employee's needs and potential workplace improvements, and yet appropriately limited so as to protect the employee's medical privacy? If not, how could the medical opinion be improved?

72. Is the requirement for latent TB testing appropriate? Does the proposed rule implement this requirement in a cost-effective manner? Provide the data or cite references that support your position.

73. Is the requirement for pulmonary function testing initially and at three-year intervals appropriate? Is there an alternate strategy or schedule for conducting follow-up testing that is better? Provide data or cite references to support your position.

74. Is the requirement for chest X-rays initially and at three-year intervals appropriate? Is there an alternate strategy or schedule for conducting follow-up chest X-rays that you believe would be better? Provide data or cite references to support your position.

75. Are there other tests that should be included in medical surveillance?

76. Do you provide medical surveillance to employees under another OSHA standard or as a matter of company policy? If so, describe your program in terms of what standards the program addresses and such factors as content and frequency of examinations

and referrals, and reports to the employer.

77. Is exposure for 30 days at or above the PEL the appropriate number of days to trigger medical surveillance? Should the appropriate reference for medical monitoring be the PEL or the action level? Is 30 days from initial assignment a reasonable amount of time to provide a medical exam? Indicate the basis for your position.

78. Are PLHCPs available in your geographic area to provide medical surveillance to workers who are covered by the proposed rule? For example, do you have access to qualified X-ray technicians, NIOSH-certified B-readers, and pulmonary specialists? Describe any difficulties you may have with regard to access to PLHCPs to provide surveillance for the rule. Note what you consider your ''geographic area'' in responding to this question.

79. OSHA is proposing to allow an ''equivalent diagnostic study'' in place of requirements to use a chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration; interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader). Two other radiological test methods, computed tomography (CT) and high resolution computed tomography (HRCT), could be considered ''equivalent diagnostic studies'' under paragraph (h)(2)(iii) of the proposal. However, the benefits of CT or HRCT should be balanced with risks, including higher radiation doses. Also, standardized methods for interpreting and reporting results of CT or HRCT are not currently available. The Agency requests comment on whether CT and HRCT should be considered ''equivalent diagnostic studies'' under the rule. Provide a rationale and evidence to support your position.

80. OSHA has not included requirements for medical removal protection (MRP) in the proposed rule, because OSHA has made a preliminary determination that there are few instances where temporary worker removal and MRP will be useful. The Agency requests comment as to whether the respirable crystalline silica rule should include provisions for the temporary removal and extension of MRP benefits to employees with certain respirable crystalline silica-related health conditions. In particular, what medical conditions or findings should trigger temporary removal and for what maximum amount of time should MRP benefits be extended? OSHA also seeks information on whether or not MRP is currently being used by employers with respirable crystalline silica-exposed workers, and the costs of such programs.

Hazard Communication and Training

81. OSHA has proposed that employers provide hazard information to employees in accordance with the Agency's Hazard Communication standard (29 CFR 1910.1200). Compliance with the Hazard Communication standard would mean that there would be a requirement for a warning label for substances that contain more than 0.1 percent crystalline silica. Should this requirement be changed so that warning labels would only be required of substances more than 1 percent by weight of silica? Provide the rationale for your position. The Agency also has proposed additional training specific to work with respirable crystalline silica. Should OSHA include these additional requirements in the final rule, or are the requirements of the Hazard Communication standard sufficient?

82. OSHA is providing an abbreviated training section in this proposal as compared to ASTM consensus standards (*see* ASTM E 1132–06, sections 4.8.1–5). The Hazard Communication standard is comprehensive and covers most of the training requirements traditionally included in an OSHA health standard. Do you concur with OSHA that performance-based training specified in the Hazard Communication standard, supplemented by the few training requirements of this section, is sufficient in its scope and depth? Are there any other training provisions you would add?

83. The proposed rule does not alter the requirements for substances to have warning labels, specify wording for labels, or otherwise modify the provisions of the OSHA's Hazard Communication standard. OSHA invites comment on these issues.

Recordkeeping

84. OSHA is proposing to require recordkeeping for air monitoring data, objective data, and medical surveillance records. The proposed rule's recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) Recordkeeping. The Agency seeks comment on the utility of these recordkeeping requirements as well as the costs of making and maintaining these records. Provide evidence to support your position.

Dates

85. OSHA requests comment on the time allowed for compliance with the provisions of the proposed rule. Is the time proposed appropriate, or should there be a longer or shorter phase-in of requirements? In particular, should requirements for engineering controls and/or medical surveillance be phased in over a longer period of time (*e.g.,* over 1, 2, 3, or more years)? Should an extended phase-in period be provided for specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule? Identify any industries, processes, or operations that have special needs for additional time, the additional time required, and the reasons for the request.

86. OSHA is proposing a two-year start-up period to allow laboratories time to achieve compliance with the proposed requirements, particularly with regard to requirements for accreditation and round robin testing. OSHA also recognizes that requirements for monitoring in the proposed rule will increase the required capacity for analysis of respirable crystalline silica samples. Do you think that this start-up period is enough time for laboratories to achieve compliance with the proposed requirements and to develop sufficient analytic capacity? If you think that additional time is needed, please tell OSHA how much additional time is required and give your reasons for this request.

Appendices

87. Some OSHA health standards include appendices that address topics such as the hazards associated with the regulated substance, health screening considerations, occupational disease questionnaires, and PLHCP obligations. In this proposed rule, OSHA has included a non-mandatory appendix to clarify the medical surveillance provisions of the rule. What would be the advantages and disadvantages of including such an appendix in the final rule? If you believe it should be included, comment on the appropriateness of the information included. What additional information, if any, should be included in the appendix?

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 et seq. (''the Act''), is to ''. . . assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b).

To achieve this goal Congress authorized the Secretary of Labor (the Secretary) to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b) (requiring employers to comply with OSHA standards), 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment).

The Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as this proposed standard regulating occupational exposure to respirable crystalline silica, the Secretary, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. 29 U.S.C. 655(b)(5).

The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, she must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 641–42 (1980) (plurality opinion) (''*The Benzene case''*). Thus, section 6(b)(5) of the Act requires health standards to reduce significant risk to the extent feasible. *Id.*

The Court further observed that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' and must be ''based largely on policy considerations.'' *The Benzene case,* 448 U.S. at 655. The Court gave the example that if,

> . . . the odds are one in a billion that a person will die from cancer . . . the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. [*Id.*]

OSHA standards must be both technologically and economically feasible. *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1980) (''The Lead I case''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–510 (1981) (''*The Cotton Dust case''*). The courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. [*See The Lead I case,* 647 F.2d at 1272]

With respect to economic feasibility, the courts have held that a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry. *Id.* at 1265. A court must examine the cost of compliance with an OSHA standard,

> . . . in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices . . . [T]he practical question is whether the standard threatens the competitive stability of an industry, . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration. [*Id.* (citing *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467 (D.C. Cir. 1974))]

The courts have further observed that granting companies reasonable time to comply with new PELs may enhance economic feasibility. *The Lead I case* at 1265. While a standard must be economically feasible, the Supreme Court has held that a cost-benefit analysis of health standards is not required by the Act because a feasibility analysis is required. *The Cotton Dust case,* 453 U.S. at 509.

Finally, sections 6(b)(7) and 8(c) of the Act authorize OSHA to include among a standard's requirements labeling, monitoring, medical testing, and other information-gathering and -transmittal provisions. 29 U.S.C. 655(b)(7), 657(c).

III. Events Leading to the Proposed Standards

OSHA's current standards for workplace exposure to respirable crystalline silica were adopted in 1971, pursuant to section 6(a) of the OSH Act (36 FR 10466, May 29, 1971). Section 6(a) provided that in the first two years after the effective date of the Act, OSHA had to promulgate ''start-up'' standards, on an expedited basis and without public hearing or comment, based on national consensus or established Federal standards that improved employee safety or health. Pursuant to that authority, OSHA in 1971 promulgated approximately 425 permissible exposure limits (PELs) for air contaminants, including silica, derived principally from Federal standards applicable to government contractors under the Walsh-Healey Public Contracts Act, 41 U.S.C. 35, and the Contract Work Hours and Safety Standards Act (commonly known as the Construction Safety Act), 40 U.S.C. 333. The Walsh-Healey Act and Construction Safety Act standards, in turn, had been adopted primarily from recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH).

For general industry (*see* 29 CFR 1910.1000, Table Z–3), the PEL for crystalline silica in the form of respirable quartz is based on two alternative formulas: (1) A particle-count formula, $PEL_{mppcf} = 250/(\% \text{ quartz} + 5)$; and (2) a mass formula proposed by ACGIH in 1968, $PEL = (10 \text{ mg/m}^3)/(\% \text{ quartz} + 2)$. The general industry PELs for cristobalite and tridymite are one-half of the value calculated from either of the above two formulas. For construction (29 CFR 1926.55, Appendix A) and shipyards (29 CFR 1915.1000, Table Z), the formula for the PEL for crystalline silica in the form of quartz ($PEL_{mppcf} = 250/(\% \text{ quartz} + 5)$), which requires particle counting, is derived from the 1970 ACGIH threshold limit value (TLV).[2] The formula based on particle-counting technology used in the general industry, construction, and shipyard PELs is now considered obsolete.

In 1974, the National Institute for Occupational Safety and Health (NIOSH) evaluated crystalline silica as a workplace hazard and issued criteria for a recommended standard on occupational exposure to crystalline silica (NIOSH, 1974). NIOSH recommended that occupational exposure to crystalline silica be controlled so that no worker is exposed to a time-weighted average (TWA) of free (respirable crystalline) silica greater than 50 $\mu g/m^3$ as determined by a full-shift sample for up to a 10-hour workday, 40-hour workweek. The document also recommended a number of ancillary provisions for a standard, such as exposure monitoring and medical surveillance.

In December 1974, OSHA published an Advanced Notice of Proposed Rulemaking (ANPRM) based on the recommendations in the NIOSH criteria document (39 FR 44771, Dec. 27, 1974). In the ANPRM, OSHA solicited ''public participation on the issues of whether a new standard for crystalline silica

[2] The Mineral Dusts tables that contain the silica PELs for construction and shipyards do not clearly express PELs for cristobalite and tridymite. 29 CFR 1926.55; 29 CFR 1915.1000. This lack of textual clarity likely results from a transcription error in the Code of Federal Regulations. OSHA's current proposal provides the same PEL for quartz, cristobalite, and tridymite, in general industry, construction, and shipyards.

should be issued on the basis of the [NIOSH] criteria or any other information, and, if so, what should be the contents of a proposed standard for crystalline silica.'' OSHA also set forth the particular issues of concern on which comments were requested. The Agency did not pursue a final rule for crystalline silica at that time.

As information developed during the 1980s and 1990s, national and international classification organizations came to recognize crystalline silica as a human carcinogen. In June 1986, the International Agency for Research on Cancer (IARC) evaluated the available evidence regarding crystalline silica carcinogenicity and concluded that it was ''probably carcinogenic to humans'' (IARC, 1987). An IARC working group met again in October 1996 to evaluate the complete body of research, including research that had been conducted since the initial 1986 evaluation. IARC concluded that ''crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans'' (IARC, 1997).

In 1991, in the Sixth Annual Report on Carcinogens, the U.S. National Toxicology Program (NTP) concluded that respirable crystalline silica was ''reasonably anticipated to be a human carcinogen'' (NTP, 1991). NTP reevaluated the available evidence and concluded, in the Ninth Report on Carcinogens (NTP, 2000), that ''respirable crystalline silica (RCS), primarily quartz dust occurring in industrial and occupational settings, is known to be a human carcinogen, based on sufficient evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure to RCS and increased lung cancer rates in workers exposed to crystalline silica dust'' (NTP, 2000). ACGIH listed respirable crystalline silica (in the form of quartz) as a suspected human carcinogen in 2000, while lowering the TLV to 0.05 mg/m^3 (ACGIH, 2001). ACGIH subsequently lowered the TLV for crystalline silica to 0.025 mg/m^3 in 2006, which is the current value (ACGIH, 2010).

In 1989, OSHA established 8-hour TWA PELs of 0.1 for quartz and 0.05 mg/m^3 for cristobalite and tridymite, as part of the Air Contaminants final rule for general industry (54 FR 2332, Jan. 19, 1989). OSHA stated that these limits presented no substantial change from the Agency's former formula limits, but would simplify sampling procedures. In providing comments on the proposed rule, NIOSH recommended that crystalline silica be considered a potential carcinogen.

In 1992, OSHA, as part of the Air Contaminants proposed rule for maritime, construction, and agriculture, proposed the same PELs as for general industry, to make the PELs consistent across all the OSHA-regulated sectors (57 FR 26002, June 12, 1992). However, on July 7 of the same year, the U.S. Court of Appeals for the Eleventh Circuit vacated the 1989 Air Contaminants final rule for general industry (*Am. Fed'n of Labor and Cong. of Indus. Orgs.* v. *OSHA,* 965 F.2d 962 (1992)), which also mooted the proposed rule for maritime, construction, and agriculture. The Court's decision to vacate the rule forced the Agency to return to the PELs adopted in the 1970s.

In 1994, OSHA launched a process to determine which safety and health hazards in the U.S. needed most attention. A priority planning committee included safety and health experts from OSHA, NIOSH, and the Mine Safety and Health Administration (MSHA). The committee reviewed available information on occupational deaths, injuries, and illnesses and held an extensive dialogue with representatives of labor, industry, professional and academic organizations, the States, voluntary standards organizations, and the public. The National Advisory Committee on Occupational Safety and Health and the Advisory Committee on Construction Safety and Health also made recommendations. Rulemaking for crystalline silica exposure was one of the priorities designated by this process. OSHA indicated that crystalline silica would be added to the Agency's regulatory agenda as other standards were completed and resources became available.

In August 1996, the Agency initiated enforcement efforts under a Special Emphasis Program (SEP) on crystalline silica. The SEP was intended to reduce worker silica dust exposures that can cause silicosis. It included extensive outreach as well as inspections. Among the outreach materials available were slides presenting information on hazard recognition and crystalline silica control technology, a video on crystalline silica and silicosis, and informational cards for workers explaining crystalline silica, health effects related to exposure, and methods of control. The SEP provided guidance for targeting inspections of worksites with employees at risk of developing silicosis.

As a follow-up to the SEP, OSHA undertook numerous non-regulatory actions to address silica exposures. For example, in October of 1996, OSHA launched a joint silicosis prevention effort with MSHA, NIOSH, and the American Lung Association (DOL, 1996). This public education campaign involved distribution of materials on how to prevent silicosis, including a guide for working safely with silica and stickers for hard hats to remind workers of crystalline silica hazards. Spanish language versions of these materials were also made available. OSHA and MSHA inspectors distributed materials at mines, construction sites, and other affected workplaces. The joint silicosis prevention effort included a National Conference to Eliminate Silicosis in Washington, DC, in March of 1997, which brought together approximately 650 participants from labor, business, government, and the health and safety professions to exchange ideas and share solutions to reach the goal of eliminating silicosis. The conference highlighted the best methods of eliminating silicosis and included problem-solving workshops on how to prevent the disease in specific industries and job operations; plenary sessions with senior government, labor, and corporate officials; and opportunities to meet with safety and health professionals who had implemented successful silicosis prevention programs.

In 2003, OSHA examined enforcement data for the years between 1997 and 2002 and identified high rates of noncompliance with the OSHA respirable crystalline silica PEL, particularly in construction. This period covers the first five years of the SEP. These enforcement data, presented in Table 1, indicate that 24 percent of silica samples from the construction industry and 13 percent from general industry were at least three times the OSHA PEL. The data indicate that 66 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, while only 58 percent of the samples collected in construction were in compliance.

TABLE III–1—RESULTS OF TIME-WEIGHTED AVERAGE (TWA) EXPOSURE RESPIRABLE CRYSTALLINE SILICA SAMPLES FOR CONSTRUCTION AND GENERAL INDUSTRY

[January 1, 1997–December 31, 2002]

Exposure (severity relative to the PEL)	Construction		Other than construction	
	Number of samples	Percent	Number of samples	Percent
< 1 PEL	424	58	2226	66
1 × PEL to < 2 × PEL	86	12	469	14
2 × PEL to < 3 × PEL	48	6	215	6
≥ 3 × PEL and higher (3+)	180	24	453	13
Total # of samples	738		3363	

Source: OSHA Integrated Management Information System.

In an effort to expand the 1996 SEP, on January 24, 2008, OSHA implemented a National Emphasis Program (NEP) to identify and reduce or eliminate the health hazards associated with occupational exposure to crystalline silica (OSHA, 2008). The NEP targeted worksites with elevated exposures to crystalline silica and included new program evaluation procedures designed to ensure that the goals of the NEP were measured as accurately as possible, detailed procedures for conducting inspections, updated information for selecting sites for inspection, development of outreach programs by each Regional and Area Office emphasizing the formation of voluntary partnerships to share information, and guidance on calculating PELs in construction and shipyards. In each OSHA Region, at least two percent of inspections every year are silica-related inspections. Additionally, the silica-related inspections are conducted at a range of facilities reasonably representing the distribution of general industry and construction work sites in that region.

A recent analysis of OSHA enforcement data from January 2003 to December 2009 (covering the period of continued implementation of the SEP and the first two years of the NEP) shows that considerable noncompliance with the PEL continues to occur. These enforcement data, presented in Table 2, indicate that 14 percent of silica samples from the construction industry and 19 percent for general industry were at least three times the OSHA PEL during this period. The data indicate that 70 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, and 75 percent of the samples collected in construction were in compliance.

TABLE III–2—RESULTS OF TIME-WEIGHTED AVERAGE (TWA) EXPOSURE RESPIRABLE CRYSTALLINE SILICA SAMPLES FOR CONSTRUCTION AND GENERAL INDUSTRY

[January 1, 2003–December 31, 2009]

Exposure (severity relative to the PEL)	Construction		Other than construction	
	Number of samples	Percent	Number of samples	Percent
< 1 PEL	548	75	948	70
1 × PEL to < 2 × PEL	49	7	107	8
2 × PEL to < 3 × PEL	32	4	46	3
≥ 3 × PEL and higher (3+)	103	14	254	19
Total # of samples	732		1355	

Source: OSHA Integrated Management Information System.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, ASTM (originally known as the American Society for Testing and Materials) has published recommended standards for addressing the hazards of crystalline silica, and the Building and Construction Trades Department, AFL–CIO also has recommended a comprehensive program standard. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance. The National Industrial Sand Association has also developed exposure assessment, medical surveillance, and training guidance products.

In 1997, OSHA announced in its Unified Agenda under Long-Term Actions that it planned to publish a proposed rule on crystalline silica ''because the agency has concluded that there will be no significant progress in the prevention of silica-related diseases without the adoption of a full and comprehensive silica standard, including provisions for product substitution, engineering controls, training and education, respiratory protection and medical screening and surveillance. A full standard will improve worker protection, ensure adequate prevention programs, and further reduce silica-related diseases.'' (62 FR 57755, 57758, Oct. 29, 1997). In November 1998, OSHA moved ''Occupational Exposure to Crystalline Silica'' to the pre-rule stage in the Regulatory Plan (63 FR 61284, 61303–304, Nov. 9, 1998). OSHA held a series of stakeholder meetings in 1999 and 2000 to get input on the rulemaking. Stakeholder meetings for all industry sectors were held in Washington, Chicago, and San Francisco. A separate stakeholder meeting for the construction sector was held in Atlanta.

OSHA initiated Small Business Regulatory Enforcement Fairness Act (SBREFA) proceedings in 2003, seeking the advice of small business representatives on the proposed rule (68 FR 30583, 30584, May 27, 2003). The SBREFA panel, including representatives from OSHA, the Small Business Administration (SBA), and the Office of Management and Budget (OMB), was convened on October 20, 2003. The panel conferred with small entity representatives (SERs) from general industry, maritime, and construction on November 10 and 12, 2003, and delivered its final report, which included comments from the SERs and recommendations to OSHA for the proposed rule, to OSHA's Assistant Secretary on December 19, 2003 (OSHA, 2003).

Throughout the crystalline silica rulemaking process, OSHA has presented information to, and has consulted with, the Advisory Committee on Construction Safety and Health (ACCSH) and the Maritime Advisory Committee on Occupational Safety and Health (MACOSH). In December of 2009, OSHA representatives met with ACCSH to discuss the rulemaking and receive their comments and recommendations. On December 11, ACCSH passed motions supporting the concept of Table 1 in the draft proposed construction rule and recognizing that the controls listed in Table 1 are effective. (As discussed with regard to paragraph (f) of the proposed rule, Table 1 presents specified control measures for selected construction operations.) ACCSH also recommended that OSHA maintain the protective clothing provision found in the SBREFA panel draft regulatory text and restore the ''competent person'' requirement and responsibilities to the proposed rule. Additionally, the group recommended that OSHA move forward expeditiously with the rulemaking process.

In January 2010, OSHA completed a peer review of the draft Health Effects analysis and Preliminary Quantitative Risk Assessment following procedures set forth by OMB in the Final Information Quality Bulletin for Peer Review, published on the OMB Web site on December 16, 2004 (*see* 70 FR 2664, Jan. 14, 2005). Each peer reviewer submitted a written report to OSHA. The Agency revised its draft documents as appropriate and made the revised documents available to the public as part of this Notice of Proposed Rulemaking. OSHA also made the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports, and the Agency's response to the peer reviewers' reports publicly available with publication of this proposed rule. OSHA will schedule time during the informal rulemaking hearing for participants to testify on the Health Effects analysis and Preliminary Quantitative Risk Assessment in the presence of peer reviewers and will request the peer reviewers to submit any amended final comments they may wish to add to the record. The Agency will consider amended final comments received from the peer reviewers during development of a final rule and will make them publicly available as part of the silica rulemaking record.

IV. Chemical Properties and Industrial Uses

Silica is a compound composed of the elements silicon and oxygen (chemical formula SiO_2). Silica has a molecular weight of 60.08, and exists in crystalline and amorphous states, both in the natural environment and as produced during manufacturing or other processes. These substances are odorless solids, have no vapor pressure, and create non-explosive dusts when particles are suspended in air (IARC, 1997).

Silica is classified as part of the ''silicate'' class of minerals, which includes compounds that are composed of silicon and oxygen and which may also be bonded to metal ions or their oxides (Hurlbut, 1966). The basic structural units of silicates are silicon tetrahedrons (SiO_4), pyramidal structures with four triangular sides where a silicon atom is located in the center of the structure and an oxygen atom is located at each of the four corners. When silica tetrahedrons bond exclusively with other silica tetrahedrons, each oxygen atom is bonded to the silicon atom of its original ion, as well as to the silicon atom from another silica ion. This results in a ratio of one atom of silicon to two atoms of oxygen, expressed as SiO_2. The silicon-oxygen bonds within the tetrahedrons use only one-half of each oxygen's total bonding energy. This leaves negatively charged oxygen ions available to bond with available positively charged ions. When they bond with metal and metal oxides, commonly of iron, magnesium, aluminum, sodium, potassium, and calcium, they form the silicate minerals commonly found in nature (Bureau of Mines, 1992).

In crystalline silica, the silicon and oxygen atoms are arranged in a three-dimensional repeating pattern. Silica is said to be polymorphic, as different forms are created when the silica tetrahedrons combine in different crystalline structures. The primary forms of crystalline silica are quartz, cristobalite, and tridymite. In an amorphous state, silicon and oxygen atoms are present in the same proportions but are not organized in a repeating pattern. Amorphous silica includes natural and manufactured glasses (vitreous and fused silica, quartz glass), biogenic silica, and opals which are amorphous silica hydrates (IARC, 1997).

Quartz is the most common form of crystalline silica and accounts for almost 12% by volume of the earth's crust. Alpha quartz, the quartz form that is stable below 573 °C, is the most prevalent form of crystalline silica found in the workplace. It accounts for the overwhelming majority of naturally found silica and is present in varying amounts in almost every type of mineral. Alpha quartz is found in igneous, sedimentary, and metamorphic rock, and all soils contain at least a trace amount of quartz (Bureau of Mines, 1992). Alpha quartz is used in many products throughout various industries and is a common component of building materials (Madsen et al., 1995). Common trade names for commercially available quartz include: CSQZ, DQ 12, Min-U-Sil, Sil-Co-Sil, Snowit, Sykron F300, and Sykron F600 (IARC, 1997).

Cristobalite is a form of crystalline silica that is formed at high temperatures (>1470 °C). Although naturally occurring cristobalite is relatively rare, volcanic eruptions, such as Mount St. Helens, can release cristobalite dust into the air. Cristobalite can also be created during some processes conducted in the workplace. For example, flux-calcined diatomaceous earth is a material used as a filtering aid and as a filler in other products (IARC, 1997). It is produced when diatomaceous earth (diatomite), a geological product of decayed unicellular organisms called diatoms, is heated with flux. The finished product can contain between 40 and 60 percent cristobalite. Also, high temperature furnaces are often lined with bricks that contain quartz. When subjected to prolonged high temperatures, this quartz can convert to cristobalite.

Tridymite is another material formed at high temperatures (>870 °C) that is associated with volcanic activity. The creation of tridymite requires the presence of a flux such as sodium oxide. Tridymite is rarely found in nature and rarely reported in the workplace (Smith, 1998).

When heated or cooled sufficiently, crystalline silica can transition between the polymorphic forms, with specific transitions occurring at different temperatures. At higher temperatures the linkages between the silica tetrahedrons break and reform, resulting in new crystalline structures. Quartz converts to cristobalite at 1470 °C, and at 1723 °C cristobalite loses its crystalline structure and becomes amorphous fused silica. These high temperature transitions reverse themselves at extremely slow rates, with different forms co-existing for a long time after the crystal cools.

Other types of transitions occur at lower temperatures when the silica-oxygen bonds in the silica tetrahedron rotate or stretch, resulting in a new crystalline structure. These low-temperature, or alpha to beta, transitions are readily and rapidly reversed as the crystal cools. At temperatures encountered by workers, only the alpha form of crystalline silica exists (IARC, 1997).

Crystalline silica minerals produce distinct X-ray diffraction patterns, specific to their crystalline structure. The patterns can be used to distinguish the crystalline polymorphs from each other and from amorphous silica (IARC, 1997).

The specific gravity and melting point of silica vary between polymorphs. Silica is insoluble in water at 20 °C and in most acids, but its solubility increases with higher temperatures and pH, and it dissolves readily in hydrofluoric acid. Solubility is also affected by the presence of trace metals and by particle size. Under humid conditions water vapor in the air reacts with the surface of silica particles to form an external layer of silinols (SiOH). When these silinols are present the crystalline silica becomes more hydrophilic. Heating or acid washing reduces the amount of silinols on the surface area of crystalline silica particles. There is an external amorphous layer found in aged quartz, called the Beilby layer, which is not found on freshly cut quartz. This amorphous layer is more water soluble than the underlying crystalline core. Etching with hydrofluoric acid removes the Beilby layer as well as the principal metal impurities on quartz.

Crystalline silica has limited chemical reactivity. It reacts with alkaline aqueous solutions, but does not readily react with most acids, with the exception of hydrofluoric acid. In contrast, amorphous silica and most silicates react with most mineral acids and alkaline solutions. Analytical chemists relied on this difference in acid reactivity to develop the silica point count analytical method that was widely used prior to the current X-ray diffraction and infrared methods (Madsen et al., 1995).

Crystalline silica is used in industry in a wide variety of applications. Sand and gravel are used in road building and concrete construction. Sand with greater than 98% silica is used in the manufacture of glass and ceramics. Silica sand is used to form molds for metal castings in foundries, and in abrasive blasting operations. Silica is also used as a filler in plastics, rubber, and paint, and as an abrasive in soaps and scouring cleansers. Silica sand is used to filter impurities from municipal water and sewage treatment plants, and in hydraulic fracturing for oil and gas recovery. Silica is also used to manufacture artificial stone products used as bathroom and kitchen countertops, and the silica content in those products can exceed 93 percent (Kramer et al., 2012).

There are over thirty major industries and operations where exposures to crystalline silica can occur. They include such diverse workplaces as foundries, dental laboratories, concrete products and paint and coating manufacture, as well as construction activities including masonry cutting, grinding and tuckpointing, operating heavy equipment, and road work. A more detailed discussion of the industries affected by the proposed standard is presented in Section VIII of this preamble. Crystalline silica exposures can also occur in mining, and in agriculture during plowing and harvesting.

V. Health Effects Summary

This section presents a summary of OSHA's review of the health effects literature for respirable crystalline silica. OSHA's full analysis is contained in Section I of the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment,'' which has been placed in rulemaking docket OSHA–2010–0034. OSHA's review of the literature on the adverse effects associated with exposure to crystalline silica covers the following topics:

(1) Silicosis (including relevant data from U.S. disease surveillance efforts);

(2) Lung cancer and cancer at other sites;

(3) Non-malignant respiratory disease (other than silicosis);

(4) Renal and autoimmune effects; and

(5) Physical factors affecting the toxicity of crystalline silica.

The purpose of the Agency's scientific review is to present OSHA's preliminary findings on the nature of the hazards presented by exposure to respirable crystalline silica, and to present an adequate basis for the quantitative risk assessment section to follow. OSHA's review reflects the relevant literature identified by the Agency through previously published reviews, literature searches, and contact with outside experts. Most of the evidence that describes the health risks associated with exposure to silica consists of epidemiological studies of worker populations; in addition, animal and *in vitro* studies on mode of action and molecular toxicology are also described. OSHA's review of the silicosis literature focused on a few particular issues, such as the factors that affect progression of the disease and the relationship between the appearance of radiological abnormalities indicative of silicosis and pulmonary function decline. Exposure to respirable crystalline silica is the only known cause of silicosis and there are literally thousands of research papers and case studies describing silicosis among working populations. OSHA did not review every one of these studies, because many of them do not relate to the issues that are of interest to OSHA.

OSHA's health effects literature review addresses exposure only to airborne respirable crystalline silica since there is no evidence that dermal or oral exposure presents a hazard to workers. This review is also confined to issues related to inhalation of respirable dust, which is generally defined as particles that are capable of reaching the gas-exchange region of the lung (*i.e.,* particles less than 10 μm in aerodynamic diameter). The available studies include populations exposed to quartz or cristobalite, the two forms of crystalline silica most often encountered in the workplace. OSHA was unable to identify any relevant epidemiological literature concerning a third polymorph, tridymite, which is also currently regulated by OSHA and included in the scope of OSHA's proposed crystalline silica standard.

OSHA's approach in this review is based on a weight-of-evidence approach, in which studies (both positive and negative) are evaluated for their overall quality, and causal inferences are drawn based on a determination of whether there is substantial evidence that exposure increases the risk of a particular effect. Factors considered in assessing the quality of studies include size of the cohort studied and power of the study to detect a sufficiently low level of disease risk; duration of follow-up of the study population; potential for study bias (such as selection bias in case-control studies or survivor effects in cross-sectional studies); and adequacy of underlying exposure information for examining exposure-response relationships. Studies were deemed suitable for inclusion in OSHA's Preliminary Quantitative Risk Assessment where there was adequate quantitative information on exposure and disease risks and the study was judged to be sufficiently high quality according to the criteria described above. The Preliminary Quantitative Risk Assessment is included in Section II of the background document and is summarized in Section VI of this preamble.

A draft health effects review document was submitted for external scientific peer review in accordance with the Office of Management and Budget's ''Final Information Quality Bulletin for Peer Review'' (OMB, 2004). A summary of OSHA's responses to the peer reviewers' comments appears in Section III of the background document. Since the draft health effects review document was submitted for external scientific peer review, new studies or reviews examining possible associations between occupational exposure to respirable crystalline silica and lung cancer have been published. OSHA's analysis of that new information is presented in a supplemental literature review and is available in the docket (OSHA, 2013).

A. Silicosis and Disease Progression

1. Pathology and Diagnosis

Silicosis is a progressive disease in which accumulation of respirable crystalline silica particles causes an inflammatory reaction in the lung, leading to lung damage and scarring, and, in some cases, progresses to complications resulting in disability and death. Three types of silicosis have been described: an *acute* form following intense exposure to respirable dust of high crystalline silica content for a relatively short period (*i.e.,* a few months or years); an *accelerated* form, resulting from about 5 to 15 years of heavy exposure to respirable dusts of high crystalline silica content; and, most commonly, a *chronic* form that typically follows less intense exposure of usually more than 20 years (Becklake, 1994; Balaan and Banks, 1992). In both the accelerated and chronic form of the disease, lung inflammation leads to the formation of excess connective tissue, or fibrosis, in the lung. The hallmark of the chronic form of silicosis is the silicotic islet or nodule, one of the few agent-specific lesions in pathology (Balaan and Banks, 1992). As the disease progresses, these nodules, or fibrotic lesions, increase in density and can develop into large fibrotic masses, resulting in progressive massive fibrosis (PMF). Once established, the fibrotic process of chronic silicosis is thought to be irreversible (Becklake, 1994), and there is no specific treatment for silicosis (Davis, 1996; Banks, 2005). Unlike chronic silicosis, the acute form of the disease almost certainly arises from exposures well in excess of current OSHA standards and presents a different pathological picture, one of pulmonary alveolar proteinosis.

Chronic silicosis is the most frequently observed type of silicosis in the U.S. today. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction and/or obstruction caused by the development of fibrotic scarring in the alveolar sacs and lower region of the lung. The scarring can be detected by chest x-ray or computerized tomography (CT) when the lesions become large enough to appear as visible opacities. The result is restriction of lung volumes and decreased pulmonary compliance with concomitant reduced gas transfer (Balaan and Banks, 1992). Early stages of chronic silicosis can be referred to as either *simple* or nodular silicosis; later stages are referred to as either *pulmonary massive fibrosis* (PMF), *complicated,* or *advanced* silicosis.

The clinical diagnosis of silicosis has three requisites (Balaan and Banks, 1992; Banks, 2005). The first is the recognition by the physician that exposure to crystalline silica adequate to cause this disease has occurred. The second is the presence of chest radiographic abnormalities consistent with silicosis. The third is the absence of other illnesses that could resemble silicosis on chest radiograph, *e.g.,* pulmonary fungal infection or miliary tuberculosis. To describe the presence and severity of silicosis from chest x-ray films or digital radiographic images, a standardized system exists to classify the opacities seen on chest radiographs (the International Labor Organization (ILO) International Classification of Radiographs of the Pneumoconioses (ILO, 1980, 2002, 2011; Merchant and Schwartz, 1998; NIOSH, 2011). This system standardizes the description of chest x-ray films or digital radiographic images with respect to the size, shape, and density of opacities, which together indicate the severity and extent of lung involvement. The density of opacities seen on chest x-ray films or digital radiographic images is classified on a 4-point major category scale (0, 1, 2, or 3), with each major category divided into three subcategories, giving a 12-point scale between 0/0 and 3/+. (For each subcategory, the top number indicates the major category that the profusion most closely resembles, and the bottom number indicates the major category that was given secondary consideration.) Major category 0 indicates the absence of visible opacities and categories 1 to 3 reflect increasing profusion of opacities and a concomitant increase in severity of disease. Biopsy is not necessary to make a diagnosis and a diagnosis does not require that chest x-ray films or digital radiographic images be rated using the ILO system (NIOSH, 2002). In addition, an assessment of pulmonary function, though not itself necessary to confirm a diagnosis of silicosis, is important to evaluate whether the individual has impaired lung function.

Although chest x-ray is typically used to examine workers exposed to respirable crystalline silica for the presence of silicosis, it is a fairly insensitive tool for detecting lung fibrosis (Hnizdo et al., 1993; Craighead and Vallyathan, 1980; Rosenman et al., 1997). To address the low sensitivity of chest x-rays for detecting silicosis, Hnizdo et al. (1993) recommended that radiographs consistent with an ILO category of 0/1 or greater be considered indicative of silicosis among workers exposed to a high concentration of silica-containing dust. In like manner, to maintain high specificity, chest x-rays classified as category 1/0 or 1/1 should be considered as a positive diagnosis of silicosis.

Newer imaging technologies with both research and clinical applications include computed tomography, and high resolution tomography. High-resolution computed tomography (HRCT) uses thinner image slices and a different reconstruction algorithm to improve spatial resolution over CT. Recent studies of high-resolution computerized tomography (HRCT) have found HRCT to be superior to chest x-ray imaging for detecting small opacities and for identifying PMF (Sun et al., 2008; Lopes et al., 2008; Blum et al., 2008).

The causal relationship between exposure to crystalline silica and silicosis has long been accepted in the scientific and medical communities. Of greater interest to OSHA is the quantitative relationship between exposure to crystalline silica and development of silicosis. A large number of cross-sectional and retrospective studies have been conducted to evaluate this relationship (Kreiss and Zhen, 1996; Love et al., 1999; Ng and Chan, 1994; Rosenman et al., 1996; Hughes et al., 1998; Muir et al., 1989a, 1989b; Park et al., 2002; Chen et al., 2001; Hnizdo and Sluis-Cremer, 1993; Miller et al., 1998; Buchanan et al., 2003; Steenland and Brown, 1995b). In general, these studies, particularly those that included retirees, have found a risk of radiological silicosis (usually defined as x-ray films classified ILO major category 1 or greater) among workers exposed near the range of cumulative exposure permitted by current exposure limits. These studies are presented in detail in OSHA's Preliminary Quantitative Risk Assessment (Section II of the background document and summarized in Section VI of this preamble).

2. Silicosis in the United States

Unlike most occupational diseases, surveillance statistics are available that provide information on the prevalence of silicosis mortality and morbidity in the U.S. The most comprehensive and current source of surveillance data in the U.S. related to occupational lung diseases, including silicosis, is the National Institute for Occupational Safety and Health (NIOSH) Work-Related Lung Disease (WoRLD) Surveillance System; the WoRLD Surveillance Report is compiled from the most recent data from the WoRLD System (NIOSH, 2008c). National statistics on mortality associated with occupational lung diseases are also compiled in the National Occupational Respiratory Mortality System (NORMS, available on the Internet at *http://webappa.cdc.gov/ords/norms.html*), a searchable database administered by NIOSH. In addition, NIOSH published a recent review of mortality statistics in its MMWR Report Silicosis Mortality, Prevention, and Control—United States, 1968–2002 (CDC, 2005). For each of these sources, data are compiled from death certificates reported to state vital statistics offices, which are collected by the National Center for Health Statistics (NCHS). Data on silicosis morbidity are available from only a few states that administer occupational disease surveillance systems, and from data on hospital discharges. OSHA believes that the mortality and morbidity statistics compiled in these sources and summarized below indicate that silicosis remains a significant occupational health problem in the U.S. today.

From 1968 to 2002, silicosis was recorded as an underlying or contributing cause of death on 16,305 death certificates; of these, a total of 15,944 (98 percent) deaths occurred in males (CDC, 2005). From 1968 to 2002, the number of silicosis deaths decreased from 1,157 (8.91 per million persons aged ≥15 years) to 148 (0.66 per million), corresponding to a 93-percent decline in the overall mortality rate. In its most recent WoRLD Report (NIOSH, 2008c), NIOSH reported that the number of silicosis deaths in 2003, 2004, and 2005 were 179, 166, and 161, respectively, slightly higher than that reported in 2002. The number of silicosis deaths identified each year has remained fairly constant since the late 1990's.

NIOSH cited two main factors that were likely responsible for the declining trend in silicosis mortality since 1968. First, many of the deaths in the early part of the study period occurred among persons whose main exposure to crystalline silica dust probably occurred before introduction of national standards for silica dust exposure established by OSHA and the Mine Safety and Health Administration (MSHA) (*i.e.,* permissible exposure limits (PELs)) that likely led to reduced silica dust exposure. Second, there has been declining employment in heavy industries (*e.g.,* foundries) where silica exposure was prevalent (CDC, 2005). Although the factors described by NIOSH are reasonable explanations for the steep reduction in silicosis-related mortality, it should be emphasized that the surveillance data are insufficient for the analysis of residual risk associated with current occupational exposure limits for crystalline silica. Analyses designed to explore this question must make use of appropriate exposure-response data, as is presented in OSHA's Preliminary Quantitative Risk Assessment (summarized in Section VI of this preamble).

Although the number of deaths from silicosis overall has declined since 1968, the number of silicosis-associated deaths reported among persons aged 15 to 44 had not declined substantially prior to 1995 (CDC 1998). Unfortunately, it is not known to what extent these deaths among younger workers were caused by acute or accelerated forms of silicosis.

Silicosis deaths among workers of all ages result in significant premature mortality; between 1996 and 2005, a total of 1,746 deaths resulted in a total of 20,234 years of life lost from life expectancy, with an average of 11.6 years of life lost. For the same period, among 307 decedents who died before age 65, or the end of a working life, there were 3,045 years of life lost to age 65, with an average of 9.9 years of life lost from a working life (NIOSH, 2008c).

Data on the prevalence of silicosis morbidity are available from only three states (Michigan, Ohio, and New Jersey) that have administered disease surveillance programs over the past several years. These programs rely primarily on hospital discharge records, reporting of cases from the medical community, workers' compensation programs, and death certificate data. For the reporting period 1993–2002, the last year for which data are available, three states (Michigan, New Jersey and Ohio) recorded 879 cases of silicosis (NIOSH 2008c). Hospital discharge records represent the primary ascertainment source for all three states. It should be noted that hospital discharge records most likely include cases of acute silicosis or very advance chronic silicosis since it is unlikely that there would be a need for hospitalization in cases with early radiographic signs of silicosis, such as for an ILO category 1/0 x-ray. Nationwide hospital discharge data compiled by NIOSH (2008c) and the Council of State and Territorial Epidemiologists (CSTE, 2005) indicates that there are at least 1,000 hospitalizations each year due to silicosis.

Data on silicosis mortality and morbidity are likely to understate the true impact of exposure of U.S. workers to crystalline silica. This is in part due to underreporting that is characteristic of passive case-based disease surveillance systems that rely on the health care community to generate records (Froines et al., 1989). Health care professionals play the main role in such surveillance by virtue of their unique role in recognizing and diagnosing diseases, but most health care professionals do not take occupational histories (Goldman and Peters, 1981; Rutstein et al., 1983). In addition to the lack of information about exposure histories, difficulty in recognizing occupational illnesses that have long latency periods, like silicosis, contributes to under-recognition and underreporting by health care providers. Based on an analysis of data from Michigan's silicosis surveillance activities, Rosenman et al. (2003) estimated that the true incidence of silicosis mortality and morbidity were understated by a factor of between 2.5 and 5, and that there were estimated to be from 3,600 to 7,300 new cases of silicosis occurring in the U.S. annually between 1987 and 1996. Taken with the surveillance data presented above, OSHA believes that exposure to crystalline silica remains a cause of significant mortality and morbidity in the U.S.

3. Progression of Silicosis and Its Associated Impairment

As described above, silicosis is a progressive lung disease that is usually first detected by the appearance of a diffuse nodular fibrosis on chest x-ray films. To evaluate the clinical significance of radiographic signs of silicosis, OSHA reviewed several studies that have examined how exposure affects progression of the disease (as seen by chest radiography) as well as the relationship between radiologic findings and pulmonary function. The following summarizes OSHA's preliminary findings from this review.

Of the several studies reviewed by OSHA that documented silicosis progression in populations of workers, four studies (Hughes et al., 1982; Hessel et al., 1988; Miller et al., 1998; Ng et al., 1987a) included quantitative exposure data that were based on either current or historical measurements of respirable quartz. The exposure variable most strongly associated in these studies with progression of silicosis was cumulative respirable quartz (or silica) exposure (Hessel et al., 1988; Hughes et al., 1982; Miller et al., 1998; Ng et al., 1987a), though both average concentration of respirable silica (Hughes et al., 1982; Ng et al., 1987a) and duration of employment in dusty jobs have also been found to be associated with the progression of silicosis (Hughes et al., 1982; Ogawa et al., 2003).

The study reflecting average exposures most similar to current exposure conditions is that of Miller et al. (1998), which followed a group of 547 British coal miners in 1990–1991 to evaluate chest x-ray changes that had occurred after the mines closed in 1981. This study had data available from chest x-rays taken during health surveys conducted between 1954 and 1978, as well as data from extensive exposure monitoring conducted between 1964 and 1978. The mean and maximum cumulative exposure reported in the study correspond to average concentrations of 0.12 and 0.55 mg/m^3, respectively, over the 15-year sampling period. However, between 1971 and 1976, workers experienced unusually high concentrations of respirable quartz in one of the two coal seams in which the miners worked. For some occupations, quarterly mean quartz concentrations ranged from 1 to 3 mg/m^3, and for a brief period, concentrations exceeded 10 mg/m^3 for one job. Some of these high exposures likely contributed to the extent of disease progression seen in these workers; in its Preliminary Quantitative Risk Assessment, OSHA reviewed a study by Buchanan et al. (2003), who found that short-term exposures to high (>2 mg/m^3) concentrations of silica can increase the silicosis risk by 3-fold over what would be predicted by cumulative exposure alone (*see* Section VI).

Among the 504 workers whose last chest x-ray was classified as ILO 0/0 or 0/1, 20 percent had experienced onset of silicosis (*i.e.,* chest x-ray was classified as ILO 1/0 by the time of follow up in 1990–1991), and 4.8 percent progressed to at least category 2. However, there are no data available to continue following the progression of this group because there have been no follow-up surveys of this cohort since 1991.

In three other studies examining the progression of silicosis, (Hessel et al., 1988; Hughes et al., 1982; Ng et al., 1987a) cohorts were comprised of silicotics (individuals already diagnosed with silicosis) that were followed further to evaluate disease progression. These studies reflect exposures of workers to generally higher average concentrations of respirable quartz than are permitted by OSHA's current exposure limit. Some general findings from this body of literature follow. First, size of opacities on initial radiograph is a determinant for further progression. Individuals with large opacities on initial chest radiograph have a higher probability of further disease progression than those with small opacities (Hughes et al., 1982; Lee, et al., 2001; Ogawa et al., 2003). Second, although silicotics who continue to be exposed are more likely to progress than silicotics who are not exposed (Hessel et al., 1988), once silicosis has been detected there remains a likelihood of progression in the absence of additional exposure to silica (Hessel et al., 1988; Miller et al., 1998; Ogawa, et al., 2003; Yang et al., 2006). There is some evidence in the literature that the probability of progression is likely to decline over time following the end of the exposure, although this observation may also reflect a survivor effect (Hughes et al., 1982; Lee et al., 2001). In addition, of borderline statistical significance was the association of tuberculosis with increased likelihood of silicosis progression (Lee et al., 2001).

Of the four studies reviewed by OSHA that provided quantitative exposure information, two studies (Miller et al., 1998; Ng et al., 1987a) provide the information most relevant to current exposure conditions. The range of average concentration of respirable crystalline silica to which workers were exposed in these studies (0.12 to 0.48 mg/m^3, respectively) is relatively narrow and is of particular interest to OSHA because current enforcement data indicate that exposures in this range or not much lower are common today, especially in construction and foundries, and sandblasting operations. These studies reported the percentage of workers whose chest x-rays show signs of progression at the time of follow-up; the annual rate at which workers showed disease progression were similar, 2 percent and 6 percent, respectively.

Several cross-sectional and longitudinal studies have examined the relationship between progressive changes observed on radiographs and corresponding declines in lung-function parameters. In general, the results are mixed: some studies have found that pulmonary function losses correlate with the extent of fibrosis seen on chest x-ray films, and others have not found such correlations. The lack of a correlation in some studies between degree of fibrotic profusion seen on chest x-rays and pulmonary function have led some to suggest that pulmonary function loss is an independent effect of exposure to respirable crystalline silica, or may be a consequence of emphysematous changes that have been seen in conjunction with radiographic silicosis.

Among studies that have reported finding a relationship between pulmonary function and x-ray abnormalities, Ng and Chan (1992) found that forced expiratory volume (FEV_1) and forced vital capacity (FVC) were statistically significantly lower for workers whose x-ray films were classified as ILO profusion categories 2 and 3, but not among workers with ILO category 1 profusion compared to those with a profusion score of 0/0. As expected, highly significant reductions in FEV_1, FVC, and FEV_1/FVC were noted in subjects with large opacities. The authors concluded that chronic simple silicosis, except that classified as profusion category 1, is associated with significant lung function impairment attributable to fibrotic disease.

Similarly, Moore et al. (1988) also found chronic silicosis to be associated with significant lung function loss, especially among workers with chest x-rays classified as ILO profusion categories 2 and 3. For those classified as category 1, lung function was not diminished. Bégin et al. (1988) also found a correlation between decreased lung function (FVC and the ratio of FEV_1/FVC) and increased profusion and coalescence of opacities as determined by CT scan. This study demonstrated increased impairment among workers with higher imaging categories (3 and 4), as expected, but also impairment (significantly reduced expiratory flow rates) among persons with more moderate pulmonary fibrosis (group 2).

In a population of gold miners, Cowie (1998) found that lung function declined more rapidly in men with silicosis than those without. In addition to the 24 ml./yr. decrements expected due to aging, this study found an additional loss of 8 ml. of FEV_1 per year would be expected from continued exposure to dust in the mines. An earlier cross-sectional study by these authors (Cowie and Mabena, 1991), which examined 1,197 black underground gold miners who had silicosis, found that silicosis (analyzed as a continuous variable based on chest x-ray film classification) was associated with reductions in FVC, FEV_1, FEV_1/FVC, and carbon monoxide diffusing capacity (DL_{co}), and these relationships persisted after controlling for duration and intensity of exposure and smoking.

In contrast to these studies, other investigators have reported finding pulmonary function decrements in exposed workers independent of radiological evidence of silicosis. Hughes et al. (1982) studied a representative sample of 83 silicotic sandblasters, 61 of whom were followed for one to seven years. A multiple regression analysis showed that the annual reductions in FVC, FEV_1 and DL_{co} were related to average silica concentrations but not duration of exposure, smoking, stage of silicosis, or time from initial exposure. Ng et al. (1987b) found that, among male gemstone workers in Hong Kong with x-rays classified as either Category 0 or 1, declines in FEV_1 and FVC were not associated with radiographic category of silicosis after adjustment for years of employment. The authors concluded that there was an independent effect of respirable dust exposure on pulmonary function. In a population of 61 gold miners, Wiles et al. (1992) also found that radiographic silicosis was not associated with lung function decrements. In a re-analysis and follow-up of an earlier study, Hnizdo (1992) found that silicosis was not a significant predictor of lung function, except for FEV_1 for non-smokers.

Wang et al. (1997) observed that silica-exposed workers (both nonsmokers and smokers), even those without radiographic evidence of silicosis, had decreased spirometric parameters and diffusing capacity (DL_{co}). Pulmonary function was further decreased in the presence of silicosis, even those with mild to moderate disease (ILO categories 1 and 2). The authors concluded that functional abnormalities precede radiographic changes of silicosis.

A number of studies were conducted to examine the role of emphysematous changes in the presence of silicosis in reducing lung function; these have been reviewed by Gamble et al. (2004), who concluded that there is little evidence that silicosis is related to development of emphysema in the absence of PMF. In addition, Gamble et al. (2004) found that, in general, studies found that the lung function of those with radiographic silicosis in ILO category 1 was indistinguishable from those in category 0, and that those in category 2 had small reductions in lung function relative to those with category 0 and little difference in the prevalence of emphysema. There were slightly greater decrements in lung function with category 3 and more significant reductions with progressive massive fibrosis. In studies for which information was available on both silicosis and emphysema, reduced lung function was more strongly related to emphysema than to silicosis.

In conclusion, many studies reported finding an association between pulmonary function decrements and ILO category 2 or 3 background profusion of small opacities; this appears to be consistent with the histopathological view, in which individual fibrotic nodules conglomerate to form a massive fibrosis (Ng and Chan, 1992). Emphysema may also play a role in reducing lung function in workers with higher grades of silicosis. Pulmonary function decrements have not been reported in some studies among workers with silicosis scored as ILO category 1. However, a number of other studies have documented declines in pulmonary function in persons exposed to silica and whose radiograph readings are in the major ILO category 1 (*i.e.* 1/0, 1/1, 1/2), or even before changes were seen on chest x-ray (Bégin et al., 1988; Cowie, 1998; Cowie and Mabena, 1991; Ng et al., 1987a; Wang et al., 1997). It may also be that studies designed to relate x-ray findings with pulmonary function declines are further confounded by pulmonary function declines caused by chronic obstructive pulmonary disease (COPD) seen among silica-exposed workers absent radiological silicosis, as has been seen in many investigations of COPD. OSHA's review of the literature on crystalline silica exposure and development of COPD appears in section II.D of the background document and is summarized in section V.D below.

OSHA believes that the literature reviewed above demonstrates decreased lung function among workers with radiological evidence of silicosis consistent with an ILO classification of major category 2 or higher. Also, given the evidence of functional impairment in some workers prior to radiological evidence of silicosis, and given the low sensitivity of radiography, particularly in detecting early silicosis, OSHA believes that exposure to silica impairs lung function in at least some individuals before silicosis can be detected on chest radiograph.

4. Pulmonary Tuberculosis

As silicosis progresses, it may be complicated by severe mycobacterial infections, the most common of which is pulmonary tuberculosis (TB). Active tuberculosis infection is a well-recognized complication of chronic silicosis, and such infections are known as silicotuberculosis (IARC, 1997; NIOSH, 2002). The risk of developing TB infection is higher in silicotics than non-silicotics (Balmes, 1990; Cowie, 1994; Hnizdo and Murray, 1998; Kleinschmidt and Churchyard, 1997; and Murray et al., 1996). There also is evidence that exposure to silica increases the risk for pulmonary tuberculosis independent of the presence of silicosis (Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude et al., 2006). In a summary of the literature on silica-related disease mechanisms, Ding et al. (2002) noted that it is well documented that exposure to silica can lead to impaired cell-mediated immunity, increasing susceptibility to mycobacterial infection. Reduced numbers of T-cells, increased numbers of B-cells, and alterations of serum immunoglobulin levels have been observed in workers with silicosis. In addition, according to Ng and Chan (1991), silicosis and TB act synergistically to increase fibrotic scar tissue (leading to massive fibrosis) or to enhance susceptibility to active mycobacterial infection. Lung fibrosis is common to both diseases and both diseases decrease the ability of alveolar macrophages to aid in the clearance of dust or infectious particles.

B. Carcinogenic Effects of Silica (Cancer of the Lung and Other Sites)

OSHA conducted an independent review of the epidemiological literature on exposure to respirable crystalline silica and lung cancer, covering more than 30 occupational groups in over a dozen industrial sectors. In addition, OSHA reviewed a pooled case-control study, a large national death certificate study, two national cancer registry studies, and six meta-analyses. In all, OSHA's review included approximately 60 primary epidemiological studies.

Based on its review, OSHA preliminarily concludes that the human data summarized in this section provides ample evidence that exposure to respirable crystalline silica increases the risk of lung cancer among workers. The strongest evidence comes from the worldwide cohort and case-control studies reporting excess lung cancer mortality among workers exposed to respirable crystalline silica dust as quartz in various industrial sectors, including the granite/stone quarrying and processing, industrial sand, mining, and pottery and ceramic industries, as well as to cristobalite in diatomaceous earth and refractory brick industries. The 10-cohort pooled case-control analysis by Steenland et al. (2001a) confirms these findings. A more recent clinic-based pooled case-control analysis of seven European countries by Cassidy et al. (2007) as well as two national death certificate registry studies (Pukkala et al., 2005 in Finland; Calvert et al., 2003 in the United States) support the findings from the cohort and case-control analysis.

1. Overall and Industry Sector-Specific Findings

Associations between exposure to respirable crystalline silica and lung cancer have been reported in worker populations from many different industrial sectors. IARC (1997) concluded that crystalline silica is a confirmed human carcinogen based largely on nine studies of cohorts in four industry sectors that IARC considered to be the least influenced by confounding factors (sectors included quarries and granite works, gold mining, ceramic/pottery/refractory brick industries, and the diatomaceous earth industry). IARC (2012) recently reaffirmed that crystalline silica is a confirmed human carcinogen. NIOSH (2002) also determined that crystalline silica is a human carcinogen after evaluating updated literature.

OSHA believes that the strongest evidence for carcinogenicity comes from studies in five industry sectors. These are:

- Diatomaceous Earth Workers (Checkoway et al., 1993, 1996, 1997, and 1999; Seixas et al., 1997);
- British Pottery Workers (Cherry et al., 1998; McDonald et al., 1995);
- Vermont Granite Workers (Attfield and Costello, 2004; Graham et al., 2004; Costello and Graham, 1988; Davis et al., 1983);
- North American Industrial Sand Workers (Hughes et al., 2001; McDonald et al., 2001, 2005; Rando et al., 2001; Sanderson et al., 2000; Steenland and Sanderson, 2001); and
- British Coal Mining (Miller et al., 2007; Miller and MacCalman, 2009).

The studies above were all retrospective cohort or case-control studies that demonstrated positive, statistically significant exposure-response relationships between exposure to crystalline silica and lung cancer mortality. Except for the British pottery studies, where exposure-response trends were noted for average exposure only, lung cancer risk was found to be related to cumulative exposure. OSHA credits these studies because in general, they are of sufficient size and have adequate years of follow up, and have sufficient quantitative exposure data to reliably estimate exposures of cohort members. As part of their analyses, the authors of these studies also found positive exposure-response relationships for silicosis, indicating that underlying estimates of worker exposures were not likely to be substantially misclassified. Furthermore, the authors of these studies addressed potential confounding due to other carcinogenic exposures through study design or data analysis.

A series of studies of the diatomaceous earth industry (Checkoway et al., 1993, 1996, 1997, 1999) demonstrated positive exposure-response trends between cristobalite exposures and lung cancer as well as non-malignant respiratory disease mortality (NMRD). Checkoway et al. (1993) developed a ''semi-quantitative'' cumulative exposure estimate that demonstrated a statistically significant positive exposure-response trend ($p = 0.026$) between duration of employment or cumulative exposure and lung cancer mortality. The quartile analysis showed a monotonic increase in lung cancer mortality, with the highest exposure quartile having a RR of 2.74 for lung cancer mortality. Checkoway et al. (1996) conducted a re-analysis to address criticisms of potential confounding due to asbestos and again demonstrated a positive exposure response risk gradient when controlling for asbestos exposure and other variables. Rice et al. (2001) conducted a re-analysis and quantitative risk assessment of the Checkoway et al. (1997) study, which OSHA has included as part of its assessment of lung cancer mortality risk (*See* Section II, Preliminary Quantitative Risk Assessment).

In the British pottery industry, excess lung cancer risk was found to be associated with crystalline silica exposure among workers in a PMR study (McDonald et al., 1995) and in a cohort and nested case-control study (Cherry et al., 1998). In the PMR study, elevated PMRs for lung cancer were found after adjusting for potential confounding by asbestos exposure. In the study by Cherry et al., odds ratios for lung cancer mortality were statistically significantly elevated after adjusting for smoking. Odds ratios were related to average, but not cumulative, exposure to crystalline silica. The findings of the British pottery studies are supported by other studies within their industrial sector. Studies by Winter et al. (1990) of British pottery workers and by McLaughlin et al. (1992) both reported finding suggestive trends of increased lung cancer mortality with increasing exposure to respirable crystalline silica.

Costello and Graham (1988) and Graham et al. (2004) in a follow-up study found that Vermont granite workers employed prior to 1930 had an excess risk of lung cancer, but lung cancer mortality among granite workers hired after 1940 (post-implementation of controls) was not elevated in the Costello and Graham (1988) study and was only somewhat elevated (not statistically significant) in the Graham et al. (2004) study. Graham et al. (2004) concluded that their results did not support a causal relationship between granite dust exposure and lung cancer mortality. Looking at the same population, Attfield and Costello (2004) developed a quantitative estimate of cumulative exposure (8 exposure categories) adapted from a job exposure matrix developed by Davis et al. (1983). They found a statistically significant trend with log-transformed cumulative exposure. Lung cancer mortality rose reasonably consistently through the first seven increasing exposure groups, but fell in the highest cumulative exposure group. With the highest exposure group omitted, a strong positive dose-response trend was found for both untransformed and log-transformed cumulative exposures. Attfield and Costello (2004) concluded that exposure to crystalline silica in the range of cumulative exposures typically experienced by contemporarily exposed workers causes an increased risk of lung cancer mortality. The authors explained that the highest exposure group would have included the most unreliable exposure estimates being reconstructed from exposures 20 years prior to study initiation when exposure estimation was less precise. Also, even though the highest exposure group consisted of only 15 percent of the study population, it had a disproportionate effect on dampening the exposure-response relationship.

OSHA believes that the study by Attfield and Costello (2004) is of superior design in that it was a categorical analysis that used quantitative estimates of exposure and evaluated lung cancer mortality rates by exposure group. In contrast, the findings by Graham et al. (2004) are based on a dichotomous comparison of risk among high- versus low-exposure groups, where date-of-hire before and after implementation of ventilation controls is used as a surrogate for exposure. Consequently, OSHA believes that the study by Attfield and Costello is the more convincing study, and is one of the studies used by OSHA for quantitative risk assessment of lung cancer mortality due to crystalline silica exposure.

The conclusions of the Vermont granite worker study (Attfield and Costello, 2004) are supported by the findings in studies of workers in the U.S. crushed stone industry (Costello et al., 1995) and Danish stone industry (Guénel et al., 1989a, 1989b). Costello et al. (1995) found a non-statistically significant increase in lung cancer mortality among limestone quarry workers and a statistically significant increased lung cancer mortality in granite quarry workers who worked 20 years or more since first exposure. Guénel et al. (1989b), in a Danish cohort study, found statistically significant increases in lung cancer incidence among skilled stone workers and skilled granite stone cutters. A study of Finnish granite workers that initially showed increasing risk of lung cancer with increasing silica exposure, upon extended follow-up, did not show an association and is therefore considered a negative study (Toxichemica, Inc., 2004).

Studies of two overlapping cohorts in the industrial sand industry (Hughes et al., 2001; McDonald et al., 2001, 2005; Rando et al., 2001; Sanderson et al., 2000; Steenland and Sanderson, 2001) reported comparable results. These studies found a statistically significantly increased risk of lung cancer mortality with increased cumulative exposure in both categorical and continuous analyses. McDonald et al. (2001) examined a cohort that entered the workforce, on average, a decade earlier than the cohorts that Steenland and Sanderson (2001) examined. The McDonald cohort, drawn from eight plants, had more years of exposure in the industry (19 versus 8.8 years). The Steenland and Sanderson (2001) cohort worked in 16 plants, 7 of which overlapped with the McDonald, et al. (2001) cohort. McDonald et al. (2001), Hughes et al. (2001), and Rando et al. (2001) had access to smoking histories, plant records, and exposure measurements that allowed for historical reconstruction and the development of a job exposure matrix. Steenland and Sanderson (2001) had limited access to plant facilities, less detailed historic exposure data, and used MSHA enforcement records for estimates of recent exposure. These studies (Hughes et al., 2001; McDonald et al., 2005; Steenland and Sanderson, 2001) show very similar exposure response patterns of increased lung cancer mortality with increased exposure. OSHA included the quantitative exposure-response analysis from the Hughes et al. (2001) study in its Preliminary Quantitative Risk Assessment (Section II).

Brown and Rushton (2005a, 2005b) found no association between risk of lung cancer mortality and exposure to respirable crystalline silica among British industrial sand workers. However, the small sample size and number of years of follow-up limited the statistical power of the analysis. Additionally, as Steenland noted in a letter review (2005a), the cumulative exposures of workers in the Brown and Ruston (2005b) study were over 10 times lower than the cumulative exposures experienced by the cohorts in the pooled analysis that Steenland et al. (2001b) performed. The low exposures experienced by this cohort would have made detecting a positive association with lung cancer mortality even more difficult.

Excess lung cancer mortality was reported in a large cohort study of British coal miners (Miller et al., 2007; Miller and MacCalman, 2009). These studies examined the mortality experience of 17,800 miners through the end of 2005. By that time, the cohort had accumulated 516,431 person years of observation (an average of 29 years per miner), with 10,698 deaths from all causes. Overall lung cancer mortality was elevated (SMR=115.7, 95% C.I. 104.8–127.7), and a positive exposure-response relationship with crystalline silica exposure was determined from Cox regression after adjusting for smoking history. Three of the strengths of this study are the detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. For lung cancer, analyses based on the Cox regression provide strong evidence that, for these coal miners, quartz exposures were associated with increased lung cancer risk but that simultaneous exposures to coal dust did not cause increased lung cancer risk. Because of these strengths, OSHA included the quantitative analysis from this study in its Preliminary Quantitative Risk Assessment (Section II).

Studies of lung cancer mortality in metal ore mining populations reflect mixed results. Many of these mining studies were subject to confounding due to exposure to other potential carcinogens such as radon and arsenic. IARC (1997) noted that in only a few ore mining studies was confounding from other occupational carcinogens taken into account. IARC (1997) also noted that, where confounding was absent or accounted for in the analysis (gold miners in the U.S., tungsten miners in China, and zinc and lead miners in Sardinia, Italy), an association between silica exposure and lung cancer was absent. Many of the studies conducted since IARC's (1997) review more strongly implicate crystalline silica as a human carcinogen. Pelucchi et al. (2006), in a meta-analysis of studies conducted since IARC's (1997) review, reported statistically significantly elevated relative risks of lung cancer mortality in underground and surface miners in three cohort and four case-control studies (*See* Table I–15). Cassidy et al. (2007), in a pooled case-control analysis, showed a statistically significant increased risk of lung cancer mortality among miners (OR = 1.48). Cassidy et al. (2007) also demonstrated a clear linear trend of increasing odds ratios for lung cancer with increasing exposures.

Among workers in Chinese tungsten and iron mines, mortality from lung cancer was not found to be statistically significantly increased (Chen et al., 1992; McLaughlin et al., 1992). In contrast, studies of Chinese tin miners found increased lung cancer mortality rates and positive exposure-response associations with increased silica exposure (Chen et al., 1992). Unfortunately, in many of these Chinese tin mines, there was potential confounding from arsenic exposure, which was highly correlated with exposure to crystalline silica (Chen and Chen, 2002; Chen et al., 2006). Two other studies (Carta et al. (2001) of Sardinian miners and stone quarrymen; Finkelstein (1998) primarily of Canadian miners) were limited to silicotics. The Sardinian study found a non-statistically significant association between crystalline silica exposure and lung cancer mortality but no apparent exposure-response trend with silica exposure. The authors attributed the increased lung cancer to increased radon exposure and smoking among cases as compared to controls. Finkelstein (1998) found a positive association between silica exposure and lung cancer.

Gold mining has been extensively studied in the United States, South

Africa, and Australia in four cohort and associated nested case-control studies, and in two separate case-control studies conducted in South Africa. As with metal ore mining, gold mining involves exposure to radon and other carcinogenic agents, which may confound the relationship between silica exposure and lung cancer. The U.S. gold miner study (Steenland and Brown, 1995a) did not find an increased risk of lung cancer, while the western Australian gold miner study (de Klerk and Musk, 1998) showed a SMR of 149 (95% CI 1.26–1.76) for lung cancer. Logistic regression analysis of the western Australian case control data showed that lung cancer mortality was statistically significantly associated with log cumulative silica exposure after adjusting for smoking and bronchitis. After additionally adjusting for silicosis, the relative risk remained elevated but was no longer statistically significant. The authors concluded that their findings showed statistically significantly increased lung cancer mortality in this cohort but that the increase in lung cancer mortality was restricted to silicotic members of the cohort.

Four studies of gold miners were conducted in South Africa. Two case control studies (Hessel et al., 1986, 1990) reported no significant association between silica exposure and lung cancer, but these two studies may have underestimated risk, according to Hnizdo and Sluis-Cremer (1991). Two cohort studies (Reid and Sluis-Cremer, 1996; Hnizdo and Sluis-Cremer, 1991) and their associated nested case-control studies found elevated SMRs and odds ratios, respectively, for lung cancer. Reid and Sluis-Cremer (1996) attributed the increased mortality due to lung cancer and other non-malignant respiratory diseases to cohort members' lifestyle choices (particularly smoking and alcohol consumption). However, OSHA notes that the study reported finding a positive, though not statistically significant, association between cumulative crystalline silica exposure and lung cancer, as well as statistically significant association with renal failure, COPD, and other respiratory diseases that have been implicated with silica exposure.

In contrast, Hnizdo and Sluis-Cremer (1991) found a positive exposure-response relationship between cumulative exposure and lung cancer mortality among South African gold miners after accounting for smoking. In a nested case-control study from the same cohort, Hnizdo et al. (1997) found a statistically significant increase in lung cancer mortality that was associated with increased cumulative dust exposure and time spent underground. Of the studies examining silica and lung cancer among South African gold miners, these two studies were the least likely to have been affected by exposure misclassification, given their rigorous methodologies and exposure measurements. Although not conclusive in isolation, OSHA considers the mining study results, particularly the gold mining and the newer mining studies, as supporting evidence of a causal relationship between exposure to silica and lung cancer risk.

OSHA has preliminarily determined that the results of the studies conducted in three industry sectors (foundry, silicon carbide, and construction sectors) were confounded by the presence of exposures to other carcinogens. Exposure data from these studies were not sufficient to distinguish between exposure to silica dust and exposure to other occupational carcinogens. Thus, elevated rates of lung cancer found in these industries could not be attributed to silica. IARC previously made a similar determination in reference to the foundry industry. However, with respect to the construction industry, Cassidy et al. (2007), in a large, European community-based case-control study, reported finding a clear linear trend of increasing odds ratio with increasing cumulative exposure to crystalline silica (estimated semi-quantitatively) after adjusting for smoking and exposure to insulation and wood dusts. Similar trends were found for workers in the manufacturing and mining industries as well. This study was a very large multi-national study that utilized information on smoking histories and exposure to silica and other occupational carcinogens. OSHA believes that this study provides further evidence that exposure to crystalline silica increases the risk of lung cancer mortality and, in particular, in the construction industry.

In addition, a recent analysis of 4.8 million death certificates from 27 states within the U.S. for the years 1982 to 1995 showed statistically significant excesses in lung cancer mortality, silicosis mortality, tuberculosis, and NMRD among persons with occupations involving medium and high exposure to respirable crystalline silica (Calvert et al., 2003). A national records and death certificate study was also conducted in Finland by Pukkala et al. (2005), who found a statistically significant excess of lung cancer incidence among men and women with estimated medium and heavy exposures. OSHA believes that these large national death certificate studies and the pooled European community-based case-control study are strongly supportive of the previously reviewed epidemiologic data and supports the conclusion that occupational exposure to crystalline silica is a risk factor for lung cancer mortality.

One of the more compelling studies evaluated by OSHA is the pooled analysis of 10 occupational cohorts (5 mines and 5 industrial facilities) conducted by Steenland et al. (2001a), which demonstrated an overall positive exposure-response relationship between cumulative exposure to silica and lung cancer mortality. These ten cohorts included 65,980 workers and 1,072 lung cancer deaths, and were selected because of the availability of raw data on exposure to crystalline silica and health outcomes. The investigators used a nested case control design and found lung cancer risk increased with increasing cumulative exposure, log cumulative exposure, and average exposure. Exposure-response trends were similar between mining and non-mining cohorts. From their analysis, the authors concluded that ''[d]espite this relatively shallow exposure–response trend, overall our results tend to support the recent conclusion by IARC (1997) that inhaled crystalline silica in occupational settings is a human carcinogen, and suggest that existing permissible exposure limits for silica need to be lowered (Steenland et al., 2001a). To evaluate the potential effect of random and systematic errors in the underlying exposure data from these 10 cohort studies, Steenland and Bartell (Toxichemica, Inc., 2004) conducted a series of sensitivity analyses at OSHA's request. OSHA's Preliminary Quantitative Risk Assessment (Section II) presents additional information on the Steenland et al. (2001a) pooled cohort study and the sensitivity analysis performed by Steenland and Bartell (Toxichemica, Inc., 2004).

2. Smoking, Silica Exposure, and Lung Cancer

Smoking is known to be a major risk factor for lung cancer. However, OSHA believes it is unlikely that smoking explains the observed exposure-response trends in the studies described above, particularly the retrospective cohort or nested case-control studies of diatomaceous earth, British pottery, Vermont granite, British coal, South African gold, and industrial sand workers. Also, the positive associations between silica exposure and lung cancer in multiple studies in multiple sectors indicates that exposure to crystalline silica independently increases the risk of lung cancer.

Studies by Hnizdo et al. (1997), McLaughlin et al. (1992), Hughes et al. (2001), McDonald et al. (2001, 2005), Miller and MacCalman (2009), and Cassidy et al. (2007) had detailed smoking histories with sufficiently large populations and a sufficient number of years of follow-up time to quantify the interaction between crystalline silica exposure and cigarette smoking. In a cohort of white South African gold miners (Hnizdo and Sluis-Cremer, 1991) and in the follow-up nested case-control study (Hnizdo et al., 1997) found that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive, suggesting a multiplicative effect. This synergy appeared to be greatest for miners with greater than 35 pack-years of smoking and higher cumulative exposure to silica. In the Chinese nested case-control studies reported by McLaughlin et al. (1992), cigarette smoking was associated with lung cancer, but control for smoking did not influence the association between silica and lung cancer in the mining and pottery cohorts studied. The studies of industrial sand workers by Hughes et al. (2001) and British coal workers by Miller and MacCalman (2009) found positive exposure-response trends after adjusting for smoking histories, as did Cassidy et al. (2007) in their community-based case-control study of exposed European workers.

In reference to control of potential confounding by cigarette smoking in crystalline silica studies, Stayner (2007), in an invited journal commentary, stated:

> Of particular concern in occupational cohort studies is the difficulty in adequately controlling for confounding by cigarette smoking. Several of the cohort studies that adjusted for smoking have demonstrated an excess of lung cancer, although the control for smoking in many of these studies was less than optimal. The results of the article by Cassidy et al. presented in this journal appear to have been well controlled for smoking and other workplace exposures. It is quite implausible that residual confounding by smoking or other risk factors for lung cancer in this or other studies could explain the observed excess of lung cancer in the wide variety of populations and study designs that have been used. Also, it is generally considered very unlikely that confounding by smoking could explain the positive exposure-response relationships observed in these studies, which largely rely on comparisons between workers with similar socioeconomic backgrounds.

Given the findings of investigators who have accounted for the impact of smoking, the weight of the evidence reviewed here implicates respirable crystalline silica as an independent risk factor for lung cancer mortality. This finding is further supported by animal studies demonstrating that exposure to silica alone can cause lung cancer (*e.g.,* Muhle et al., 1995).

3. Silicosis and Lung Cancer Risk

In general, studies of workers with silicosis, as well as meta-analyses that include these studies, have shown that workers with radiologic evidence of silicosis have higher lung cancer risk than those without radiologic abnormalities or mixed cohorts. Three meta-analyses attempted to look at the association of increasing ILO radiographic categories of silicosis with increasing lung cancer mortality. Two of these analyses (Kurihara and Wada, 2004; Tsuda et al., 1997) showed no association with increasing lung cancer mortality, while Lacasse et al. (2005) demonstrated a positive dose-response for lung cancer with increasing ILO radiographic category. A number of other studies, discussed above, found increased lung cancer risk among exposed workers absent radiological evidence of silicosis (Cassidy et al., 2007; Checkoway et al., 1999; Cherry et al., 1998; Hnizdo et al., 1997; McLaughlin et al., 1992). For example, the diatomaceous earth study by Checkoway et al. (1999) showed a statistically significant exposure-response for lung cancer among non-silicotics. Checkoway and Franzblau (2000), reviewing the international literature, found all epidemiological studies conducted to that date were insufficient to conclusively determine the role of silicosis in the etiology of lung cancer. OSHA preliminarily concludes that the more recent pooled and meta-analyses do not provide compelling evidence that silicosis is a necessary precursor to lung cancer. The analyses that do suggest an association between silicosis and lung cancer may simply reflect that more highly exposed individuals are at a higher risk for lung cancer.

Animal and *in vitro* studies have demonstrated that the early steps in the proposed mechanistic pathways that lead to silicosis and lung cancer seem to share some common features. This has led some of these researchers to also suggest that silicosis is a prerequisite to lung cancer. Some have suggested that any increased lung cancer risk associated with silica may be a consequence of the inflammation (and concomitant oxidative stress) and increased epithelial cell proliferation associated with the development of silicosis. However, other researchers have noted that other key factors and proposed mechanisms, such as direct damage to DNA by silica, inhibition of p53, loss of cell cycle regulation, stimulation of growth factors, and production of oncogenes, may also be involved in carcinogenesis induced by silica (*see* Section II.F of the background document for more information on these studies). Thus, OSHA preliminarily concludes that available animal and *in vitro* studies do not support the hypothesis that development of silicosis is necessary for silica exposure to cause lung cancer.

4. Relationship Between Silica Polymorphs and Lung Cancer Risk

OSHA's current PELs for respirable crystalline silica reflects a once-held belief that cristobalite is more toxic than quartz (*i.e.,* the existing general industry PEL for cristobalite is one-half the general industry PEL for quartz). Available evidence indicates that this does not appear to be the case with respect to the carcinogenicity of crystalline silica. A comparison between cohorts having principally been exposed to cristobalite (the diatomaceous earth study and the Italian refractory brick study) with other well conducted studies of quartz-exposed cohorts suggests no difference in the toxicity of cristobalite versus quartz. The data indicates that the SMRs for lung cancer mortality among workers in the diatomaceous earth (SMR = 141) and refractory brick (SMR=151) cohort studies are within the range of the SMR point estimates of other cohort studies with principally quartz exposures (quartz exposure of Vermont granite workers yielding an SMR of 117; quartz and possible post-firing cristobalite exposure of British pottery workers yielding an SMR of 129; quartz exposure among industrial sand workers yielding SMRs of 129, (McDonald et al., 2001) and 160 (Steenland and Sanderson, 2001)). Also, the SMR point estimates for the diatomaceous earth and refractory brick studies are similar to, and fall within the 95 percent confidence interval of, the odds ratio (OR=1.37, 95% CI 1.14–1.65) of the recently conducted multi-center case-control study in Europe (Cassidy et al., 2007).

OSHA believes that the current epidemiological literature provides little, if any, support for treating cristobalite as presenting a greater lung cancer risk than comparable exposure to respirable quartz. Furthermore, the weight of the available toxicological literature no longer supports the hypothesis that cristobalite has a higher toxicity than quartz, and quantitative estimates of lung cancer risk do not suggest that cristobalite is more carcinogenic than quartz. (*See* Section I.F of the background document, Physical Factors that May Influence Toxicity of Crystalline Silica, for a fuller discussion of this issue.) OSHA preliminary concludes that respirable cristobalite and quartz dust have similar potencies for increasing lung cancer risk. Both IARC (1997) and NIOSH (2002) reached similar conclusions.

5. Cancers of Other Sites

Respirable crystalline silica exposure has also been investigated as a potential risk factor for cancer at other sites such as the larynx, nasopharynx and the digestive system including the esophagus and stomach. Although many of these studies suggest an association between exposure to crystalline silica and an excess risk of cancer mortality, most are too limited in terms of size, study design, or potential for confounding to be conclusive. Other than for lung cancer, cancer mortality studies demonstrating a dose-response relationship are quite limited. In their silica hazard review, NIOSH (2002) concluded that, exclusive of the lung, an association has not been established between silica exposure and excess mortality from cancer at other sites. A brief summary of the relevant literature is presented below.

a. Cancer of the Larynx and Nasopharynx

Several studies, including three of the better-quality lung cancer studies (Checkoway et al., 1997; Davis et al., 1983; McDonald et al., 2001) suggest an association between exposure to crystalline silica and increased mortality from laryngeal cancer. However, the evidence for an association is not strong due to the small number of cases reported and lack of statistical significance of most of the findings.

b. Gastric (Stomach) Cancer

In their 2002 hazard review of respirable crystalline silica, NIOSH identified numerous epidemiological studies and reported statistically significant increases in death rates due to gastric or stomach cancer. OSHA preliminarily concurs with observations made previously by Cocco et al. (1996) and the NIOSH (2002) crystalline silica hazard review that the vast majority of epidemiology studies of silica and stomach cancer have not sufficiently adjusted for the effects of confounding factors or have not been sufficiently designed to assess a dose-response relationship (*e.g.,* Finkelstein and Verma, 2005; Moshammer and Neuberger, 2004; Selikoff, 1978, Stern et al., 2001). Other studies did not demonstrate a statistically significant dose-response relationship (*e.g.,* Calvert et al., 2003; Tsuda et al., 2001). Therefore, OSHA believes the evidence is insufficient to conclude that silica is a gastric carcinogen.

c. Esophageal Cancer

Three well-conducted nested case-control studies of Chinese workers indicated an increased risk of esophageal cancer mortality attributed by the study's authors to respirable crystalline silica exposure in refractory brick production, boiler repair, and foundry workers (Pan et al., 1999; Wernli et al., 2006) and caisson construction work (Yu et al., 2005). Each study demonstrated a dose-response association with some surrogate measure of exposure, but confounding due to other occupational exposures is possible in all three work settings (heavy metal exposure in the repair of boilers in steel plants, PAH exposure in foundry workers, radon and radon daughter exposure in Hong Kong caisson workers). Other less well-constructed studies also indicated elevated rates of esophageal cancer mortality with silica exposure (Tsuda et al., 2001; Xu et al., 1996a).

In contrast, two large national mortality studies in Finland and the United States, using qualitatively ranked exposure estimates, did not show a positive association between silica exposure and esophageal cancer mortality (Calvert et al., 2003; Weiderpass et al., 2003). OSHA preliminarily concludes that the epidemiological literature is not sufficiently robust to attribute increased esophageal cancer mortality to exposure to respirable crystalline silica.

d. Other Miscellaneous Cancers

In 2002, NIOSH conducted a thorough literature review of the health effects potentially associated with crystalline silica exposure including a review of lung cancer and other carcinogens. NIOSH noted that for workers who may have been exposed to crystalline silica, there have been infrequent reports of statistically significant excesses of deaths for other cancers. A summary of these cancer studies as cited in NIOSH (2002) have been reported in the following organ systems (*see* NIOSH, 2002 for full bibliographic references): salivary gland; liver; bone; pancreatic; skin; lymphopoetic or hematopoietic; brain; and bladder.

According to NIOSH (2002), an association has not been established between these cancers and exposure to crystalline silica. OSHA believes that these isolated reports of excess cancer mortality at these sites are not sufficient to draw any inferences about the role of silica exposure. The findings have not been consistently seen among epidemiological studies and there is no evidence of an exposure response relationship.

C. Other Nonmalignant Respiratory Disease

In addition to causing silicosis, exposure to crystalline silica has been associated with increased risks of other non-malignant respiratory diseases (NMRD), primarily chronic obstructive pulmonary disease (COPD). COPD is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases. In patients with COPD, either chronic bronchitis or emphysema may be present or both conditions may be present together. The following presents OSHA's discussion of the literature describing the relationships between silica exposure and non-malignant respiratory disease.

1. Emphysema

OSHA has considered a series of longitudinal studies of white South African gold miners conducted by Hnizdo and co-workers. Hnizdo et al. (1991) found a significant association between emphysema (both panacinar and centriacinar) and years of employment in a high dust occupation (respirable dust was estimated to contain 30 percent free silica). There was no such association found for non-smokers, as there were only four non-smokers with a significant degree of emphysema found in the cohort. A further study by Hnizdo et al. (1994) looked at only life-long non-smoking South African gold miners. In this population, no significant degree of emphysema or association with years of exposure or cumulative dust exposure was found. However, the degree of emphysema was significantly associated with the degree of hilar gland nodules, which the authors suggested might act as a surrogate for exposure to silica. The authors concluded that the minimal degree of emphysema seen in non-smoking miners exposed to the cumulative dust levels found in this study (mean 6.8 mg/m^3, SD 2.4, range 0.5 to 20.2, 30 percent crystalline silica) was unlikely to cause meaningful impairment of lung function.

From the two studies above, Hnizdo et al. (1994) concluded that the statistically significant association between exposure to silica dust and the degree of emphysema in smokers suggests that tobacco smoking potentiates the effect of silica dust. In contrast to their previous studies, a later study by Hnizdo et al. (2000) of South African gold miners found that emphysema prevalence was decreased in relation to dust exposure. The authors suggested that selection bias was responsible for this finding.

The findings of several cross-sectional and case-control studies were more mixed. Becklake et al. (1987), in an unmatched case-control study of white South African gold miners, determined that a miner who had worked in high dust for 20 years had a greater chance of getting emphysema than a miner who had never worked in high dust. A reanalysis of this data (de Beer et al., 1992) including added-back cases and controls (because of possible selection bias in the original study), still found an increased risk for emphysema, although the reported odds ratio was smaller than previously reported by Becklake et al. (1987). Begin et al. (1995), in a study of the prevalence of emphysema in silica-exposed workers with and without silicosis, found that silica-exposed smokers without silicosis had a higher prevalence of emphysema than a group of asbestos-exposed workers with similar smoking history. In non-smokers, the prevalence of emphysema was much higher in those with silicosis than in those without silicosis. A study of black underground gold miners found that the presence and grade of emphysema were statistically significantly associated with the presence of silicosis but not with years of mining (Cowie et al., 1993).

Several of the above studies (Becklake et al., 1987; Begin et al., 1995; Hnizdo et al., 1994) found that emphysema can occur in silica-exposed workers who do not have silicosis and suggest that a causal relationship may exist between exposure to silica and emphysema. The findings of experimental (animal) studies that emphysema occurs at lower silica doses than does fibrosis in the airways or the appearance of early silicotic nodules (*e.g.,* Wright et al., 1988) tend to support the findings in human studies that silica-induced emphysema can occur absent signs of silicosis.

Others have also concluded that there is a relationship between emphysema and exposure to crystalline silica. Green and Vallyathan (1996) reviewed several studies of emphysema in workers exposed to silica. The authors stated that these studies show an association between cumulative dust exposure and death from emphysema. IARC (1997) has also briefly reviewed studies on emphysema in its monograph on crystalline silica carcinogenicity and concluded that exposure to crystalline silica increases the risk of emphysema. In their 2002 Hazard Review, NIOSH concluded that occupational exposure to respirable crystalline silica is associated with emphysema but that some epidemiologic studies suggested that this effect may be less frequent or absent in non-smokers.

Hnizdo and Vallyathan (2003) also conducted a review of studies addressing COPD due to occupational silica exposure and concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause emphysema.

Based on these findings, OSHA preliminarily concludes that exposure to respirable crystalline silica or silica-containing dust can increase the risk of emphysema, regardless of whether silicosis is present. This appears to be clearly the case for smokers. It is less clear whether nonsmokers exposed to silica would also be at higher risk and if so, at what levels of exposure. It is also possible that smoking potentiates the effect of silica dust in increasing emphysema risk.

2. Chronic Bronchitis

There were no longitudinal studies available designed to investigate the relationship between silica exposure and bronchitis. However, several cross-sectional studies provide useful information. Studies are about equally divided between those that have reported a relationship between silica exposure and bronchitis and those that have not. Several studies demonstrated a qualitative or semiquantitative relationship between silica exposure and chronic bronchitis. Sluis-Cremer et al. (1967) found a significant difference between the prevalence of chronic bronchitis in dust-exposed and non-dust exposed male residents of a South African gold mining town who smoked, but found no increased prevalence among non-smokers. In contrast, a different study of South African gold miners found that the prevalence of chronic bronchitis increased significantly with increasing dust concentration and cumulative dust exposure in smokers, nonsmokers, and ex-smokers (Wiles and Faure, 1977). Similarly, a study of Western Australia gold miners found that the prevalence of chronic bronchitis, as indicated by odds ratios (controlled for age and smoking), was significantly increased in those that had worked in the mines for 1 to 9 years, 10 to 19 years, and more than 20 years, as compared to lifetime non-miners (Holman et al., 1987). Chronic bronchitis was present in 62 percent of black South African gold miners and 45 percent of those who had never smoked in a study by Cowie and Mabena (1991). The prevalence of what the researchers called ''chronic bronchitic symptom complex'' reflected the intensity of dust exposure. A higher prevalence of respiratory symptoms, independent of smoking and age, was also found for granite quarry workers in Singapore in a high exposure group as compared to low exposure and control groups, even after excluding those with silicosis from the analysis (Ng et al., 1992b).

Other studies found no relationship between silica exposure and the prevalence of chronic bronchitis. Irwig and Rocks (1978) compared silicotic and non-silicotic South African gold miners and found no significant difference in symptoms of chronic bronchitis. The prevalence of symptoms of chronic bronchitis were also not found to be associated with years of mining, after adjusting for smoking, in a population of current underground uranium miners (Samet et al., 1984). Silica exposure was described in the study to be ''on occasion'' above the TLV. It was not possible to determine, however, whether miners with respiratory diseases had left the workforce, making the remaining population unrepresentative. Hard-rock (molybdenum) miners, with 27 and 49 percent of personal silica samples greater than 100 and 55 $\mu g/m^3$, respectively, also showed no increase in prevalence of chronic bronchitis in association with work in that industry (Kreiss et al., 1989). However, the authors thought that differential out-migration of symptomatic miners and retired miners from the industry and town might explain that finding. Finally, grinders of agate stones (with resulting dust containing 70.4 percent silica) in India also had no increase in the prevalence of chronic bronchitis compared to controls matched by socioeconomic status, age and smoking, although there was a significantly higher prevalence of acute bronchitis in female grinders. A significantly higher prevalence and increasing trend with exposure duration for pneumoconiosis in the agate workers indicated that had an increased prevalence in chronic bronchitis been present, it would have been detected (Rastogi et al., 1991). However, control workers in this study may also have been exposed to silica and the study and control workers both had high tuberculosis prevalence, possibly masking an association of exposure with bronchitis (NIOSH, 2002). Furthermore, exposure durations were very short.

Thus, some prevalence studies supported a finding of increased bronchitis in workers exposed to silica-containing dust, while other studies did not support such a finding. However, OSHA believes that many of the studies that did not find such a relationship were likely to be biased towards the null. For example, some of the molybdenum miners studied by Kreiss et al. (1989), particularly retired and symptomatic miners, may have left the town and the industry before the time that the cross-sectional study was conducted, resulting in a survivor effect that could have interfered with detection of a possible association between silica exposure and bronchitis. This survivor effect may also have been operating in the study of uranium miners in New Mexico (Samet et al., 1984). In two of the negative studies, members of comparison and control groups were also exposed to crystalline silica (Irwig and Rocks, 1978; Rastogi et al., 1991), creating a potential bias toward the null. Additionally, tuberculosis in both exposed and control groups in the agate worker study (Rastogi et al., 1991)) may have masked an effect (NIOSH, 2002), and the exposure durations were very short. Several of the positive studies demonstrated a qualitative or semi-quantitative relationship between silica exposure and chronic bronchitis.

Others have reviewed relevant studies and also concluded that there is a relationship between exposure to crystalline silica and the development of bronchitis. The American Thoracic Society (ATS) (1997) published an official statement on the adverse effects of crystalline silica exposure that included a section that discussed studies on chronic bronchitis (defined by chronic sputum production). According to the ATS review, chronic bronchitis was found to be common among worker groups exposed to dusty environments contaminated with silica. In support of this conclusion, ATS cited studies with what they viewed as positive findings of South African (Hnizdo et al., 1990) and Australian (Holman et al., 1987) gold miners, Indonesian granite workers (Ng et al., 1992b), and Indian agate workers (Rastogi et al., 1991). ATS did not mention studies with negative findings.

A review published by NIOSH in 2002 discussed studies related to silica exposure and development of chronic bronchitis. NIOSH concluded, based on the same studies reviewed by OSHA, that occupational exposure to respirable crystalline silica is associated with bronchitis, but that some epidemiologic studies suggested that this effect may be less frequent or absent in non-smokers.

Hnizdo and Vallyathan (2003) also reviewed studies addressing COPD due to occupational silica exposure and concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause chronic bronchitis. They based this conclusion on studies that they cited as showing that the prevalence of chronic bronchitis increases with intensity of exposure. The cited studies were also reviewed by OSHA (Cowie and Mabena, 1991; Holman et al., 1987; Kreiss et al., 1989; Sluis-Cremer et al., 1967; Wiles and Faure, 1977).

OSHA preliminarily concludes that exposure to respirable crystalline silica may cause chronic bronchitis and an exposure-response relationship may exist. Smokers may be at increased risk as compared to non-smokers. Chronic bronchitis may occur in silica-exposed workers who do not have silicosis.

3. Pulmonary Function Impairment

OSHA has reviewed numerous studies on the relationship of silica exposure to pulmonary function impairment as measured by spirometry. There were several longitudinal studies available. Two groups of researchers conducted longitudinal studies of lung function impairment in Vermont granite workers and reached opposite conclusions. Graham et al (1981, 1994) examined stone shed workers, who had the highest exposures to respirable crystalline silica (between 50 and 100 μg/m³), along with quarry workers (presumed to have lower exposure) and office workers (expected to have negligible exposure). The longitudinal losses of FVC and FEV_1 were not correlated with years employed, did not differ among shed, quarry, and office workers, and were similar, according to the authors, to other blue collar workers not exposed to occupational dust.

Eisen et al. (1983, 1995) found the opposite. They looked at lung function in two groups of granite workers: ''survivors'', who participated in each of five annual physical exams, and ''dropouts'', who did not participate in the final exam. There was a significant exposure-response relationship between exposure to crystalline silica and FEV_1 decline among the dropouts but not among the survivors. The dropout group had a steeper FEV_1 loss, and this was true for each smoking category. The authors concluded that exposures of about 50 ug/m³ produced a measurable effect on pulmonary function in the dropouts. Eisen et al. (1995) felt that the ''healthy worker effect'' was apparent in this study and that studies that only looked at ''survivors'' would be less likely to see any effect of silica on pulmonary function.

A 12-year follow-up of age- and smoking-matched granite crushers and referents in Sweden found that over the follow-up period, the granite crushers had significantly greater decreases in FEV_1, FEV_1/FVC, maximum expiratory flow, and FEF_{50} than the referents (Malmberg et al., 1993). A longitudinal study of South African gold miners conducted by Hnizdo (1992) found that cumulative dust exposure was a significant predictor of most indices of decreases in lung function, including FEV_1 and FVC. A multiple linear regression analysis showed that the effects of silica exposure and smoking were additive. Another study of South African gold miners (Cowie, 1998) also found a loss of FEV_1 in those without silicosis. Finally, a study of U.S. automotive foundry workers (Hertzberg et al., 2002) found a consistent association with increased pulmonary function abnormalities and estimated measures of cumulative silica exposure within 0.1 mg/m³. The Hnizdo (1992), Cowie et al. (1993), and Cowie (1998) studies of South African gold miners and the Malmberg et al. (1993) study of Swedish granite workers found very similar reductions in FEV_1 attributable to silica dust exposure.

A number of prevalence studies have described relationships between lung function loss and silica exposure or exposure measurement surrogates (*e.g.,* duration of exposure). These findings support those of the longitudinal studies. Such results have been found in studies of white South African gold miners (Hnizdo et al., 1990; Irwig and Rocks, 1978), black South African gold miners (Cowie and Mabena, 1991), Quebec silica-exposed workers (Begin, et al., 1995), Singapore rock drilling and crushing workers (Ng et al., 1992b), Vermont granite shed workers (Theriault et al., 1974a, 1974b), aggregate quarry workers and coal miners in Spain (Montes et al., 2004a, 2004b), concrete workers in The Netherlands (Meijer et al., 2001), Chinese refractory brick manufacturing workers in an iron-steel plant (Wang et al., 1997), Chinese gemstone workers (Ng et al., 1987b), hard-rock miners in Manitoba, Canada (Manfreda et al., 1982) and Colorado (Kreiss et al., 1989), pottery workers in France (Neukirch et al., 1994), potato sorters exposed to diatomaceous earth containing crystalline silica in The Netherlands

(Jorna et al., 1994), slate workers in Norway (Suhr et al., 2003), and men in a Norwegian community (Humerfelt et al., 1998). Two of these prevalence studies also addressed the role of smoking in lung function impairment associated with silica exposure. In contrast to the longitudinal study of South African gold miners discussed above (Hnizdo, 1992), another study of South African gold miners (Hnizdo et al., 1990) found that the joint effect of dust and tobacco smoking on lung function impairment was synergistic, rather than additive. Also, Montes et al. (2004b) found that the criteria for dust-tobacco interactions were satisfied for FEV_1 decline in a study of Spanish aggregate quarry workers.

One of the longitudinal studies and many of the prevalence studies discussed above directly addressed the question of whether silica-exposed workers can develop pulmonary function impairment in the absence of silicosis. These studies found that pulmonary function impairment: (1) Can occur in silica-exposed workers in the absence of silicosis, (2) was still evident when silicosis was controlled for in the analysis, and (3) was related to the magnitude and duration of silica exposure rather than to the presence or severity of silicosis.

Many researchers have concluded that a relationship exists between exposure to silica and lung function impairment. IARC (1997) has briefly reviewed studies on airways disease (*i.e.,* chronic airflow limitation and obstructive impairment of lung function) in its monograph on crystalline silica carcinogenicity and concluded that exposure to crystalline silica causes these effects. In its official statement on the adverse effects of crystalline silica exposure, the American Thoracic Society (ATS) (1997) included a section on airflow obstruction. The ATS noted that, in most of the studies reviewed, airflow limitation was associated with chronic bronchitis. The review of Hnizdo and Vallyathan (2003) also addressed COPD due to occupational silica exposure. They examined the epidemiological evidence for an exposure-response relationship for airflow obstruction in studies where silicosis was present or absent. Hnizdo and Vallyathan (2003) concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause airflow obstruction.

Based on the evidence discussed above from a number of longitudinal studies and numerous cross-sectional studies, OSHA preliminarily concludes that there is an exposure-response relationship between exposure to respirable crystalline silica and the development of impaired lung function. The effect of tobacco smoking on this relationship may be additive or synergistic. Also, pulmonary function impairment has been shown to occur among silica-exposed workers who do not show signs of silicosis.

4. Non-malignant Respiratory Disease Mortality

In this section, OSHA reviews studies on NMRD mortality that focused on causes of death other than from silicosis. Two studies of gold miners, a study of diatomaceous earth workers, and a case-control analysis of death certificate data provide useful information.

Wyndham et al. (1986) found a significant excess mortality for chronic respiratory diseases in a cohort of white South African gold miners. Although these data did include silicosis mortality, the authors found evidence demonstrating that none of the miners certified on the death certificate as dying from silicosis actually died from that disease. Instead, pneumoconiosis was always an incidental finding in those dying from some other cause, the most common of which was chronic obstructive lung disease. A case-referent analysis found that, although the major risk factor for chronic respiratory disease was smoking, there was a statistically significant additional effect of cumulative dust exposure, with the relative risk estimated to be 2.48 per ten units of 1000 particle years of exposure.

A synergistic effect of smoking and cumulative dust exposure on mortality from COPD was found in another study of white South African gold miners (Hnizdo, 1990). Analysis of various combinations of dust exposure and smoking found a trend in odds ratios that indicated this synergism. There was a statistically significant increasing trend for dust particle-years and for cigarette-years of smoking. For cumulative dust exposure, an exposure-response relationship was found, with the analysis estimating that those with exposures of 10,000, 17,500, or 20,000 particle-years of exposure had a 2.5-, 5.06-, or 6.4-times higher mortality risk for COPD, respectively, than those with the lowest dust exposure of less than 5000 particle-years. The authors concluded that dust alone would not lead to increased COPD mortality but that dust and smoking act synergistically to cause COPD and were thus the main risk factor for death from COPD in their study.

Park et al. (2002) analyzed the California diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994, to quantify the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park et al. (2002) to at least partially adjust for smoking. Using the exposure estimates developed for the cohort by Rice et al. (2001) in their exposure-response study of lung cancer risks, Park et al. (2002) evaluated the quantitative exposure-response relationship for LDOC mortality and found a strong positive relationship with exposure to respirable crystalline silica. OSHA finds this study particularly compelling because of the strengths of the study design and availability of smoking history data on part of the cohort and high-quality exposure and job history data; consequently, OSHA has included this study in its Preliminary Quantitative Risk Assessment.

In a case-control analysis of death certificate data drawn from 27 U.S. states, Calvert et al. (2003) found increased mortality odds ratios among those in the medium and higher crystalline silica exposure categories, a significant trend of increased risk for COPD mortality with increasing silica exposures, and a significantly increased odds ratio for COPD mortality in silicotics as compared to those without silicosis.

Green and Vallyathan (1996) also reviewed several studies of NMRD mortality in workers exposed to silica. The authors stated that these studies showed an association between cumulative dust exposure and death from the chronic respiratory diseases.

Based on the evidence presented in the studies above, OSHA preliminarily concludes that respirable crystalline silica increases the risk for mortality from non-malignant respiratory disease (not including silicosis) in an exposure-related manner. However, it appears that the risk is strongly influenced by smoking, and the effects of smoking and silica exposure may be synergistic.

D. Renal and Autoimmune Effects

In recent years, evidence has accumulated that suggests an association between exposure to crystalline silica and an increased risk of renal disease. Over the past 10 years, epidemiologic studies have been conducted that provide evidence of exposure-response trends to support this association. There is also suggestive evidence that silica can increase the risk of rheumatoid arthritis and other autoimmune diseases (Steenland, 2005b). In fact, an autoimmune mechanism has been postulated for some silica-associated renal disease (Calvert et al., 1997). This section will discuss the evidence supporting an association of silica exposure with renal and autoimmune diseases.

Overall, there is substantial evidence suggesting an association between exposure to crystalline silica and increased risks of renal and autoimmune diseases. In addition to a number of case reports, epidemiologic studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (*e.g.,* Calvert et al., 1997), subclinical renal changes (*e.g.,* Ng et al., 1992c), end-stage renal disease morbidity (*e.g.,* Steenland et al., 1990), chronic renal disease mortality (Steenland et al., 2001b, 2002a), and Wegener's granulomatosis (Nuyts et al., 1995). In other findings, silica-exposed individuals, both with and without silicosis, had an increased prevalence of abnormal renal function (Hotz et al., 1995), and renal effects have been reported to persist after cessation of silica exposure (Ng et al., 1992c). Possible mechanisms suggested for silica-induced renal disease include a direct toxic effect on the kidney, deposition in the kidney of immune complexes (IgA) following silica-related pulmonary inflammation, or an autoimmune mechanism (Calvert et al., 1997; Gregorini et al., 1993).

Several studies of exposed worker populations reported finding excess renal disease mortality and morbidity. Wyndham et al. (1986) reported finding excess mortality from acute and chronic nephritis among South African goldminers that had been followed for 9 years. Italian ceramic workers experienced an overall increase in the prevalence of end-stage renal disease (ESRD) cases compared to regional rates; the six cases that occurred among the workers had cumulative exposures to crystalline silica of between 0.2 and 3.8 mg/m^3-years (Rapiti et al., 1999).

Calvert et al. (1997) found an increased incidence of non-systemic ESRD cases among 2,412 South Dakota gold miners exposed to a median crystalline silica concentration of 0.09 mg/m^3. In another study of South Dakota gold miners, Steenland and Brown (1995a) reported a positive trend of chronic renal disease mortality risk and cumulative exposure to respirable crystalline silica, but most of the excess deaths were concentrated among workers hired before 1930 when exposures were likely higher than in more recent years.

Excess renal disease mortality has also been described among North American industrial sand workers. McDonald et al., (2001, 2005) found that nephritis/nephrosis mortality was elevated overall among 2,670 industrial sand workers hired 20 or more years prior to follow-up, but there was no apparent relationship with either cumulative or average exposure to crystalline silica. However, Steenland et al. (2001b) did find that increased mortality from acute and chronic renal disease was related to increasing quartiles of cumulative exposure among a larger cohort of 4,626 industrial sand workers. In addition, they also found a positive trend for ESRD case incidence and quartiles of cumulative exposure.

In a pooled cohort analysis, Steenland et al. (2002a) combined the industrial sand cohort from Steenland et al. (2001b), gold mining cohort from Steenland and Brown (1995a), and the Vermont granite cohort studies by Costello and Graham (1988). In all, the combined cohort consisted of 13,382 workers with exposure information available for 12,783. The exposure estimates were validated by the monotonically increasing exposure-response trends seen in analyses of silicosis, since cumulative silica levels are known to predict silicosis risk. The mean duration of exposure, cumulative exposure, and concentration of respirable silica for the cohort were 13.6 years, 1.2 mg/m^3-years, and 0.07 mg/m^3, respectively.

The analysis demonstrated statistically significant exposure-response trends for acute and chronic renal disease mortality with quartiles of cumulative exposure to respirable crystalline silica. In a nested case-control study design, a positive exposure-response relationship was found across the three cohorts for both multiple-cause mortality (*i.e.,* any mention of renal disease on the death certificate) and underlying cause mortality. Renal disease risk was most prevalent among workers with cumulative exposures of 0.5 mg/m^3 or more (Steenland et al., 2002a).

Other studies failed to find an excess renal disease risk among silica-exposed workers. Davis et al. (1983) found an elevated, but not a statistically significant increase, in mortality from diseases of the genitourinary system among Vermont granite shed workers. There was no observed relationship between mortality from this cause and cumulative exposure. A similar finding was reported by Koskela et al. (1987) among Finnish granite workers, where there were 4 deaths due to urinary tract disease compared to 1.8 expected. Both Carta et al. (1994) and Cocco et al. (1994) reported finding no increased mortality from urinary tract disease among workers in an Italian lead mine and a zinc mine. However, Cocco et al. (1994) commented that exposures to respirable crystalline silica were low, averaging 0.007 and 0.09 mg/m^3 in the two mines, respectively, and that their study in particular had low statistical power to detect excess mortality.

There are many case series, case-control, and cohort studies that provide support for a causal relationship between exposure to respirable crystalline silica and an increased renal disease risk (Kolev et al., 1970; Osorio et al., 1987; Steenland et al., 1990; Gregorini et al., 1993; Nuyts et al., 1995). In addition, a number of studies have demonstrated early clinical signs of renal dysfunction (*i.e.,* urinary excretion of low- and high-molecular weight proteins and other markers of renal glomerular and tubular disruption) in workers exposed to crystalline silica, both with and without silicosis (Ng et al., 1992c; Hotz et al., 1995; Boujemaa, 1994; Rosenman et al., 2000).

OSHA believes that there is substantial evidence on which to base a finding that exposure to respirable crystalline silica increases the risk of renal disease mortality and morbidity. In particular, OSHA believes that the 3-cohort pooled analysis conducted by Steenland et al. (2002a) is particularly convincing. OSHA believes that the findings of this pooled analysis seem credible because the analysis involved a large number of workers from three cohorts with well-documented, validated job-exposure matrices and found a positive and monotonic increase in renal disease risk with increasing exposure for both underlying and multiple cause data. However, there are considerably less data, and thus the findings based on them are less robust, than what is available for silicosis mortality or lung cancer mortality. Nevertheless, OSHA preliminarily concludes that the underlying data are sufficient to provide useful estimates of risk and has included the Steenland et al. (2002a) analysis in its Preliminary Quantitative Risk Assessment.

Several studies of different designs, including case series, cohort, registry linkage and case-control, conducted in a variety of exposed groups suggest an association between silica exposure and increased risk of systemic autoimmune disease (Parks et al., 1999). Studies have found that the most common autoimmune diseases associated with silica exposure are scleroderma (*e.g.,* Sluis-Cremer et al., 1985); rheumatoid arthritis (*e.g.* Klockars et al., 1987; Rosenman and Zhu, 1995); and systemic lupus erythematosus (*e.g.,* Brown et al., 1997). Mechanisms suggested for silica-related autoimmune disease include an adjuvant effect of silica (Parks et al., 1999), activation of the immune system by the fibrogenic proteins and growth factors released as a result of the interaction of silica particles with macrophages (*e.g.,* Haustein and Anderegg, 1998), and a direct local effect of non-respirable silica particles penetrating the skin and producing scleroderma (Green and Vallyathan, 1996). However, there are no quantitative exposure-response data available at this time on which to base a quantitative risk assessment for autoimmune diseases.

Therefore, OSHA preliminarily concludes that there is substantial evidence that silica exposure increases the risks of renal and autoimmune disease. The positive and monotonic exposure-response trends demonstrated for silica exposure and renal disease risk more strongly suggest a causal link. The studies by Steenland et al. (2001b, 2002a) and Steenland and Brown (1995a) provide evidence of a positive exposure-response relationship. For autoimmune diseases, the available data did not provide an adequate basis for assessing exposure-response relationships. However, OSHA believes that the available exposure-response data on silica exposure and renal disease is sufficient to allow for quantitative estimates of risk.

E. Physical Factors That May Influence Toxicity of Crystalline Silica

Much research has been conducted to investigate the influence of various physical factors on the toxicologic potency of crystalline silica. Such factors examined include crystal polymorphism; the age of fractured surfaces of the crystal particle; the presence of impurities, particularly metals, on particle surfaces; and clay occlusion of the particle. These factors likely vary among different workplace settings suggesting that the risk to workers exposed to a given level of respirable crystalline silica may not be equivalent in different work environments. In this section, OSHA examines the research demonstrating the effects of these factors on the toxicologic potency of silica.

The modification of surface characteristics by the physical factors noted above may alter the toxicity of silica by affecting the physical and biochemical pathways of the mechanistic process. Thus, OSHA has reviewed the proposed mechanisms by which silica exposure leads to silicosis and lung cancer. It has been proposed that silicosis results from a cycle of cell damage, oxidant generation, inflammation, scarring and fibrosis. A silica particle entering the lung can cause lung damage by two major mechanisms: direct damage to lung cells due to the silica particle's unique surface properties or by the activation or stimulation of alveolar macrophages (after phagocytosis) and/or alveolar epithelial cells. In either case, an elevated production of reactive oxygen and nitrogen species (ROS/RNS) results in oxidant damage to lung cells. The oxidative stress and lung injury stimulates alveolar macrophages and/or alveolar epithelial cells to produce growth factors and fibrogenic mediators, resulting in fibroblast activation and pulmonary fibrosis. A continuous ingestion-reingestion cycle, with cell activation and death, is established.

OSHA has examined evidence on the comparative toxicity of the silica polymorphs (quartz, cristobalite, and tridymite). A number of animal studies appear to suggest that cristobalite and tridymite are more toxic to the lung than quartz and more tumorigenic (*e.g.,* King et al., 1953; Wagner et al., 1980). However, in contrast to these findings, several authors have reviewed the studies done in this area and concluded that cristobalite and tridymite are not more toxic than quartz (*e.g.,* Bolsaitis and Wallace, 1996; Guthrie and Heaney, 1995). Furthermore, a difference in toxicity between cristobalite and quartz has not been observed in epidemiologic studies (tridymite has not been studied) (NIOSH, 2002). In an analysis of exposure-response for lung cancer, Steenland et al. (2001a) found similar exposure-response trends between cristobalite-exposed workers and other cohorts exposed to quartz.

A number of studies have compared the toxicity of freshly fractured versus aged silica. Although animal studies have demonstrated that freshly fractured silica is more toxic than aged silica, aged silica still retains significant toxicity (Porter et al., 2002; Shoemaker et al., 1995; Vallyathan et al., 1995). Studies of workers exposed to freshly fractured silica have demonstrated that these workers exhibit the same cellular effects as seen in animals exposed to freshly fractured silica (Castranova et al., 1998; Goodman et al., 1992). There have been no studies, however, comparing workers exposed to freshly fractured silica to those exposed to aged silica. Animal studies also suggest that pulmonary reactions of rats to short-duration exposure to freshly fractured silica mimic those seen in acute silicosis in humans (Vallyathan et al., 1995).

Surface impurities, particularly metals, have been shown to alter silica toxicity. Iron, depending on its state and quantity, has been shown to either increase or decrease toxicity. Aluminum has been shown to decrease toxicity (Castranova et al., 1997; Donaldson and Borm, 1998; Fubini, 1998). Silica coated with aluminosilicate clay exhibits lower toxicity, possibly as a result of reduced bioavailability of the silica particle surface (Donaldson and Borm, 1998; Fubini, 1998). This reduced bioavailability may be due to aluminum ions left on the silica surface by the clay (Bruch et al., 2004; Cakmak et al., 2004; Fubini et al., 2004). Aluminum and other metal ions are thought to modify silanol groups on the silica surface, thus decreasing the membranolytic and cytotoxic potency and resulting in enhanced particle clearance from the lung before damage can take place (Fubini, 1998). An epidemiologic study found that the risk of silicosis was less in pottery workers than in tin and tungsten miners (Chen et al., 2005; Harrison et al., 2005), possibly reflecting that pottery workers were exposed to silica particles having less biologically available, non-clay-occluded surface area than was the case for miners. The authors concluded that clay occlusion of silica particles can be a factor in reducing disease risk.

Although it is evident that a number of factors can act to mediate the toxicological potency of crystalline silica, it is not clear how such considerations should be taken into account to evaluate lung cancer and silicosis risks to exposed workers. After evaluating many *in vitro* studies that had been conducted to investigate the surface characteristics of crystalline silica particles and their influence on fibrogenic activity, NIOSH (2002) concluded that further research is needed to associate specific surface characteristics that can affect toxicity with specific occupational exposure situations and consequent health risks to workers. According to NIOSH (2002), such exposures may include work processes that produce freshly fractured silica surfaces or that involve quartz contaminated with trace elements such as iron. NIOSH called for further *in vitro* and *in vivo* studies of the toxicity and pathogenicity of alpha quartz compared with its polymorphs, quartz contaminated with trace elements, and further research on the association of surface properties with specific work practices and health effects.

In discussing the ''considerable'' heterogeneity shown across the 10 studies used in the pooled lung cancer risk analysis, Steenland et al. (2001a) pointed to hypotheses that physical differences in silica exposure (*e.g.,* freshness of particle cleavage) between cohorts may be a partial explanation of observed differences in exposure-response coefficients derived from those cohort studies. However, the authors did not have specific information on whether or how these factors might have actually influenced the observed differences. Similarly, in the pooled analysis and risk assessments for silicosis mortality conducted by Mannetje et al. (2002b), differences in biological activity of different types of silica dust could not be specifically taken into account. Mannetje et al. (2002b) determined that the exposure-response relationship between silicosis and log-transformed cumulative exposure to crystalline silica was comparable between studies and no significant heterogeneity was found. The authors therefore concluded that their findings were relevant for different circumstances of occupational exposure to crystalline silica. Both the Steenland et al. (2001a) and Mannetje et al. (2002b) studies are discussed in detail in OSHA's Preliminary Quantitative Risk Assessment (section II of the background document and summarized in section VI of this preamble).

OSHA preliminarily concludes that there is considerable evidence to support the hypothesis that surface activity of crystalline silica particles plays an important role in producing disease, and that several environmental influences can modify surface activity to either enhance or diminish the toxicity of silica. However, OSHA believes that the available information is insufficient to determine in any quantitative way how these influences may affect disease risk to workers in any particular workplace setting.

VI. Summary of OSHA's Preliminary Quantitative Risk Assessment

A. Introduction

The Occupational Safety and Health Act (OSH Act or Act) and some landmark court cases have led OSHA to rely on quantitative risk assessment, to the extent possible, to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. A determining factor in the decision to perform a quantitative risk assessment is the availability of suitable data for such an assessment. In the case of crystalline silica, there has been extensive research on its health effects, and several quantitative risk assessments have been published in the peer-reviewed scientific literature that describe the risk to exposed workers of lung cancer mortality, silicosis mortality and morbidity, non-malignant respiratory disease mortality, and renal disease mortality. These assessments were based on several studies of occupational cohorts in a variety of industry sectors, the underlying studies of which are described in OSHA's review of the health effects literature (*see* section V of this preamble). In this section, OSHA summarizes its Preliminary Quantitative Risk Assessment (QRA) for crystalline silica, which is presented in Section II of the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (placed in Docket OSHA–2010–0034).

OSHA has done what it believes to be a comprehensive review of the literature to provide quantitative estimates of risk for crystalline silica-related diseases. Quantitative risk assessments for lung cancer and silicosis mortality were published after the International Agency for Research on Cancer (IARC) determined more than a decade ago that there was sufficient evidence to regard crystalline silica as a human carcinogen (IARC, 1997). This finding was based on several studies of worker cohorts demonstrating associations between exposure to crystalline silica and an increased risk of lung cancer. Although IARC judged the overall evidence as being sufficient to support this conclusion, IARC also noted that some studies of crystalline silica-exposed workers did not demonstrate an excess risk of lung cancer and that exposure-response trends were not always consistent among studies that were able to describe such trends. These findings led Steenland et al. (2001a) and Mannetje et al. (2002b) to conduct comprehensive exposure-response analyses of the risk of lung cancer and silicosis mortality associated with exposure to crystalline silica. These studies, referred to as the IARC multi-center studies of lung cancer and silicosis mortality, relied on all available cohort data from previously published epidemiological studies for which there were adequate quantitative data on worker exposures to crystalline silica to derive pooled estimates of disease risk. In addition, OSHA identified four single-cohort studies of lung cancer mortality that it judged suitable for quantitative risk assessment; two of these cohorts (Attfield and Costello, 2004; Rice et al., 2001) were included among the 10 used in the IARC multi-center study and studies of two other cohorts appeared later (Hughes et al., 2001; McDonald et al., 2001, 2005; Miller and MacCalman, 2009). For non-malignant respiratory disease mortality, in addition to the silicosis mortality study by Mannetje et al. (2002b), Park et al. (2002) conducted an exposure-response analysis of non-malignant respiratory disease mortality (including silicosis and other chronic obstructive pulmonary diseases) among diatomaceous earth workers. Exposure-response analyses for silicosis morbidity have been published in several single-cohort studies (Chen et al., 2005; Hnizdo and Sluis-Cremer, 1993; Steenland and Brown, 1995b; Miller et al., 1998; Buchanan et al., 2003). Finally, a quantitative assessment of end-stage renal disease mortality based on data from three worker cohorts was developed by Steenland et al. (2002a).

In addition to these published studies, OSHA's contractor, Toxichemica, Inc., commissioned Drs. Kyle Steenland and Scott Bartell of Emory University to perform an uncertainty analysis to examine the effect on lung cancer and silicosis mortality risk estimates of uncertainties that exist in the exposure assessments underlying the two IARC multi-center analyses (Toxichemica, Inc., 2004).

OSHA's Preliminary QRA presents estimates of the risk of silica-related diseases assuming exposure over a working life (45 years) to the proposed 8-hour time-weighted average (TWA) PEL and action level of 0.05 and 0.025 mg/m^3, respectively, of respirable crystalline silica, as well as to OSHA's current PELs. OSHA's current general industry PEL for respirable quartz is expressed both in terms of a particle count formula and a gravimetric concentration formula, while the current construction and shipyard employment PELs for respirable quartz are only expressed in terms of a particle count formula. The current PELs limit exposure to respirable dust; the specific limit in any given instance depends on the concentration of crystalline silica in the dust. For quartz, the gravimetric general industry PEL approaches a limit of 0.1 mg/m^3 as respirable quartz as the quartz content increases (*see* discussion in Section XVI of this preamble, Summary and Explanation for paragraph (c)). OSHA's Preliminary QRA presents risk estimates for exposure over a working lifetime to 0.1 mg/m³ to represent the risk associated with exposure to the current general industry PEL. OSHA's current PEL for construction and shipyard employment is a formula PEL that limits exposure to respirable dust expressed as a respirable particle count concentration. As with the gravimetric general industry PEL, the limit varies depending on quartz content of the dust. There is no single mass concentration equivalent for the construction and shipyard PELs; OSHA's Preliminary QRA reviews several studies that suggest that the current construction/shipyard PEL likely lies in the range between 0.25 and 0.5 mg/m³ respirable quartz, and OSHA presents risk estimates for this range of exposure to represent the risks associated with exposure to the current construction/shipyard PEL. In general industry, for both the gravimetric and particle count PELs, OSHA's current PEL for cristobalite and tridymite are half the value for quartz. Thus, OSHA's Preliminary QRA presents risk estimates associated with exposure over a working lifetime to 0.025, 0.05, 0.1, 0.25, and 0.5 mg/m³ respirable silica (corresponding to cumulative exposures over 45 years to 1.125, 2.25, 4.5, 11.25, and 22.5 mg/m³-years).

Risk estimates for lung cancer mortality, silicosis and non-malignant respiratory disease mortality, and renal disease mortality are presented in terms of lifetime (up to age 85) excess risk per 1,000 workers for exposure over an 8-hour working day, 250 days per year, and a 45-year working life. For silicosis morbidity, OSHA based its risk estimates on cumulative risk models used by the various investigators to develop quantitative exposure-response relationships. These models characterized the risk of developing silicosis (as detected by chest radiography) up to the time that cohort members (including both active and retired workers) were last examined. Thus, risk estimates derived from these studies represent less-than-lifetime risks of developing radiographic silicosis. OSHA did not attempt to estimate lifetime risk (*i.e.,* up to age 85) for silicosis morbidity because the relationships between age, time, and disease onset post-exposure have not been well characterized.

A draft preliminary quantitative risk assessment document was submitted for external scientific peer review in accordance with the Office of Management and Budget's ''Final Information Quality Bulletin for Peer Review'' (OMB, 2004). A summary of OSHA's responses to the peer reviewers' comments appears in Section III of the background document.

In the sections below, OSHA describes the studies and the published risk assessments it uses to estimate the occupational risk of crystalline silica-related disease. (The Preliminary QRA itself also discusses several other available studies that OSHA does not include and OSHA's reasons for not including these studies.)

B. Lung Cancer Mortality

1. Summary of Studies

In its Preliminary QRA, OSHA discusses risk assessments from six published studies that quantitatively analyzed exposure-response relationships for crystalline silica and lung cancer; some of these also provided estimates of risks associated with exposure to OSHA's current PEL or NIOSH's Recommended Exposure Limit (REL) of 0.05 mg/m³. These studies include: (1) A quantitative analysis by Steenland et al. (2001a) of worker cohort data pooled from ten studies; (2) an exposure-response analysis by Rice et al. (2001) of a cohort of diatomaceous earth workers primarily exposed to cristobalite; (3) an analysis by Attfield and Costello (2004) of U.S. granite workers; (4) a risk assessment by Kuempel et al. (2001), who employed a kinetic rat lung model to describe the relationship between quartz lung burden and cancer risk, then calibrated and validated that model using the diatomaceous earth worker and granite worker cohort mortality data; (5) an exposure-response analysis by Hughes et al., (2001) of U.S. industrial sand workers; and (6) a risk analysis by Miller et al. (2007) and Miller and MacCalman (2009) of British coal miners. These six studies are described briefly below and are followed by a summary of the lung cancer risk estimates derived from these studies.

a. Steenland et al. (2001a) Pooled Cohort Analysis

OSHA considers the lung cancer analysis conducted by Steenland et al. (2001a) to be of prime importance for risk estimation because of its size, incorporation of data from multiple cohorts, and availability of detailed exposure and job history data. Subsequent to its publication, Steenland and Bartell (Toxichemica, Inc., 2004) conducted a quantitative uncertainty analysis on the pooled data set to evaluate the potential impact on the risk estimates of random and systematic exposure misclassification, and Steenland (personal communication, 2010) conducted additional exposure-response modeling.

The original study consisted of a pooled exposure-response analysis and risk assessment based on raw data obtained from ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths). Steenland et al. (2001a) initially identified 13 cohort studies as containing exposure information sufficient to develop a quantitative exposure assessment; the 10 studies included in the pooled analysis were those for which data on exposure and health outcome could be obtained for individual workers. The cohorts in the pooled analysis included U.S. gold miners (Steenland and Brown, 1995a), U.S. diatomaceous earth workers (Checkoway et al., 1997), Australian gold miners (de Klerk and Musk, 1998), Finnish granite workers (Koskela et al., 1994), U.S. industrial sand employees (Steenland and Sanderson, 2001), Vermont granite workers (Costello and Graham, 1988), South African gold miners (Hnizdo and Sluis-Cremer, 1991; Hnizdo et al., 1997), and Chinese pottery workers, tin miners, and tungsten miners (Chen et al., 1992).

The exposure assessments developed for the pooled analysis are described by Mannetje et al. (2002a). The exposure information and measurement methods used to assess exposure from each of the 10 cohort studies varied by cohort and by time and included dust measurements representing particle counts, mass of total dust, and respirable dust mass. All exposure information was converted to units of mg/m³ respirable crystalline silica by generating cohort-specific conversion factors based on the silica content of the dust to which workers were exposed.

A case-control study design was employed for which cases and controls were matched for race, sex, age (within 5 years) and study; 100 controls were matched to each case. To test the reasonableness of the cumulative exposure estimates for cohort members, Mannetje et al. (2002a) examined exposure-response relationships for silicosis mortality by performing a nested case-control analysis for silicosis or unspecified pneumoconiosis using conditional logistic regression. Each cohort was stratified into quartiles by cumulative exposure, and standardized rate ratios (SRR) for silicosis were calculated using the lowest-exposure quartile as the baseline. Odds ratios (OR) for silicosis were also calculated for the pooled data set overall, which was stratified into quintiles based on cumulative exposure.

For the pooled data set, the relationship between odds ratio for silicosis mortality and increasing cumulative exposure was ''positive and reasonably monotonic'', ranging from 3.1 for the lowest quartile of exposure to 4.8 for the highest. In addition, in seven of the ten individual cohorts, there were statistically significant trends between silicosis mortality rate ratios (SRR) and cumulative exposure. For two of the cohorts (U.S. granite workers and U.S. gold miners), the trend test was not statistically significant (p=0.10). A trend analysis could not be performed on the South African gold miner cohort since silicosis was not coded as an underlying cause of death in that country. A more rigorous analysis of silicosis mortality on pooled data from six of these cohorts also showed a strong, statistically significant increasing trend with increasing decile of cumulative exposure (Mannetje et al., 2002b), providing additional evidence for the reasonableness of the exposure assessment used for the Steenland et al (2001a) lung cancer analysis.

For the pooled lung cancer mortality analysis, Steenland et al. (2001a) conducted a nested case-control analysis via Cox regression, in which there were 100 controls chosen for each case randomly selected from among cohort members who survived past the age at which the case died, and matched on age (the time variable in Cox regression), study, race/ethnicity, sex, and date of birth within 5 years (which, in effect, matched on calendar time given the matching on age). Using alternative continuous exposure variables in a log-linear relative risk model (log RR=βx, where x represents the exposure variable and β the coefficient to be estimated), Steenland et al. (2001a) found that the use of either 1) cumulative exposure with a 15-year lag, 2) the log of cumulative exposure with a 15-year lag, or 3) average exposure resulted in positive statistically significant (p≤0.05) exposure-response coefficients. The models that provided the best fit to the data were those that used cumulative exposure and log-transformed cumulative exposure. The fit of the log-linear model with average exposure was clearly inferior to those using cumulative and log-cumulative exposure metrics.

There was significant heterogeneity among studies (cohorts) using either cumulative exposure or average exposure. The authors suggested a number of possible reasons for such heterogeneity, including errors in measurement of high exposures (which tends to have strong influence on the exposure-response curve when untransformed exposure measures are used), the differential toxicity of silica depending on the crystalline polymorph, the presence of coatings or trace minerals that alter the reactivity of the crystal surfaces, and the age of the fractured surfaces. Models that used the log transform of cumulative exposure showed no statistically significant heterogeneity among cohorts (p=0.36), possibly because they are less influenced by very high exposures than models using untransformed cumulative exposure. For this reason, as well as the good fit of the model using log-cumulative exposure, Steenland et al. (2001a) conducted much of their analysis using log-transformed cumulative exposure. The sensitivity analysis by Toxichemica, Inc. (2004) repeated this analysis after correcting some errors in the original coding of the data set. At OSHA's request, Steenland (2010) also conducted a categorical analysis of the pooled data set and additional analyses using linear relative risk models (with and without log-transformation of cumulative exposure) as well as a 2-piece spline model.

The cohort studies included in the pooled analysis relied in part on particle count data and the use of conversion factors to estimate exposures of workers to mass respirable quartz. A few studies were able to include at least some respirable mass sampling data. OSHA believes that uncertainty in the exposure assessments that underlie each of the 10 studies included in the pooled analysis is likely to represent one of the most important sources of uncertainty in the risk estimates. To evaluate the potential impact of uncertainties in the underlying exposure assessments on estimates of the risk, OSHA's contractor, Toxichemica, Inc. (2004), commissioned Drs. Kyle Steenland and Scott Bartell of Emory University to conduct an uncertainty analysis using the raw data from the pooled cancer risk assessment. The uncertainty analysis employed a Monte Carlo technique in which two kinds of random exposure measurement error were considered; these were (1) random variation in respirable dust measurements and (2) random error in estimating respirable quartz exposures from historical data on particle count concentration, total dust mass concentration, and respirable dust mass concentration measurements. Based on the results of this uncertainty analysis, OSHA does not have reason to believe that random error in the underlying exposure estimates in the Steenland et al. (2001a) pooled cohort study of lung cancer is likely to have substantially influenced the original findings, although a few individual cohorts (particularly the South African and Australian gold miner cohorts) appeared to be sensitive to measurement errors.

The sensitivity analysis also examined the potential effect of systematic bias in the use of conversion factors to estimate respirable crystalline silica exposures from historical data. Absent *a priori* reasons to suspect bias in a specific direction (with the possible exception of the South African cohort), Toxichemica, Inc. (2004) considered possible biases in either direction by assuming that exposure was under-estimated by 100% (*i.e.,* the true exposure was twice the estimated) or over-estimated by 100% (*i.e.,* the true exposure was half the estimated) for any given cohort in the original pooled dataset. For the conditional logistic regression model using log cumulative exposure with a 15-year lag, doubling or halving the exposure for a specific study resulted in virtually no change in the exposure-response coefficient for that study or for the pooled analysis overall. Therefore, based on the results of the uncertainty analysis, OSHA believes that misclassification errors of a reasonable magnitude in the estimation of historical exposures for the 10 cohort studies were not likely to have substantially biased risk estimates derived from the exposure-response model used by Steenland et al. (2001a).

b. Rice et al. (2001) Analysis of Diatomaceous Earth Workers

Rice et al. (2001) applied a variety of exposure-response models to the same California diatomaceous earth cohort data originally reported on by Checkoway et al. (1993, 1996, 1997) and included in the pooled analysis conducted by Steenland et al. (2001a) described above. The cohort consisted of 2,342 white males employed for at least one year between 1942 and 1987 in a California diatomaceous earth mining and processing plant. The cohort was followed until 1994, and included 77 lung cancer deaths. Rice et al. (2001) relied on the dust exposure assessment developed by Seixas et al. (1997) from company records of over 6,000 samples collected from 1948 to 1988; cristobalite was the predominate form of crystalline silica to which the cohort was exposed. Analysis was based on both Poisson regression models Cox's proportional hazards models with various functions of cumulative silica exposure in mg/m³-years to estimate the relationship between silica exposure and lung cancer mortality rate. Rice et al. (2001) reported that exposure to crystalline silica was a significant predictor of lung cancer mortality for nearly all of the models employed, with the linear relative risk model providing the best fit to the data in the Poisson regression analysis.

c. Attfield and Costello (2004) Analysis of Granite Workers

Attfield and Costello (2004) analyzed the same U.S. granite cohort originally studied by Costello and Graham (1988) and Davis et al. (1983) and included in the Steenland et al. (2001a) pooled analysis, consisting of 5,414 male granite workers who were employed in the Vermont granite industry between 1950 and 1982 and who had received at least one chest x-ray from the surveillance program of the Vermont Department of Industrial Hygiene. Their 2004 report extended follow-up from 1982 to 1994, and found 201 deaths. Workers' cumulative exposures were estimated by Davis et al. (1983) based on historical exposure data collected in six environmental surveys conducted between 1924 and 1977, plus work history information.

Using Poisson regression models and seven cumulative exposure categories, the authors reported that the results of the categorical analysis showed a generally increasing trend of lung cancer rate ratios with increasing cumulative exposure, with seven lung cancer death rate ratios ranging from 1.18 to 2.6. A complication of this analysis was that the rate ratio for the highest exposure group in the analysis (cumulative exposures of 6.0 mg/m^3-years or higher) was substantially lower than those for other exposure groups. Attfield and Costello (2004) reported that the best-fitting model was based on a 15-year lag, use of untransformed cumulative exposure, and omission of the highest exposure group.

The authors argued that it was appropriate to base their risk estimates on a model that was fitted without the highest exposure group for several reasons. They believed the underlying exposure data for the high-exposure group was weaker than for the others, and that there was a greater likelihood that competing causes of death and misdiagnoses of causes of death attenuated the lung cancer death rate. Second, all of the remaining groups comprised 85 percent of the deaths in the cohort and showed a strong linear increase in lung cancer mortality with increasing exposure. Third, Attfield and Costello (2004) believed that the exposure-response relationship seen in the lower exposure groups was more relevant given that the exposures of these groups were within the range of current occupational standards. Finally, the authors stated that risk estimates derived from the model after excluding the highest exposure group were more consistent with other published risk estimates than was the case for estimates derived from the model using all exposure groups. Because of these reasons, OSHA believes it is appropriate to rely on the model employed by Attfield and Costello (2004) after omitting the highest exposure group.

d. Kuempel et al. (2001) Rat-Based Model for Human Lung Cancer

Kuempel et al. (2001) published a rat-based toxicokinetic/toxicodynamic model for silica exposure for predicting human lung cancer, based on lung burden concentrations necessary to cause the precursor events that can lead to adverse physiological effects in the lung. These adverse physiological effects can then lead to lung fibrosis and an indirect genotoxic cause of lung cancer. The hypothesized first step, or earliest expected response, in these disease processes is chronic lung inflammation, which the authors consider as a disease limiting step. Since the NOAEL of lung burden associated with this inflammation, based on the authors' rat-to-human lung model conversion, is the equivalent of exposure to 0.036 mg/m^3 (M_{crit}) for 45 years, exposures below this level would presumably not lead to (based on an indirect genotoxic mechanism) lung cancer, at least in the ''average individual.'' Since silicosis also is inflammation mediated, this exposure could also be considered to be an average threshold level for that disease as well.

Kuempel et al. (2001) have used their rat-based lung cancer model with human data, both to validate their model and to estimate the lung cancer risk as a function of quartz lung burden. First they ''calibrated'' human lung burdens from those in rats based on exposure estimates and lung autopsy reports of U.S. coal miners. Then they validated these lung burden estimates using quartz exposure data from U.K. coal miners. Using these human lung burden/exposure concentration equivalence relationships, they then converted the cumulative exposure-lung cancer response slope estimates from both the California diatomaceous earth workers (Rice et al., 2001) and Vermont granite workers (Attfield and Costello, 2001) to lung burden-lung cancer response slope estimates. Finally, they used these latter slope estimates in a life table program to estimate lung cancer risk associated with their ''threshold'' exposure of 0.036 mg/m^3 and to the OSHA PEL and NIOSH REL. Comparing the estimates from the two epidemiology studies with those based on a male rat chronic silica exposure study the authors found that, '' the lung cancer excess risk estimates based on male rat data are approximately three times higher than those based on the male human data.'' Based on this modeling and validation exercise, Keumpel et al. concluded, ''the rat-based estimates of excess lung cancer risk in humans exposed to crystalline silica are reasonably similar to those based on two human occupational epidemiology studies.''

Toxichemica, Inc. (2004) investigated whether use of the dosimetry model would substantially affect the results of the pooled lung cancer data analysis initially conducted by Steenland et al. (2001a). They replicated the lung dosimetry model using Kuempel et al.'s (2001) reported median fit parameter values, and compared the relationship between log cumulative exposure and 15-year lagged lung burden at the age of death in case subjects selected for the pooled case-control analysis. The two dose metrics were found to be highly correlated (r=0.99), and models based on either log silica lung burden or log cumulative exposure were similarly good predictors of lung cancer risk in the pooled analysis (nearly identical log-likelihoods of –4843.96 and—4843.996, respectively). OSHA believes that the Kuempel et al. (2001) analysis is a credible attempt to quantitatively describe the retention and accumulation of quartz in the lung, and to relate the external exposure and its associated lung burden to the inflammatory process. However, using the lung burden model to convert the cumulative exposure coefficients to a different exposure metric appears to add little additional information or insight to the risk assessments conducted on the diatomaceous earth and granite cohort studies. Therefore, for the purpose of quantitatively evaluating lung cancer risk in exposed workers, OSHA has chosen to rely on the epidemiology studies themselves and the cumulative exposure metrics used in those studies.

e. Hughes et al. (2001), McDonald et al. (2001), and McDonald et al. (2005) Study of North American Industrial Sand Workers

McDonald et al. (2001), Hughes et al. (2001) and McDonald et al. (2005) followed up on a cohort study of North American industrial sand workers that overlapped with the industrial sand cohort (18 plants, 4,626 workers) studied by Steenland and Sanderson (2001) and included in Steenland et al.'s (2001a) pooled cohort analysis. The McDonald et al. (2001) follow-up cohort included 2,670 men employed before 1980 for three years or more in one of nine North American (8 U.S. and 1 Canadian) sand-producing plants, including 1 large associated office complex. Information on cause of death was obtained, from 1960 through 1994, for 99 percent of the deceased workers for a total 1,025 deaths representing 38 percent of the cohort. A nested case-control study and analysis based on 90 lung cancer deaths from this cohort was also conducted by Hughes et al. (2001). A later update through 2000, of both the cohort and nested case-control studies by McDonald et al. (2005), eliminated the Canadian plant, following 2,452 men from the eight U.S. plants. For the lung cancer case-control part of the study the update included 105 lung cancer deaths. Both the initial and updated case control studies used up to two controls per case.

Although the cohort studies provided evidence of increased risk of lung cancer (SMR = 150, p = 0.001, based on U.S. rates) for deaths occurring 20 or more years from hire, the nested case-control studies, Hughes et al. (2001) and McDonald et al. (2005), allowed for individual job, exposure, and smoking histories to be taken into account in the exposure-response analysis for lung cancer. Both of these case-control analyses relied on an analysis of exposure information reported by Sanderson et al. (2000) and by Rando et al. (2001) to provide individual estimates of average and cumulative exposure. Statistically significant positive exposure-response trends for lung cancer were found for both cumulative exposure (lagged 15 years) and average exposure concentration, but not for duration of employment, after controlling for smoking. A monotonic increase was seen for both lagged and unlagged cumulative exposure when the four upper exposure categories were collapsed into two. With exposure lagged 15 years and after adjusting for smoking, increasing quartiles of cumulative silica exposure were associated with lung cancer mortality (odds ratios of 1.00, 0.84, 2.02 and 2.07, p-value for trend=0.04). There was no indication of an interaction effect of smoking and cumulative silica exposure (Hughes et al., 2001).

OSHA considers this Hughes et al. (2001) study and analysis to be of high enough quality to provide risk estimates for excess lung cancer for silica exposure to industrial sand workers. Using the median cumulative exposure levels of 0, 0.758, 2.229 and 6.183 mg/m^3-years, Hughes et al. estimated lung cancer odds ratios, ORs (no. of deaths), for these categories of 1.00 (14), 0.84 (15), 2.02 (31), and 2.07 (30), respectively, on a 15-year lag basis (p-value for trend=0.04.) For the updated nested case control analysis, McDonald et al. (2005) found very similar results, with exposure lagged 15 years and, after adjusting for smoking, increasing quartiles of cumulative silica exposure were associated with lung cancer ORs (no. of deaths) of 1.00 (13), 0.94 (17), 2.24 (38), and 2.66 (37) (p-value for trend=0.006). Because the Hughes et al. (2001) report contained information that allowed OSHA to better calculate exposure-response estimates and because of otherwise very similar results in the two papers, OSHA has chosen to base its lifetime excess lung cancer risk estimate for these industrial sand workers on the Hughes et al. (2001) case-control study. Using the median exposure levels of 0, 0.758, 2.229 and 6.183 mg-years/m^3, respectively, for each of the four categories described above, and using the model: $\ln OR = \alpha + \beta \times$ Cumulative Exposure, the coefficient for the exposure estimate was $\beta = 0.13$ per (mg/m^3-years), with a standard error of $\beta = 0.074$ (calculated from the trend test p-value in the same paper). In this model, with background lung cancer risks of about 5 percent, the OR provides a suitable estimate of the relative risk.

f. Miller et al. (2007) and Miller and MacCalman (2009) Study of British Coal Workers Exposed to Respirable Quartz

Miller et al. (2007) and Miller and MacCalman (2009) continued a follow-up mortality study, begun in 1970, of 18,166 coalminers from 10 British coalmines initially followed through the end of 1992 (Miller et al., 1997). The two recent reports on mortality analyzed the cohort of 17,800 miners and extended the analysis through the end of 2005. By that time there were 516,431 person years of observation, an average of 29 years per miner, with 10,698 deaths from all causes. Causes of deaths of interest included pneumoconiosis, other non-malignant respiratory diseases (NMRD), lung cancer, stomach cancer, and tuberculosis. Three of the strengths of this study are its use of detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. However, the authors noted that no additional exposure measurements were included in the updated analysis, since all the mines had closed by the mid 1980's.

For this cohort mortality study there were analyses using both external (regional age-time and cause specific mortality rates) internal controls. For the analysis from external mortality rates, the all-cause mortality SMR from 1959 through 2005 was 100.9 (95% C.I., 99.0–102.8), based on all 10,698 deaths. However, these death ratios were not uniform over time. For the period from 1990 to 2005, the all-cause SMR was 109.6 (95% C.I., 106.5–112.8), while the ratios for previous periods were less than 100. This pattern of recent increasing SMRs was also seen in the recent cause-specific death rate for lung cancer, SMR=115.7 (95% C.I., 104.8–127.7). For the analysis based on internal rates and using Cox regression methods, the relative risk for lung cancer risk based on a cumulative quartz exposure equivalent to approximately 0.055 mg/m^3 for 45 years was RR = 1.14 (95% C.I., 1.04 to 1.25). This risk is adjusted for concurrent coal dust exposure and smoking status, and incorporated a 15-year lag in quartz exposures. The analysis showed a strong effect for smoking (independent of quartz exposure) on lung cancer. For lung cancer, OSHA believes that the analyses based on the Cox regression method provides strong evidence that for these coal miners' quartz exposures were associated with increased lung cancer risk, but that simultaneous exposures to coal dust did not cause increased lung cancer risk. To estimate lung cancer risk from this study, OSHA estimated the regression slope for a log-linear relative risk model based on the Miller and MacCalman's (2009) finding of a relative risk of 1.14 for a cumulative exposure of 0.055 mg/m^3-years.

2. Summary of OSHA's Estimates of Lung Cancer Mortality Risk

Tables VI–1 and VI–2 summarize the excess lung cancer risk estimates from occupational exposure to crystalline silica, based on five of the six lung cancer risk assessments discussed above. OSHA's estimates of lifetime excess lung cancer risk associated with 45 years of exposure to crystalline silica at 0.1 mg/m^3 (approximately the current general industry PEL) range from 13 to 60 deaths per 1,000 workers. For exposure to the proposed PEL of 0.05 mg/m^3, the lifetime risk estimates calculated by OSHA are in the range of 6 to 26 deaths per 1,000 workers. For a 45-year exposure at the proposed action level of 0.025 mg/m^3, OSHA estimates the risk to range from 3 to 23 deaths per 1,000 workers. The results from these assessments are reasonably consistent despite the use of data from different cohorts and the reliance on different analytical techniques for evaluating dose-response relationships. Furthermore, OSHA notes that in this range of exposure, 0.025—0.1 mg/m^3, there is statistical consistency between the risk estimates, as evidenced by the considerable overlap in the 95-percent confidence intervals of the risk estimates presented in Table VI–1.

OSHA also estimates the lung cancer risk associated with 45 years of exposure to the current construction/shipyard PEL (in the range of 0.25 to 0.5 mg/m^3) to range from 37 to 653 deaths per 1,000 workers. Exposure to 0.25 or 0.5 mg/m^3 over 45 years represents cumulative exposures of 11.25 and 22.5 mg-years/m^3, respectively. This range of cumulative exposure is well above the median cumulative exposure for most of the cohorts used in the risk assessment, primarily because most of the individuals in these cohorts had not been exposed for as long as 45 years. Thus, estimating lung cancer excess risks over this higher range of cumulative exposures of interest to OSHA required some degree of extrapolation and adds uncertainty to the estimates.

C. Silicosis and Non-Malignant Respiratory Disease Mortality

There are two published quantitative risk assessment studies of silicosis and non-malignant respiratory disease (NMRD) mortality; a pooled analysis of silicosis mortality by Mannetje et al. (2002b) of data from six epidemiological studies, and an exposure-response analysis of NMRD mortality among diatomaceous earth workers (Park et al., 2002).

1. Mannetje et al. (2002b) Six Cohort Pooled Analysis

The Mannetje et al. (2002b) silicosis analysis was part of the IARC ten cohort pooled study included in the Steenland et al. (2001a) lung cancer mortality analysis above. These studies included 18,634 subjects and 170 silicosis deaths (n = 150 for silicosis, and n = 20 unspecified pneumoconiosis). The silicosis deaths had a median duration of exposure of 28 years, a median cumulative exposure of 7.2 mg/m^3-years, and a median average exposure of 0.26 mg/m^3, while the respective values of the whole cohort were 10 years, 0.62 mg/m^3-years, and 0.07 mg/m^3. Rates for silicosis adjusted for age, calendar time, and study were estimated by Poisson regression; rates increased nearly monotonically with deciles of cumulative exposure, from a mortality rate of 5/100,000 person-years in the lowest exposure category (0–0.99 mg/m^3-years) to 299/100,000 person-years in the highest category (>28.10 mg/m^3-years). Quantitative estimates of exposure to respirable silica (mg/m^3) were available for all six cohorts (Mannetje et al. 2002a). Lifetime risk of silicosis mortality was estimated by accumulating mortality rates over time using the formula

$$\text{Risk} = 1 - \exp(-\boldsymbol{\Sigma}\text{time} * \text{rate}).$$

To estimate the risk of silicosis mortality at the current and proposed PELs, OSHA used the model described by Mannetje et al. (2002b) to estimate risk to age 85 but used rate ratios that were estimated from a nested case-control design that was part of a sensitivity analysis conducted by Toxichemica, Inc. (2004), rather than the Poisson regression originally conducted by Mannetje et al. (2002b). The case-control design was selected because it was expected to better control for age; in addition, the rate ratios derived from the case-control study reflect exposure measurement uncertainty via conduct of a Monte Carlo analysis (Toxichemica, Inc., 2004).

2. Park et al. (2002) Study of Diatomaceous Earth Workers

Park et al. (2002) analyzed the California diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994, to quantify the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Industrial hygiene data for the cohort were available from the employer for total dust, silica (mostly cristobalite), and asbestos. Park et al. (2002) used the exposure assessment previously reported by Seixas et al. (1997) and used by Rice et al. (2001) to estimate cumulative crystalline silica exposures for each worker in the cohort based on detailed work history files. The mean silica concentration for the cohort overall was 0.29 mg/m^3 over the period of employment (Seixas et al., 1997). The mean cumulative exposure values for total respirable dust and respirable crystalline silica were 7.31 and 2.16 mg/m^3-year, respectively. Similar cumulative exposure estimates were made for asbestos. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park et al. (2002) to at least partially adjust for smoking. Estimates of LDOC mortality risks were derived via Poisson and Cox's proportional hazards models; a variety of relative rate model forms were fit to the data, with a linear relative rate model being selected for risk estimation.

3. Summary Risk Estimates for Silicosis and NMRD Mortality

Table VI–2 presents OSHA's risk estimates for silicosis and NMRD mortality derived from the Mannetje et al. (2002b) and Park et al. (2002) studies, respectively. For 45 years of exposure to the current general industry PEL (approximately 0.1 mg/m^3 respirable crystalline silica), OSHA's estimates of excess lifetime risk are 11 deaths per 1,000 workers for the pooled analysis and 83 deaths per 1,000 workers based on Park et al.'s (2002) estimates. At the proposed PEL, estimates of silicosis and NMRD mortality are 7 and 43 deaths per 1,000, respectively. For exposures up to 0.25 mg/m^3, the estimates based on Park et al. are about 5 to 11 times as great as those calculated for the pooled analysis of silicosis mortality (Mannetje et al., 2002b). However, these two sets of risk estimates are not directly comparable. First, the Park et al. analysis used untransformed cumulative exposure as the exposure metric, whereas the Mannertje et al. analysis used *log* cumulative exposure, which causes the exposure-response to flatten out in the higher exposure ranges. Second, the mortality endpoint for the Park et al. (2002) analysis is death from all non-cancer lung diseases, including pneumoconiosis, emphysema, and chronic bronchitis, whereas the pooled analysis by Mannetje et al. (2002b) included only deaths coded as silicosis or other pneumoconiosis. Less than 25 percent of the LDOC deaths in the Park et al. (2002) analysis were coded as silicosis or other pneumoconiosis (15 of 67). As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis; thus, Mannetje et al.'s (2002b) selection of deaths may tend to underestimate the true risk of silicosis mortality, and Park et al.'s (2002) analysis would more fairly capture the total respiratory mortality risk from all non-malignant causes, including silicosis and chronic obstructive pulmonary disease.

D. Renal Disease Mortality

Steenland et al. (2002a) examined renal disease mortality in three cohorts and evaluated exposure-response relationships from the pooled cohort data. The three cohorts included U.S. gold miners (Steenland and Brown, 1995a), U.S. industrial sand workers (Steenland et al., 2001b), and Vermont granite workers (Costello and Graham, 1988), all three of which are included in both the lung cancer mortality and silicosis mortality pooled analyses reported above. Follow up for the U.S.

gold miners study was extended six years from that in the other pooled analyses. Steenland et al. (2002a) reported that these cohorts were chosen because data were available for both underlying cause mortality and multiple cause mortality; this was believed important because renal disease is often listed on death certificates without being identified as an underlying cause of death. In the three cohorts, there were 51 total renal disease deaths using underlying cause, and 204 total renal deaths using multiple cause mortality.

The combined cohort for the pooled analysis (Steenland et al., 2002a) consisted of 13,382 workers with exposure information available for 12,783 (95 percent). Exposure matrices for the three cohorts had been used in previous studies (Steenland and Brown, 1995a; Attfield and Costello, 2001; Steenland et al., 2001b). The mean duration of exposure, the mean cumulative exposure, and the mean concentration of respirable silica for the pooled cohort were 13.6 years, 1.2 mg/m^3-years, and 0.07 mg/m^3, respectively. SMRs (compared to the U.S. population) for renal disease (acute and chronic glomerulonephritis, nephrotic syndrome, acute and chronic renal failure, renal sclerosis, and nephritis/nephropathy) were statistically significantly elevated using multiple cause data (SMR 1.29, 95% CI 1.10–1.47, 193 deaths) and underlying cause data (SMR 1.41, 95% CI 1.05–1.85, 51 observed deaths).

OSHA's estimates of renal disease mortality appear in Table VI–2. Based on the life table analysis, OSHA estimates that exposure to the current (0.10 mg/m^3) and proposed general industry PEL (0.0.05 mg/m^3) over a working life would result in a lifetime excess renal disease risk of 39 (95% CI 2–200) and 32 (95% CI 1.7–147) deaths per 1,000, respectively. For exposure to the current construction/shipyard PEL, OSHA estimates the excess lifetime risk to range from 52 (95% CI 2.2–289) to 63 (95% CI 2.5–368) deaths per 1,000 workers.

E. Silicosis Morbidity

OSHA's Preliminary QRA summarizes the principal cross-sectional and cohort studies that have quantitatively characterized relationships between exposure to crystalline silica and development of radiographic evidence of silicosis. Each of these studies relied on estimates of cumulative exposure to evaluate the relationship between exposure and silicosis prevalence in the worker populations examined. The health endpoint of interest in these studies is the appearance of opacities on chest roentgenograms indicative of pulmonary fibrosis.

The International Labour Organization's (ILO) 1980 International Classification of Radiographs of the Pneumoconioses is accepted as the standard against which chest radiographs are measured in epidemiologic studies, for medical surveillance and for clinical evaluation. According to this standard, if radiographic findings are or may be consistent with pneumoconiosis, then the size, shape, and extent of profusion of opacities are characterized by comparing the radiograph to standard films. Classification by shape (rounded vs. irregular) and size involves identifying primary and secondary types of small opacities on the radiograph and classifying them into one of six size/shape categories. The extent of profusion is judged from the concentrations of opacities as compared with that on the standard radiographs and is graded on a 12-point scale of four major categories (0–3, with Category 0 representing absence of opacities), each with three subcategories. Most of the studies reviewed by OSHA considered a finding consistent with an ILO classification of 1/1 to be a positive diagnosis of silicosis, although some also considered an x-ray classification of 1/0 or 0/1 to be positive.

Chest radiography is not the most sensitive tool used to diagnose or detect silicosis. In 1993, Hnizdo et al. reported the results of a study that compared autopsy and radiological findings of silicosis in a cohort of 557 white South African gold miners. The average period from last x-ray to autopsy was 2.7 years. Silicosis was not diagnosed radiographically for over 60 percent of the miners for whom pathological examination of lung tissue showed slight to marked silicosis. The likelihood of false negatives (negative by x-ray, but silicosis is actually present) increased with years of mining and average dust exposure of the miners. The low sensitivity seen for radiographic evaluation suggests that risk estimates derived from radiographic evidence likely understate the true risk of developing fibrotic lesions as a result of exposure to crystalline silica.

OSHA's Preliminary QRA examines multiple studies from which silicosis occupational morbidity risks can be estimated. The studies evaluated fall into three major types. Some are cross-sectional studies in which radiographs taken at a point in time were examined to ascertain cases (Kreiss and Zhen, 1996; Love et al., 1999; Ng and Chan, 1994; Rosenman et al., 1996; Churchyard et al., 2003, 2004); these radiographs may have been taken as part of a health survey conducted by the investigators or represent the most recent chest x-ray available for study subjects. Other studies were designed to examine radiographs over time in an effort to determine onset of disease. Some of these studies examined primarily active, or current, workers (Hughes et al., 1998; Muir et al., 1989a, 1989b; Park et al., 2002), while others included both active and retired workers (Chen et al., 2001, 2005; Hnizdo and Sluis-Cremer, 1993; Miller et al., 1998; Buchanan et al., 2003; Steenland and Brown, 1995b).

Even though OSHA has presented silicosis risk estimates for all of the studies identified, the Agency is relying primarily on those studies that examined radiographs over time and included both active and retired workers. It has been pointed out by others (Chen et al., 2001; Finkelstein, 2000; NIOSH, 2002) that lack of follow-up of retired workers consistently resulted in lower risk estimates compared to studies that included retired workers. OSHA believes that the most reliable estimates of silicosis morbidity, as detected by chest radiographs, come from the studies that evaluated radiographs over time, included radiographic evaluation of workers after they left employment, and derived cumulative or lifetime estimates of silicosis disease risk. Brief descriptions of these cumulative risk studies used to estimate silicosis morbidity risks are presented below.

1. Hnizdo and Sluis Cremer (1993) Study of South African White Gold Miners

Hnizdo and Sluis-Cremer (1993) described the results of a retrospective cohort study of 2,235 white gold miners in South Africa. These workers had received annual examinations and chest x-rays while employed; most returned for occasional examinations after employment. A case was defined as one with an x-ray classification of ILO 1/1 or greater. A total of 313 miners had developed silicosis and had been exposed for an average of 27 years at the time of diagnosis. Forty-three percent of the cases were diagnosed while employed and the remaining 57 percent were diagnosed an average of 7.4 years after leaving the mines. The average latency for the cohort was 35 years (range of 18–50 years) from start of exposure to diagnosis.

The average respirable dust exposure for the cohort overall was 0.29 mg/m^3 (range 0.11–0.47), corresponding to an estimated average respirable silica concentration of 0.09 mg/m^3 (range

0.033–0.14). The average cumulative dust exposure for the overall cohort was 6.6 mg/m³-years (range 1.2–18.7), or an average cumulative silica exposure of 1.98 mg/m³-years (range 0.36–5.61). OSHA believes that the exposure estimates for the cohort are uncertain given the need to rely on particle count data generated over a fairly narrow production period.

Silicosis risk increased exponentially with cumulative exposure to respirable dust and was modeled using log-logistic regression. Using the exposure-response relationship developed by Hnizdo and Sluis-Cremer (1993), and assuming a quartz content of 30 percent in respirable dust, Rice and Stayner (1995) and NIOSH (2002) estimated the risk of silicosis to be 70 percent and 13 percent for a 45-year exposure to 0.1 and 0.05 mg/m³ respirable crystalline silica, respectively.

2. Steenland and Brown (1995b) Study of South Dakota Gold Miners

Three thousand three hundred thirty South Dakota gold miners who had worked at least a year underground between 1940 and 1965 were studied by Steenland and Brown (1995b). Workers were followed though 1990 with 1,551 having died; loss to follow up was low (2 percent). Chest x-rays taken in cross-sectional surveys in 1960 and 1976 and death certificates were used to ascertain cases of silicosis. One hundred twenty eight cases were found via death certificate, 29 by x-ray (defined as ILO 1/1 or greater), and 13 by both. Nine percent of deaths had silicosis mentioned on the death certificate. Inclusion of death certificate diagnoses probably increases the risk estimates from this study compared to those that rely exclusively on radiographic findings to evaluate silicosis morbidity risk (*see* discussion of Hnizdo et al. (1993) above).

Exposure was estimated by conversion of impinger (particle count) data and was based on measurements indicating an average of 13 percent silica in the dust. Based on these data, the authors estimated the mean exposure concentration to be 0.05 mg/m³ for the overall cohort, with those hired before 1930 exposed to an average of 0.15 mg/m³. The average duration of exposure for cases was 20 years (s.d = 8.7) compared to 8.2 years (s.d = 7.9) for the rest of the cohort. This study found that cumulative exposure was the best disease predictor, followed by duration of exposure and average exposure. Lifetime risks were estimated from Poisson regression models using standard life table techniques. The authors estimated a risk of 47 percent associated with 45 years of exposure to 0.09 mg/m³ respirable crystalline silica, which reduced to 35 percent after adjustment for age and calendar time.

3. Miller et al. (1995, 1998) and Buchanan et al. (2003) Study of Scottish Coal Miners

Miller et al. (1995, 1998) and Buchanan et al. (2003) reported on a 1990/1991 follow-up study of 547 survivors of a 1,416 member cohort of Scottish coal workers from a single mine. These men had all worked in the mine during a period between early 1971 and mid 1976, during which they had experienced ''unusually high concentrations of freshly cut quartz in mixed coalmine dust. The population's exposures to both coal and quartz dust had been measured in unique detail, for a substantial proportion of the men's working lives.'' Thus, this cohort allowed for the study of the effects of both higher and lower silica concentrations, and exposure-rate effects on the development of silicosis. The 1,416 men had all had previous radiographs dating from before, during, or just after this high concentration period, and the 547 participating survivors received their follow-up chest x-rays between November 1990 and April 1991. Follow-up interviews consisted of questions on current and past smoking habits, and occupational history since leaving the coal mine, which closed in 1981.

Silicosis cases were identified as such if the median classification of the three readers indicated an ILO (1980) classification of 1/0 or greater, plus a progression from the earlier reading. Of the 547 men, 203 (38 percent) showed progression of at least one ILO category from the 1970's surveys to the 1990–91 survey; in 128 of these (24 percent) there was progression of two or more steps. In the 1970's survey 504 men had a profusion score of 0; of these, 120 (24 percent) progressed to an ILO classification of 1/0 or greater. Of the 36 men who had shown earlier profusions of 1/0 or greater, 27 (75 percent) showed further progression at the 1990/1991 follow-up. Only one subject showed a regression from any earlier reading, and that was slight, from ILO 1/0 to 0/1.

To study the effects of exposure to high concentrations of quartz dust, the Buchanan et al. (2003) analysis presented the results of logistic regression modeling that incorporated two independent terms for cumulative exposure, one arising from exposure to concentrations less than 2 mg/m³ respirable quartz and the other from exposure to concentrations greater than or equal to 2 mg/m³. Both of the cumulative quartz exposure concentration variables were ''highly statistically significant in the presence of the other,'' and independent of the presence of coal dust. Since these quartz variables were in the same units, g–hr/m³, the authors noted that coefficient for exposure concentrations equal to or above 2.0 mg/m³ was 3 times that of the coefficient for concentrations less than 2.0 mg/m³. From this, the authors concluded that their analysis showed that ''the risk of silicosis over a working lifetime can rise dramatically with exposure to such high concentrations over a timescale of merely a few months.''

Buchanan et al., (2003) provided analysis and risk estimates only for silicosis cases defined as having an x-ray classified as ILO 2/1+, after adjusting for the disproportionately severe effect of exposure to high concentrations on silicosis risk. Estimating the risk of acquiring a chest x-ray classified as ILO 1/0+ from the Buchanan (2003) or the earlier Miller et al. (1995, 1998) publications can only be roughly approximated because of the limited summary information included; this information suggests that the risk of silicosis defined as an ILO classification of 1/0+ could be about three times higher than the risk of silicosis defined as an ILO 2/1+ x-ray. OSHA has a high degree of confidence in the estimates of progression to stages 2/1+ from this Scotland coal mine study, mainly because of the highly detailed and extensive exposure measurements, the radiographic records, and the detailed analyses of high exposure-rate effects.

4. Chen et al. (2001) Study of Tin Miners

Chen et al. (2001) reported the results of a retrospective study of a Chinese cohort of 3,010 underground miners who had worked in tin mines at least one year between 1960 and 1965. They were followed through 1994, by which time 2,426 (80.6%) workers had either retired or died, and only 400 (13.3%) remained employed at the mines.

The study incorporated occupational histories, dust measurements and medical examination records. Exposure data consisted of high-flow, short-term gravimetric total dust measurements made routinely since 1950; the authors used data from 1950 to represent earlier exposures since dust control measures were not implemented until 1958. Results from a 1998–1999 survey indicated that respirable silica measurements were 3.6 percent (s.d = 2.5 percent) of total dust measurements. Annual radiographs were taken since 1963 and all cohort members continued to have chest x-rays taken every 2 or 3 years after leaving work. Silicosis was diagnosed when at least 2 of 3 radiologists classified a radiograph as being a ''suspected case'' or at Stage I, II, or III under the 1986 Chinese pneumoconiosis roentgen diagnostic criteria. According to Chen et al. (2001), these four categories under the Chinese system were found to agree closely with ILO categories 0/1, Category 1, Category 2, and Category 3, respectively, based on studies comparing the Chinese and ILO classification systems. Silicosis was observed in 33.7 percent of the group; 67.4 percent of the cases developed after exposure ended.

5. Chen et al. (2005) Study of Chinese Pottery Workers, Tin Miners, and Tungsten Miners

In a later study, Chen et al. (2005) investigated silicosis morbidity risks among three cohorts to determine if the risk varied among workers exposed to silica dust having different characteristics. The cohorts consisted of 4,547 pottery workers, 4,028 tin miners, and 14,427 tungsten miners selected from a total of 20 workplaces. Cohort members included all males employed after January 1, 1950 and who worked for at least one year between 1960 and 1974. Radiological follow-up was through December 31, 1994 and x-rays were scored according to the Chinese classification system as described above by Chen et al. (2001) for the tin miner study. Exposure estimates of cohort members to respirable crystalline silica were based on the same data as described by Chen et al. (2001). In addition, the investigators measured the extent of surface occlusion of crystalline silica particles by alumino-silicate from 47 dust samples taken at 13 worksites using multiple-voltage scanning electron microscopy and energy dispersive X-ray spectroscopy (Harrison et al., 2005); this method yielded estimates of the percent of particle surface that is occluded.

Compared to tin and tungsten miners, pottery workers were exposed to significantly higher mean total dust concentrations (8.2 mg/m^3, compared to 3.9 mg/m^3 for tin miners and 4.0 mg/m^3 for tungsten miners), worked more net years in dusty occupations (mean of 24.9 years compared to 16.4 years for tin miners and 16.5 years for tungsten miners), and had higher mean cumulative dust exposures (205.6 mg/m^3-years compared to 62.3 mg/m^3-years for tin miners and 64.9 mg/m^3-years for tungsten miners) (Chen et al., 2005). Applying the authors' conversion factors to estimate respirable crystalline silica from Chinese total dust measurements, the approximate mean cumulative exposures to respirable silica for pottery, tin, and tungsten workers are 6.4 mg/m^3-years, 2.4 mg/m^3-years, and 3.2 mg/m^3-years, respectively. Measurement of particle surface occlusion indicated that, on average, 45 percent of the surface area of respirable particles collected from pottery factory samples was occluded, compared to 18 percent of the particle surface area for tin mine samples and 13 percent of particle surface area for tungsten mines.

Based on Chen et al. (2005), OSHA estimated the cumulative silicosis risk associated with 45 years of exposure to 0.1 mg/m^3 respirable crystalline silica (a cumulative exposure of 4.5 mg/m^3-years) to be 6 percent for pottery workers, 12 percent for tungsten miners, and 40 percent for tin miners. For a cumulative exposure of 2.25 mg/m^3-years (*i.e.,* 45 years of exposure to 0.05 mg/m^3), cumulative silicosis morbidity risks were estimated to be 2, 2, and 10 percent for pottery workers, tungsten miners, and tin miners, respectively. When cumulative silica exposure was adjusted to reflect exposure to surface-active quartz particles (*i.e.,* not occluded), the estimated cumulative risk among pottery workers more closely approximated those of the tin and tungsten miners, suggesting to the authors that alumino-silicate occlusion of the crystalline particles in pottery factories at least partially explained the lower risk seen among workers, despite their having been more heavily exposed.

6. Summary of Silicosis Morbidity Risk Estimates.

Table VI–2 presents OSHA's risk estimates for silicosis morbidity that are derived from each of the studies described above. Estimates of silicosis morbidity derived from the seven cohorts in cumulative risk studies with post-employment follow-up range from 60 to 773 per 1,000 workers for 45-year exposures to the current general industry PEL of 0.10 mg/m^3, and from 20 to 170 per 1,000 workers for a 45-year exposure to the proposed PEL of 0.05 mg/m^3. The study results provide substantial evidence that the disease can progress for years after exposure ends. Results from an autopsy study (Hnizdo et al., 1993), which found pathological evidence of silicosis absent radiological signs, suggest that silicosis cases based on radiographic diagnosis alone tend to underestimate risk since pathological evidence of silicosis. Other results (Chen et al., 2005) suggest that surface properties among various types of silica dusts can have different silicosis potencies. Results from the Buchanan et al. (2003) study of Scottish coal miners suggest that short-term exposures to >2 mg/m^3 silica can cause a disproportionately higher risk of silicosis than would be predicted by cumulative exposure alone, suggesting a dose-rate effect for exposures to concentrations above this level. OSHA believes that, given the consistent finding of a monotonic exposure-response relationship for silicosis morbidity with cumulative exposure in the studies reviewed, that cumulative exposure is a reasonable exposure metric upon which to base risk estimates in the exposure range of interest to OSHA (*i.e.,* between 0.025 and 0.5 mg/m^3 respirable crystalline silica).

F. Other Considerations in OSHA's Risk Analysis

Uncertainties are inherent to any risk modeling process and analysis; assessing risk and associated complexities of silica exposure among workers is no different. However, the Agency has a high level of confidence that the preliminary risk assessment results reasonably reflect the range of risks experienced by workers exposed to silica in all occupational settings. First, the preliminary assessment is based on an analysis of a wide range of studies, conducted in multiple industries across a wide range of exposure distributions, which included cumulative exposures equivalent to 45 years of exposure to and below the current PEL.

Second, risk models employed in this assessment are based on a cumulative exposure metric, which is the product of average daily silica concentration and duration of worker exposure for a specific job. Consequently, these models predict the same risk for a given cumulative exposure regardless of the pattern of exposure. For example, a manufacturing plant worker exposed to silica at 0.05 mg/m^3 for eight hours per day will have the same cumulative exposure over a given period of time as a construction worker who is exposed each day to silica at 0.1 mg/m^3 for one hour, at 0.075 mg/m^3 for four hours and not exposed to silica for three hours. The cumulative exposure metric thus reflects a worker's long-term average exposure without regard to the pattern of exposure experienced by the worker, and is therefore generally applicable to all workers who are exposed to silica in the various industries. For example, at construction sites, conditions may change often since the nature of work can be intermittent and involve working with a variety of materials that contain different concentrations of quartz. Additionally, workers may perform construction operations for relatively short periods of time where they are exposed to concentrations of silica that may be significantly higher than many continuous operations in general industry. However, these differences are taken into account by the use of the cumulative exposure metric that relates exposure to disease risk. OSHA believes that use of cumulative exposure is the most appropriate dose-metric because each of the studies that provide the basis for the risk assessment demonstrated strong exposure-response relationships between cumulative exposure and disease risk. This metric is especially important in terms of progression of silica-related disease, as discussed in Section VII of the preamble, Significance of Risk, in section B.1.a.

OSHA's risk assessment relied upon many studies that utilized cumulative exposures of cohort members. Table VI–3 summarizes these lung cancer studies, including worker exposure quartile data across a number of industry sectors. The cumulative exposures exhibited in these studies are equivalent to the cumulative exposure that would result from 45 years of exposure to the current and proposed PELs (*i.e.,* 4.5 and 2,25 mg/m³, respectively). For this reason, OSHA has a high degree of confidence in the risk estimates associated with exposure to the current and proposed PELs; additionally, the risk assessment does not require significant low-dose extrapolation of the model beyond the observed range of exposures. OSHA acknowledges there is greater uncertainty in the risk estimates for the proposed action level of 0.025 mg/m³, particularly given some evidence of a threshold for silicosis between the proposed PEL and action level. Given the Agency's findings that controlling exposures below the proposed PEL would not be technologically feasible for employers, OSHA believes that estimating risk for exposures below the proposed action level, which becomes increasingly more uncertain, is not necessary to further inform the Agency's regulatory action.

Although the Agency believes that the results of its risk assessment are broadly relevant to all occupational exposure situations involving crystalline silica, OSHA acknowledges that differences exist in the relative toxicity of crystalline silica particles present in different work settings due to factors such as the presence of mineral or metal impurities on quartz particle surfaces, whether the particles have been freshly fractured or are aged, and size distribution of particles. At this time, however, OSHA preliminarily concludes that it is not yet possible to use available information on factors that mediate the potency of silica to refine available quantitative estimates of the lung cancer and silicosis mortality risks, and that the estimates from the studies and analyses relied upon are fairly representative of a wide range of workplaces reflecting differences in silica polymorphism, surface properties, and impurities.

TABLE VI–1—ESTIMATES OF LIFETIME [A] LUNG CANCER MORTALITY RISK RESULTING FROM 45-YEARS OF EXPOSURE TO CRYSTALLINE SILICA

[Deaths per 1,000 workers (95% confidence interval)]

Cohort	Model	Exposure lag (years)	Model parameters (standard error)	Exposure level (mg/m³)				
				0.025	0.05	0.10	0.25	0.50
Ten pooled cohorts (*see* Table II–1).	Log-linear [b]	15	β = 0.60 (0.015)	22 (11–36)	26 (12–41)	29 (13–48)	34 (15–56)	38 (17–63)
	Linear [b]	15	β = 0.074950 (0.024121).	23 (9–38)	26 (10–43)	29 (11–47)	33 (12–53)	36 (14–58)
	Linear	15	β_1 = 0.16498 (0.0653) and.	9 (2–16)	18 (4–31)	22 (6–38)	27 (12–43)	36 (20–51)
	Spline§ [c d]		β_2 = −0.1493 (0.0657).					
Range from 10 cohorts.		15	Various	0.21–13	0.41–28	0.83–69	2.1–298	4.2–687
	Log-linear [c]							
Diatomaceous earth workers.	Linear [c]	10	β = 0.1441 [e]	9 (2–21)	17 (5–41)	34 (10–79)	81 (24–180)	152 (46–312)
U.S.Granite workers.	Log-linear [c]	15	β = 0.19 [e]	11 (4–18)	25 (9–42)	60 (19–111)	250 (59–502)	653 (167–760)
North American industrial sand workers.	Log-linear [c]	15	β = 0.13 (0.074) [f]	7 (0–16)	15 (0–37)	34 (0–93)	120 (0–425)	387 (0–750)
British coal miners	Log-linear [c]	15	Β = 0.0524 (0.0188).	3 (1–5)	6 (2–11)	13 (4–23)	37 (9–75)	95 (20–224)

[a] Risk to age 85 and based on 2006 background mortality rates for all males (*see* Appendix for life table method).
[b] Model with log cumulative exposure (mg/m³-days + 1).
[c] Model with cumulative exposure (mg/m³-years).
[d] 95% confidence interval calculated as follows (where CE = cumulative exposure in mg/m³-years and SE is standard error of the parameter estimate):
For CE ≤ 2.19: $1 + [(\beta_1 \pm (1.96*SE_1)) * CE]$.
For CE > 2.19: $1 + [(\beta_1 * CE) + (\beta_2 * (CE–2.19))] \pm 1.96 * SQRT[(CE^2 * SE_1^2) + ((CE–2.19)^2 * SE_2^2) + (2*CE*(CE–3.29)*-0.00429)]$.
[e] Standard error not reported, upper and lower confidence limit on beta estimated from confidence interval of risk estimate reported in original article.
[f] Standard error of the coefficient was estimated from the p-value for trend.

TABLE VI–2—SUMMARY OF LIFETIME OR CUMULATIVE RISK ESTIMATES FOR CRYSTALLINE SILICA

Health endpoint (source)	Risk associated with 45 years of occupational exposure (per 1,000 workers)				
	Respirable crystalline silica exposure level (mg/m³)				
	0.025	0.05	0.100	0.250	0.500
Lung Cancer Mortality (Lifetime Risk):					
Pooled Analysis, Toxichemica, Inc (2004) [a b]	9–23	18–26	22–29	27–34	36–38

TABLE VI–2—SUMMARY OF LIFETIME OR CUMULATIVE RISK ESTIMATES FOR CRYSTALLINE SILICA—Continued

Health endpoint (source)	Risk associated with 45 years of occupational exposure (per 1,000 workers)				
	Respirable crystalline silica exposure level (mg/m³)				
	0.025	0.05	0.100	0.250	0.500
Diatomaceous Earth Worker study (Rice et al., 2001) [a,c]	9	17	34	81	152
U.S. Granite Worker study (Attfield and Costello, 2004) [a,d]	11	25	60	250	653
North American Industrial Sand Worker study (Hughes et al., 2001) [a,e]	7	15	34	120	387
British Coal Miner study (Miller and MacCalman, 2009) [a,f]	3	6	13	37	95
Silicosis and Non-Malignant Lung Disease Mortality (Lifetime Risk):					
Pooled Analysis (Toxichemica, Inc., 2004) (silicosis) [g]	4	7	11	17	22
Diatomaceous Earth Worker study (Park et al., 2002) (NMRD) [h]	22	43	83	188	321
Renal Disease Mortality (Lifetime Risk):					
Pooled Cohort study (Steenland et al., 2002a)	25	32	39	52	63
Silicosis Morbidity (Cumulative Risk):					
Chest x-ray category of 2/1 or greater (Buchanan et al., 2003) [j]	21	55	301	994	1000
Silicosis mortality and/or x-ray of 1/1 or greater (Steenland and Brown, 1995b) [k]	31	74	431	593	626
Chest x-ray category of 1/1 or greater (Hnizdo and Sluis-Cremer, 1993) [l]	6	127	773	995	1000
Chest x-ray category of 1 or greater (Chen et al., 2001) [m]	40	170	590	1000	1000
Chest x-ray category of 1 or greater (Chen et al., 2005) [n]					
Tin miners	40	100	400	950	1000
Tungsten miners	5	20	120	750	1000
Pottery workers	5	20	60	300	700

From Table II–12, ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (Docket OSHA–2010–0034).

TABLE VI–3—EXPOSURE DISTRIBUTION IN LUNG CANCER STUDIES

Study	n	Primary exposure (as described in study)	No. of deaths from lung cancer	*Cum(exp) (mg/m³-y)*				*Average* exposure (mg/m³)*				Mean respirable crystalline silica exposure over employment period (mg/m∧3)
				q¹	median (q²)	q³	max	25th (q¹)	median (q²)	75th (q³)	max	
U.S. diatomaceous earth workers [1] (Checkoway et al., 1997).	2,342	cristobalite	77	0.37	1.05	2.48	62.52	0.11	0.18	0.46	2.43	n/a
S. African gold miners [1] (Hnizdo and Sluis-cremer, 1991 & Hnizdo et al., 1997).	2,260	quartz and other silicates.	77	n/a	4.23	n/a	n/a	0.15	0.19	0.22	0.31	n/a
U.S. gold miners [1] (Steenland and Brown, 1995a).	3,328	silica dust	156	0.1	0.23	0.74	6.2	0.02	0.05	0.1	0.24	n/a
Australian gold miners [1] (de Klerk and Musk, 1998).	2,297	silica dust	135	6.52	11.37	17.31	50.22	0.25	0.43	0.65	1.55	n/a
U.S. granite workers (Costello and Graham, 1988).	5,414	silica dust from granite.	124	0.14	0.71	2.19	50	0.02	0.05	0.08	1.01	n/a
Finnish granite workers (Koskela et al., 1994).	1,026	quartz dust	38	0.84	4.63	15.42	100.98	0.39	0.59	1.29	3.6	n/a

TABLE VI–3—EXPOSURE DISTRIBUTION IN LUNG CANCER STUDIES—Continued

Study	n	Primary exposure (as described in study)	No. of deaths from lung cancer	*Cum(exp) (mg/m³-y)*				*Average* exposure (mg/m³)*				Mean respirable crystalline silica exposure over employment period (mg/m^3)
				q[1]	median (q[2])	q[3]	max	25th (q[1])	median (q[2])	75th (q[3])	max	
U.S. industrial sand workers [1] (Steenland et al., 2001b).	4,626	silica dust	85	0.03	0.13	5.2	8.265	0.02	0.04	0.06	0.4	n/a
North American industrial sand workers [1] (Hughes et al., 2001).	90	crystalline silica.	95	1.11	2.73	5.20	n/a	0.069	0.15	0.025	n/a	n/a
Ch. Tungsten (Chen et al., 1992).	28,442	silica dust	174	3.49	8.56	29.79	232.26	0.15	0.32	1.28	4.98	6.1
Ch. Pottery (Chen et al., 1992).	13,719	silica dust	81	3.89	6.07	9.44	63.15	0.18	0.22	0.34	2.1	11.4
Ch. Tin (Chen et al., 1992).	7,849	silica dust	119	2.79	5.27	5.29	83.09	0.12	0.19	0.49	1.95	7.7
British coal workers [1] (Miller and MacCalman, 2009).	17,820	quartz	973	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

[1] Study adjusted for effects smoking.
* Average exposure is cumulative exposure averaged over the entire exposure period.
n/a Data not available.

VII. Significance of Risk

A. Legal Requirements

To promulgate a standard that regulates workplace exposure to toxic materials or harmful physical agents, OSHA must first determine that the standard reduces a ''significant risk'' of ''material impairment.'' The first part of this requirement, ''significant risk,'' refers to the likelihood of harm, whereas the second part, ''material impairment,'' refers to the severity of the consequences of exposure.

The Agency's burden to establish significant risk derives from the OSH Act, 29 U.S.C. 651 et seq. Section 3(8) of the Act requires that workplace safety and health standards be ''reasonably necessary and appropriate to provide safe or healthful employment.'' 29 U.S.C. 652(8). The Supreme Court, in the ''benzene'' decision, stated that section 3(8) ''implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe.'' *Indus. Union Dep't, AFL–CIO* v. *Am.* Petroleum Inst., 448 U.S. 607, 642 (1980). Examining section 3(8) more closely, the Court described OSHA's obligation to demonstrate significant risk:

> ''[S]afe'' is not the equivalent of ''risk-free.'' A workplace can hardly be considered ''unsafe'' unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate *any* permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices.

Id. While clarifying OSHA's responsibilities, the Court emphasized the Agency's discretion in determining what constitutes significant risk, stating, ''[the Agency's] determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' *Benzene,* 448 U.S. at 655, n. 62. The Court explained that significant risk is not a ''mathematical straitjacket,'' and maintained that OSHA could meet its burden without ''wait[ing] for deaths to occur before taking any action.'' *Benzene,* 448 U.S. at 655.

Because section 6(b)(5) of the Act requires that the Agency base its findings on the ''best available evidence,'' a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.'' *Benzene,* 448 U.S. at 656. Thus, while OSHA's significant risk determination must be supported by substantial evidence, the Agency ''is not required to support the finding that a significant risk exists with anything approaching scientific certainty.'' *Id.* Furthermore, ''the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of over protection rather than under protection,'' so long as such assumptions are based in ''a body of reputable scientific thought.'' *Id.*

The Act also requires that the Agency make a finding that the toxic material or harmful physical agent at issue causes material impairment to workers' health. Section 6(b)(5) of the Act directs the Secretary of Labor to ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.'' 29 U.S.C. 655(b)(5). As with significant risk, what constitutes material impairment in any given case is a policy determination for which OSHA is given substantial leeway. ''OSHA is not required to state with scientific certainty or precision the exact point at which each type of [harm] becomes a material impairment.'' *AFL–CIO* v. *OSHA,* 965 F.2d 962, 975 (11th Cir. 1992). Courts have also noted that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm—and that OSHA may act with a ''pronounced bias towards worker safety.'' *Id; Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988).

It is the Agency's practice to estimate risk to workers by using quantitative risk assessment and determining the significance of that risk based on judicial guidance, the language of the OSH Act, and Agency policy considerations. Thus, using the best available evidence, OSHA identifies material health impairments associated with potentially hazardous occupational exposures, and, when possible, provides a quantitative assessment of exposed workers' risk of these impairments. The Agency then evaluates whether these risks are severe enough to warrant regulatory action and determines whether a new or revised rule will substantially reduce these risks.

In this case, OSHA has reviewed extensive toxicological, epidemiological, and experimental research pertaining to adverse health effects of occupational exposure to respirable crystalline silica, including silicosis, other non-malignant respiratory disease, lung cancer, and autoimmune and renal diseases. As a result of this review, the Agency has developed preliminary quantitative estimates of the excess risk of mortality and morbidity that is attributable to currently allowable respirable crystalline silica exposure concentrations. The Agency is proposing a new PEL of 0.05 mg/m^3 because exposures at and above this level present a significant risk to workers' health. Even though OSHA's preliminary risk assessment indicates that a significant risk exists at the proposed action level of 0.025 mg/m^3, the Agency is not proposing a PEL below the proposed 0.05 mg/m^3 limit because OSHA must also consider technological and economic feasibility in determining exposure limits. As explained in the Summary and Explanation for paragraph (c), Permissible Exposure Limit (PEL), OSHA has preliminary determined that the proposed PEL of 0.05 mg/m^3 is technologically and economically feasible, but that a lower PEL of 0.025 mg/m^3 is not technologically feasible. OSHA has preliminarily determined that long-term exposure at the current PEL presents a significant risk of material harm to workers' health, and that adoption of the proposed PEL will substantially reduce this risk to the extent feasible.

As discussed in Section V of this preamble (Health Effects Summary), inhalation exposure to respirable crystalline silica increases the risk of a variety of adverse health effects, including silicosis, chronic obstructive pulmonary disease (COPD), lung cancer, immunological effects, kidney disease, and infectious tuberculosis (TB). OSHA considers each of these conditions to be a material impairment of health. These diseases result in significant discomfort, permanent functional limitations including permanent disability or reduced ability to work, reduced quality of life, and decreased life expectancy. When these diseases coexist, as is common, the effects are particularly debilitating (Rice and Stayner, 1995; Rosenman et al., 1999). Based on these findings and on the scientific evidence that respirable crystalline silica substantially increases the risk of each of these conditions, OSHA preliminarily concludes that workers who are exposed to respirable crystalline silica at the current PEL are at significant risk of material impairment of health or functional capacity.

B. OSHA's Preliminary Findings

1. Material Impairments of Health

Section I of OSHA's Health Effects Literature Review and Preliminary Quantitative Risk Assessment (available in Docket OSHA–2010–0034) describes in detail the adverse health conditions that workers who are exposed to respirable crystalline silica are at risk of developing. The Agency's findings are summarized in Section V of this preamble (Health Effects Summary). The adverse health effects discussed include lung cancer, silicosis, other non-malignant respiratory disease (NMRD), and immunological and renal effects.

a. Silicosis

Silicosis refers to a spectrum of lung diseases attributable to the inhalation of respirable crystalline silica. As described in Section V (Health Effects Summary), the three types of silicosis are acute, accelerated, and chronic. Acute silicosis can occur within a few weeks to months after inhalation exposure to extremely high levels of respirable crystalline silica. Death from acute silicosis can occur within months to a few years of disease onset, with the exposed person drowning in their own lung fluid (NIOSH, 1996). Accelerated silicosis results from exposure to high levels of airborne respirable crystalline silica, and disease usually occurs within 5 to 10 years of initial exposure (NIOSH, 1996). Both acute and accelerated silicosis are associated with exposures that are substantially above the current general industry PEL, although precise information on the relationships between exposure and occurrence of disease are not available.

Chronic silicosis is the most common form of silicosis seen today, and is a progressive and irreversible condition characterized as a diffuse nodular pulmonary fibrosis (NIOSH, 1996). Chronic silicosis generally occurs after 10 years or more of inhalation exposure to respirable crystalline silica at levels below those associated with acute and accelerated silicosis. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction caused by the development of fibrotic scarring in the alveolar sacs and the ends of the lung tissue. The scarring can be detected in chest x-ray films when the lesions become large enough to appear as visible opacities. The result is restriction of lung volumes and decreased pulmonary compliance with concomitant reduced gas transfer (Balaan and Banks, 1992). Chronic silicosis is characterized by small, rounded opacities that are symmetrically distributed in the upper lung zones on chest radiograph.

The diagnosis of silicosis is based on a history of exposure to respirable crystalline silica, chest radiograph findings, and the exclusion of other conditions, including tuberculosis (TB). Because workers affected by early stages of chronic silicosis are often asymptomatic, the finding of opacities in the lung is key to detecting silicosis and characterizing its severity. The International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses (ILO, 1980, 2002, 2011) is the currently accepted standard against which chest radiographs are evaluated in epidemiologic studies, for medical surveillance, and for clinical evaluation. The ILO system standardizes the description of chest x-rays, and is based on a 12-step scale of severity and extent of silicosis as evidenced by the size, shape, and density of opacities seen on the x-ray film. Profusion (frequency) of small opacities is classified on a 4-point major category scale (0–3), with each major category divided into three, giving a 12-point scale between 0/− and 3/+. Large opacities are defined as any opacity greater than 1 cm that is present in a film.

The small rounded opacities seen in early stage chronic silicosis (*i.e.,* ILO major category 1 profusion) may progress (through ILO major categories 2 and/or 3) and develop into large fibrotic masses that destroy the lung architecture, resulting in progressive massive fibrosis (PMF). This stage of advanced silicosis is usually characterized by impaired pulmonary function, disability, and premature death. In cases involving PMF, death is commonly attributable to progressive respiratory insufficiency (Balaan and Banks, 1992).

The appearance of ILO category 2 or 3 background profusion of small opacities has been shown to increase the risk of developing large opacities characteristic of PMF. In one study of silicosis patients in Hong Kong, Ng and Chan (1991) found the risk of PMF increased by 42 and 64 percent among patients whose chest x-ray films were classified as ILO major category 2 or 3, respectively. Research has shown that people with silicosis advanced beyond ILO major category 1 have reduced median survival times compared to the general population (Infante-Rivard et al., 1991; Ng et al., 1992a; Westerholm, 1980).

Silicosis is the oldest known occupational lung disease and is still today the cause of significant premature mortality. In 2005, there were 161 deaths in the U.S. where silicosis was recorded as an underlying or contributing cause of death on a death certificate (NIOSH, 2008c). Between 1996 and 2005, deaths attributed to silicosis resulted in an average of 11.6 years of life lost by affected workers (NIOSH, 2007). In addition, exposure to respirable crystalline silica remains an important cause of morbidity and hospitalizations. State-based hospital discharge data show that in the year 2000, 1,128 silicosis-related hospitalizations occurred, indicating that silicosis continues to be a significant health issue in the U.S. (CSTE, 2005). Although there is no national silicosis disease surveillance system in the U.S., a published analysis of state-based surveillance data from the time period 1987–1996 estimated that between 3,600–7,000 new cases of silicosis occurred in the U.S. each year (Rosenman et al., 2003). It has been widely reported that available statistics on silicosis-related mortality and morbidity are likely to be understated due to misclassification of causes of death (for example, as tuberculosis, chronic bronchitis, emphysema, or cor pulmonale), errors in recording occupation on death certificates, or misdiagnosis of disease by health care providers (Goodwin, 2003; Windau et al., 1991; Rosenman et al., 2003). Furthermore, reliance on chest x-ray findings may miss cases of silicosis because fibrotic changes in the lung may not be visible on chest radiograph; thus, silicosis may be present absent x-ray signs or may be more severe than indicated by x-ray (Hnizdo et al., 1993; Craighead and Vallyathan, 1980; Rosenman et al., 1997).

Although most workers with early-stage silicosis (ILO categories 0/1 or 1/0) typically do not experience respiratory symptoms, the primary risk to the affected worker is progression of disease with progressive decline of lung function. Several studies of workers exposed to crystalline silica have shown that, once silicosis is detected by x-ray, a substantial proportion of affected workers can progress beyond ILO category 1 silicosis, even after exposure has ceased (for example, Hughes et al., 1982; Hessel et al., 1988; Miller et al., 1998; Ng et al., 1987a; Yang et al., 2006). In a population of coal miners whose last chest x-ray while employed was classified as major category 0, and who were examined again 10 years after the mine had closed, 20 percent had developed opacities consistent with a classification of at least 1/0, and 4 percent progressed further to at least 2/1 (Miller et al., 1998). Although there were periods of extremely high exposure to respirable quartz in the mine (greater than 2 mg/m^3 in some jobs between 1972 and 1976, and more than 10 percent of exposures between 1969 and 1977 were greater than 1 mg/m^3), the mean cumulative exposure for the cohort over the period 1964–1978 was 1.8 mg/m^3-years, corresponding to an average silica concentration of 0.12 mg/m^3. In a population of granite quarry workers exposed to an average respirable silica concentration of 0.48 mg/m^3 (mean length of employment was 23.4 years), 45 percent of those diagnosed with simple silicosis showed radiological progression of disease after 2 to 10 years of follow up (Ng et al., 1987a). Among a population of gold miners, 92 percent progressed in 14 years; exposures of high-, medium-, and low-exposure groups were 0.97, 0.45, and 0.24 mg/m^3, respectively (Hessel et al., 1988). Chinese mine and factory workers categorized under the Chinese system of x-ray classification as ''suspected'' silicosis cases (analogous to ILO 0/1) had a progression rate to stage I (analogous to ILO major category 1) of 48.7 percent and the average interval was about 5.1 years (Yang et al., 2006). These and other studies discussed in the Health Effects section are of populations of workers exposed to average concentrations of respirable crystalline silica above those permitted by OSHA's current general industry PEL. The studies, however, are of interest to OSHA because the Agency's current enforcement data indicate that exposures in this range are still common in some industry sectors. Furthermore, the Agency's preliminary risk assessment is based on use of an exposure metric that is less influenced by exposure pattern and, instead, characterizes the accumulated exposure of workers over time. Further, the use of a cumulative exposure metric reflects the progression of silica-related diseases: While it is not known that silicosis is a precursor to lung cancer, continued exposure to respirable crystalline silica among workers with silicosis has been shown to be associated with malignant respiratory disease (Chen et al., 1992). The Chinese pottery workers study offers an example of silicosis-associated lung cancer among workers in the clay industry, reflecting the variety of health outcomes associated with diverse silica exposures across industrial settings.

The risk of silicosis, and particularly its progression, carries with it an increased risk of reduced lung function. There is strong evidence in the literature for the finding that lung function deteriorates more rapidly in workers exposed to silica, especially those with silicosis, than what is expected from a normal aging process (Cowie 1998; Hughes et al., 1982; Malmberg et al., 1993; Ng and Chan, 1992). The rates of decline in lung function are greater in those whose disease showed evidence of radiologic progression (Bégin et al., 1987a; Cowie 1998; Ng and Chan, 1992; Ng et al., 1987a). Additionally, the average deterioration of lung function exceeds that in smokers (Hughes et al., 1982).

Several studies have reported no decrease in pulmonary function with an ILO category 1 level of profusion of small opacities but found declines in pulmonary function with categories 2 and 3 (Ng et al., 1987a; Begin et al., 1988; Moore et al., 1988). A study by Cowie (1998), however, found a statistically significantly greater annual loss in FVC and FEV_1 among those with category 1 profusion compared to category 0. In another study, Cowie and Mabena (1991) found that the degree of profusion of opacities was associated with reductions in several pulmonary function metrics. Still, other studies have reported no associations between radiographic silicosis and decreases in pulmonary function (Ng et al., 1987a; Wiles et al., 1992; Hnizdo, 1992), with some studies (Ng et al., 1987a; Wang et al., 1997) finding that measurable changes in pulmonary function are evident well before the changes seen on chest x-ray. This may reflect the general insensitivity of chest radiography in detecting lung fibrosis, and/or may reflect that exposure to respirable silica has also been shown to increase the risk of chronic obstructive pulmonary disease (COPD) (*see* Section V, Health Effects Summary).

Finally, silicosis, and exposure to respirable crystalline silica in and of itself, increases the risk that latent tuberculosis infection can convert to active disease. Early descriptions of dust diseases of the lung did not distinguish between TB and silicosis, and most fatal cases described in the first half of this century were a combination of silicosis and TB (Castranova et al., 1996). More recent findings demonstrate that exposure to silica, even without silicosis, increases the risk of infectious (*i.e.,* active) pulmonary TB (Sherson et al., 1990; Cowie, 1994; Hnizdo and Murray, 1998; WaterNaude et al., 2006). Both conditions together can hasten the development of respiratory impairment and increase mortality risk even beyond that experienced by unexposed persons with active TB (Banks, 2005).

Based on the information presented above and in its review of the health literature, OSHA preliminarily concludes that silicosis remains a significant cause of early mortality and of serious morbidity, despite the existence of an enforceable exposure limit over the past 40 years. Silicosis in its later stages of progression (*i.e.,* with chest x-ray findings of ILO category 2 or 3 profusion of small opacities, or the presence of large opacities) is characterized by the likely appearance of respiratory symptoms and decreased pulmonary function, as well as increased risk of progression to PMF, disability, and early mortality. Early-stage silicosis, although without symptoms among many who are affected, nevertheless reflects the formation of fibrotic lesions in the lung and increases the risk of progression to later stages, even after exposure to respirable crystalline silica ceases. In addition, the presence of silicosis increases the risk of pulmonary infections, including conversion of latent TB infection to active TB. Silicosis is not a reversible condition and there is no specific treatment for the disease, other than administration of drugs to alleviate inflammation and maintain open airways, or administration of oxygen therapy in severe cases. Based on these considerations, OSHA preliminarily finds that silicosis of any form, and at any stage, is a material impairment of health and that fibrotic scarring of the lungs represents loss of functional respiratory capacity.

b. Lung Cancer

OSHA considers lung cancer, an irreversible and usually fatal disease, to be a clear material impairment of health. According to the National Cancer Institute (Horner et al., 2009), the five-year survival rate for all forms of lung cancer is only 15.6 percent, a rate that has not improved in nearly two decades. OSHA's preliminary finding that respirable crystalline silica exposure substantially increases the risk of lung cancer mortality is based on the best available toxicological and epidemiological data, reflects substantial supportive evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations, including the International Agency for Research on Cancer (IARC, 1997), the National Toxicology Program (NTP, 2000), the National Institute for Occupational Safety and Health (NIOSH, 2002), the American Thoracic Society (1997), and the American Conference of Governmental Industrial Hygienists (ACGIH, 2001). The Agency's primary evidence comes from evaluation of more than 50 studies of occupational cohorts from many different industry sectors in which exposure to respirable crystalline silica occurs, including granite and stone quarrying; the refractory brick industry; gold, tin, and tungsten mining; the diatomaceous earth industry; the industrial sand industry; and construction. Studies key to OSHA's risk assessment are outlined in Table VII–1, which summarizes exposure characterization and related lung cancer risk across several different industries. In addition, the association between exposure to respirable crystalline silica and lung cancer risk was reported in a national mortality surveillance study (Calvert et al., 2003) and in two community-based studies (Pukkala et al., 2005; Cassidy et al., 2007), as well as in a pooled analysis of 10 occupational cohort studies (Steenland et al., 2001a).

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
U.S. Diatomaceous earth workers.	Cohort study. Same as Checkoway et al., 1993, excluding 317 workers whose exposures could not be characterized, and including 89 workers with asbestos exposure who were previously excluded from the 1993 study. Follow up through 1994.	Assessment based on almost 6,400 samples taken from 1948–1988; about 57 percent of samples represented particle counts, 17 percent were personal respirable dust samples. JEM included 135 jobs over 4 time periods (Seixas et al., 1997).	77	SMR 129 (CI 101–161) based on national rates, and SMR 144 (CI 114–180) based on local rates. Risk ratios by exposure quintile were 1.00, 0.96, 0.77, 1.26, and 2.15, with the latter being stat. sig. RR= 2.15 and 1.67.	Smoking history available for half cohort. Under worst-case assumptions, the risk ratio for the high-exposure group would be reduced to 1.67 after accounting for smoking.	Checkoway et al., 1997.
South African gold miners.	Cohort study. N=2,209 white male miners employed between 1936 and 1943. Followed from 1968–1986.	Particle count data from Beadle (1971).	77	RR 1.023 (CI 1.005–1.042) per 1,000 particle-years of exposure based on Cox proportional hazards model.	Model adjusted for smoking and year of birth. Lung cancer was associated with silicosis of the hilar glands not silicosis of lung or pleura. Possible confounding by radon exposure among miners with 20 or more years experience.	Hnizdo and Sluis-Cremer, 1991.

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES—Continued

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
South African gold miners.	Nested case-control study from population study by Hnizdo and Sluis-Cremer,1991. N=78 cases, 386 controls.	Particle count data converted to respirable dust mass (Beadle and Bradley, 1970, and Page-Shipp and Harris, 1972).	78	RR 2.45 (CI 1.2–5.2) when silicosis was included in model.	Lung cancer mortality associated with smoking, cumulative dust exposure, and duration of underground work. Latter two factors were most significantly associated with lung cancer with exposure lagged 20 years.	Hnizdo et al., 1997.
US gold miners.	Cohort and nested case-control study, same population as Brown et al. (1986); workers with at least 1 year underground work between 1940 and 1965. Follow up through 1990.	Particle count data, conversion to mass concentration based on Vt. Granite study, construction of JEM. Median quartz exposures were 0.15, 0.07, and 0.02 mg/m³ prior to 1930, from 1930–1950, and after 1950 respectively.	115	SMR 113 (CI 94–136) overall. SMRs increased for workers with 30 or more years of latency, and when local cancer rates used as referents. Case-control study showed no relationship of risk to cumulative exposure to dust.	Smoking data available for part of cohort, habits comparable to general US population; attributable smoking-related cancer risk estimated to be 1.07.	Steenland and Brown, 1995a, 1995b
Australian gold miners.	Cohort and nested case-control study. N=2,297, follow up of Armstrong et al. (1979). Follow up through 1993.	Expert ranking of dustiness by job.	Nested case control of 138 lung cancer deaths.	SMR 126 (CI 107–159) lower bound; SMR 149 (CI 126–176) upper bound. From case-control, RR 1.31 (CI 1.10–1.7) per unit exposure score.	Association between exposure and lung cancer mortality not stat. sig. after adjusting for smoking, bronchitis, and silicosis. Authors concluded lung cancer restricted to miners who received compensation for silicosis..	de Klerk and Musk, 1998
U.S. (Vermont) granite shed and quarry workers –.	Cohort study. N=5,414 employed at least 1 year between 1950 and 1982.	Exposure data not used in analysis.	53 deaths among those hired before 1930; 43 deaths among those hired after 1940.	SMR 129 for pre-1930 hires (not stat. sig.); SMR 95 for post-1940 hires (not stat. sig). SMR 181 (stat. sig) for shed workers hired before 1930 and with long tenure and latency.	Dust controls employed between 1938 and 1940 with continuing improvement afterwards.	Costello and Graham, 1988.
Finnish granite workers.	Cohort and nested case-control studies. N=1,026, follow up from 1972–1981, extended to 1985 (Koskella et al., 1990) and 1989 (Koskella et al., 1994).	Personal sampling data collected from 1970–1972 included total and respirable dust and respirable silica sampling. Average silica concentrations ranged form 0.3–4.9 mg/m³.	31 through 1989	Through 1989, SMR 140 (CI 98–193). For workers in two regions where silica content of rock was highest, SMRs were 126 (CI 71–208) and 211 (CI 120–342), respectively.	Smoking habits similar to other Finnish occupational groups. Minimal work-related exposures to other carcinogens.	Koskela et al., 1987, 1990, 1994.
North American industrial sand workers.	Case-control study from McDonald et al. (2001) cohort.	Assessment based on 14,249 respirable dust and silica samples taken from 1974 to 1998. Exposures prior to this based on particle count data. Adjustments made for respirator use (Rando et al., 2001).	95 cases, two controls per case.	OR 1.00, 0.84, 2.02 and 2.07 for increasing quartiles of exposure p for trend=0.04).	Adjusted for smoking. Positive association between silica exposure and lung cancer. Median exposure for cases and controls were 0.148 and 0.110 mg/m³ respirable silica, respectively.	Hughes et al., 2001.

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES—Continued

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
U.S. industrial sand workers.	Cohort and nested case-control study. N=4,626 workers. Follow up from 1960–1996.	Exposure assessment based on 4,269 compliance dust samples taken from 1974–1996 and analyzed for respirable quartz. Exposures prior to 1974 based on particle count data and quartz analysis of settled dust and dust collected by high-volume air samplers, and use of a conversion factor (1 mppcf=0.1 mg/m³).	109 deaths overall	SMR 160 (CI 131–193) overall. Positive trends seen with cumulative silica exposure (p=0.04 for unlagged, p=0.08 for lagged).	Smoking data from 358 workers suggested that smoking could not explain the observed increase in lung cancer mortality rates.	Steenland and Sanderson, 2001.
Chinese Tin, Tungsten, and Copper miners.	Cohort study. N=54,522 workers employed 1 yr. or more between 1972 and 1974. Follow up through 1989.	Measurements for total dust, quartz content, and particle size taken from 1950's-1980's. Exposures categorized as high, medium, low, or non-exposed.	....	SMRs 198 for tin workers (no CI reported but stat. sig.). No stat. sig. increased SMR for tungsten or copper miners.	Non-statistically significantly increased risk ratio for lung cancer among silicotics. No increased gradient in risk observed with exposure.	Chen et al., 1992.
Chinese Pottery workers.	Cohort study. N=13,719 workers employed in 1972–1974. Follow up through 1989.	Measurements of job-specific total dust and quartz content of settled dust used to classify workers into one of four total dust exposure groups.	....	SMR 58 (p<0.05) overall. RR 1.63 (CI 0.8–3.4) among silicotics compared to non-silicotics.	No reported increase in lung cancer with increasing exposure.	Chen et al., 1992.
British Coal workers.	Cohort study. N=17,820 miners from 10 collieries..	Quartz exposure assessed from personal respirable dust samples.	973	Significant relationship between cumulative silica exposure (lagged 15 years) and lung cancer mortality VIA Cox regression.	Adjusted for smoking ..	Miller et al, 2007; Miller and MacCalman, 2009

Toxicity studies provide additional evidence of the carcinogenic potential of crystalline silica (Health Effects Summary, Section V). Acellular studies using DNA exposed directly to freshly fractured crystalline silica demonstrate the direct effect silica has on DNA breakage. Cell culture research has investigated the processes by which crystalline silica disrupts normal gene expression and replication (Section V). Studies demonstrate that chronic inflammatory and fibrotic processes resulting in oxidative and cellular damage set up another possible mechanism that leads to neoplastic changes in the lung (Goldsmith, 1997; *see also* Health Effects discussion in Section V). In addition, the biologically damaging physical characteristics of crystalline silica, and the direct and indirect genotoxicity of crystalline silica (Schins, 2002; Borm and Driscoll, 1996), support the Agency's preliminary position that respirable crystalline silica should be considered as an occupational carcinogen that causes lung cancer, a clear material impairment of health.

c. Non-Malignant Respiratory Disease (Other Than Silicosis)

Exposure to respirable crystalline silica increases the risk of developing chronic obstructive pulmonary disease (COPD), in particular chronic bronchitis and emphysema. COPD results in loss of pulmonary function that restricts normal activity in individuals afflicted with these conditions (ATS, 2003). Both chronic bronchitis and emphysema can occur in conjunction with development of silicosis. Several studies have documented increased prevalence of chronic bronchitis and emphysema among silica-exposed workers even absent evidence of silicosis (*see* Section I of the Health Effects Literature Review and Preliminary Quantitative Risk Assessment; NIOSH, 2002; ATS, 1997). There is evidence that smoking may have an additive or synergistic effect on silica-related COPD morbidity or mortality (Hnizdo, 1990; Hnizdo et al., 1990; Wyndham et al., 1986; NIOSH, 2002). In a study of diatomaceous earth workers, Park et al. (2002) found a positive exposure-response relationship between exposure to respirable cristobalite and increased mortality from non-malignant respiratory disease.

Decrements in pulmonary function have often been found among workers exposed to respirable crystalline silica absent radiologic evidence of silicosis. Several cross-sectional studies have reported such findings among granite workers (Theriault, 1974a, 1974b; Ng et al., 1992b; Montes et al., 2004b), South African gold miners (Irwig and Rocks, 1978; Hnizdo et al., 1990; Cowie and Mabena, 1991), gemstone cutters (Ng et al., 1987b), concrete workers (Meijer et al., 2001), refractory brick workers (Wang et al., 1997), hard rock miners (Manfreda et al., 1982; Kreiss et al., 1989), pottery workers (Neukirch et al., 1994), slate workers (Suhr et al., 2003), and potato sorters (Jorna et al., 1994).

OSHA also evaluated several longitudinal studies where exposed workers were examined over a period of time to track changes in pulmonary function. Among both active and retired Vermont granite workers exposed to an average of 60 μg/m³, Graham did not find exposure-related decrements in pulmonary function (Graham et al., 1981, 1994). However, Eisen et al.

(1995) did find significant pulmonary decrements among a subset of granite workers (termed ''dropouts'') who left work and consequently did not voluntarily participate in the last of a series of annual pulmonary function tests. This group of workers experienced steeper declines in FEV_1 compared to the subset of workers who remained at work and participated in all tests (termed ''survivors''), and these declines were significantly related to dust exposure. Thus, in this study, workers who had left work had exposure-related declines in pulmonary function to a greater extent than did workers who remained on the job, clearly demonstrating a survivor effect among the active workers. Exposure-related changes in lung function were also reported in a 12-year study of granite workers (Malmberg et al., 1993), in two 5-year studies of South African miners (Hnizdo, 1992; Cowie, 1998), and in a study of foundry workers whose lung function was assessed between 1978 and 1992 (Hertzberg et al., 2002).

Each of these studies reported their findings in terms of rates of decline in any of several pulmonary function measures, such as FVC, FEV_1, and FEV_1/FVC. To put these declines in perspective, Eisen et al. (1995), reported that the rate of decline in FEV_1 seen among the dropout subgroup of Vermont granite workers was 4 ml per mg/m^3-year of exposure to respirable granite dust; by comparison, FEV_1 declines at a rate of 10 ml/year from smoking one pack of cigarettes daily. From their study of foundry workers, Hertzberg et al., (2002) reported finding a 1.1 ml/year decline in FEV_1 and a 1.6 ml/year decline in FVC for each mg/m^3-year of respirable silica exposure after controlling for ethnicity and smoking. From these rates of decline, they estimated that exposure to the current OSHA quartz standard of 0.1 mg/m^3 for 40 years would result in a total loss of FEV_1 and FVC that is less than but still comparable to smoking a pack of cigarettes daily for 40 years. Hertzberg et al. (2002) also estimated that exposure to the current standard for 40 years would increase the risk of developing abnormal FEV_1 or FVC by factors of 1.68 and 1.42, respectively. OSHA believes that this magnitude of reduced pulmonary function, as well as the increased morbidity and mortality from non-malignant respiratory disease that has been documented in the studies summarized above, constitute material impairments of health and loss of functional respiratory capacity.

d. Renal and Autoimmune Effects

OSHA's review of the literature summarized in Section V, Health Effects Summary, reflects substantial evidence that exposure to crystalline silica increases the risk of renal and autoimmune diseases. Epidemiologic studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (*e.g.,* Calvert et al., 1997), subclinical renal changes including proteinurea and elevated serum creatinine (*e.g.,* Ng et al., 1992c; Rosenman et al., 2000; Hotz et al., 1995), end-stage renal disease morbidity (*e.g.,* Steenland et al., 1990), chronic renal disease mortality (Steenland et al., 2001b, 2002a), and Wegener's granulomatosis (Nuyts et al., 1995), the latter of which represents severe injury to the glomeruli that, if untreated, rapidly leads to renal failure. Possible mechanisms suggested for silica-induced renal disease include a direct toxic effect on the kidney, deposition in the kidney of immune complexes (IgA) following silica-related pulmonary inflammation, or an autoimmune mechanism (Calvert et al., 1997; Gregorini et al., 1993). Steenland et al. (2002a) demonstrated a positive exposure-response relationship between exposure to respirable crystalline silica and end-stage renal disease mortality.

In addition, there are a number of studies that show exposure to be related to increased risks of autoimmune disease, including scleroderma (*e.g.,* Sluis-Cremer et al., 1985), rheumatoid arthritis (*e.g.* Klockars et al., 1987; Rosenman and Zhu, 1995), and systemic lupus erythematosus (*e.g.,* Brown et al., 1997). Scleroderma is a degenerative disorder that leads to over-production of collagen in connective tissue that can cause a wide variety of symptoms including skin discoloration and ulceration, joint pain, swelling and discomfort in the extremities, breathing problems, and digestive problems. Rheumatoid arthritis is characterized by joint pain and tenderness, fatigue, fever, and weight loss. Systemic lupus erythematosus is a chronic disease of connective tissue that can present a wide range of symptoms including skin rash, fever, malaise, joint pain, and, in many cases, anemia and iron deficiency. OSHA believes that chronic renal disease, end-stage renal disease mortality, Wegener's granulomatosis, scleroderma, rheumatoid arthritis, and systemic lupus erythematosus clearly represent material impairments of health.

2. Significance of Risk

To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on toxicological, epidemiological, and experimental data, as well as statistical methods. The Agency uses these data and methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime at levels of exposure reflecting both compliance with current standards and compliance with the new standard being proposed. In the case of crystalline silica, the current general industry, construction, and shipyard PELs are formulas that limit 8-hour TWA exposures to respirable dust; the limit on exposure decreases with increasing crystalline silica content of the dust. OSHA's current general industry PEL for respirable quartz is expressed both in terms of a particle count as well as a gravimetric concentration, while the current construction and shipyard employment PELs for respirable quartz are only expressed in terms of a particle count formula. For general industry, the gravimetric formula PEL for quartz approaches 0.1 mg/m^3 (100 μg/m^3) of respirable crystalline silica when the quartz content of the dust is about 10 percent or greater. For the construction and shipyard industries, the current PEL is a formula that is based on concentration of respirable particles in the air; on a mass concentration basis, it is believed by OSHA to lie within a range of between about 0.25 mg/m^3 (250 μg/m^3) to 0.5 mg/m^3 (500 μg/m^3) expressed as respirable quartz (*see* Section VI). In general industry, the current PELs for cristobalite and tridymite are one-half the PEL for quartz.

OSHA is proposing to revise the current PELs for general industry, construction, and shipyards to 0.05 mg/m^3 (50 μg/m^3) of respirable crystalline silica. OSHA is also proposing an action level of 0.025 mg/m^3 (25 μg/m^3). In the Summary of the Preliminary Quantitative Risk Assessment (Section VI of the preamble), OSHA presents estimates of health risks associated with 45 years of exposure to 0.025, 0.05, and 0.1 mg/m^3 respirable crystalline silica to represent the risks associated with exposure over a working lifetime to the proposed action level, proposed PEL, and current general industry PEL, respectively. OSHA also presents estimates associated with exposure to 0.25 and 0.5 mg/m^3 to represent a range of risks likely to be associated with exposure to the current construction and shipyard PELs. Risk estimates are presented for mortality due to lung cancer, silicosis and other non-malignant lung disease, and end-stage renal disease, as well as silicosis morbidity. The preliminary findings from this assessment are summarized below.

a. Summary of Excess Risk Estimates for Excess Lung Cancer Mortality

For preliminary estimates of lung cancer risk from crystalline silica exposure, OSHA has relied upon studies of exposure-response relationships presented in a pooled analysis of 10 cohort studies (Steenland, et al. 2001a; Toxichemica, Inc., 2004) as well as on individual studies of granite (Attfield and Costello, 2004), diatomaceous earth (Rice et al., 2001), and industrial sand (Hughes et al., 2001) worker cohorts, and a study of coal miners exposed to respirable quartz (Miller et al., 2007; Miller and MacCalman, 2009). OSHA believes these studies are suitable for use to quantitatively characterize health risks to exposed workers because (1) study populations were of sufficient size to provide adequate power to detect low levels of risk, (2) sufficient quantitative exposure data were available to characterize cumulative exposures of cohort members to respirable crystalline silica, (3) the studies either adjusted for or otherwise adequately addressed confounding factors such as smoking and exposure to other carcinogens, and (4) investigators developed quantitative assessments of exposure-response relationships using appropriate statistical models or otherwise provided sufficient information that permits OSHA to do so. Where investigators estimated excess lung cancer risks associated with exposure to the current PEL or NIOSH recommended exposure limit, OSHA provided these estimates in its Preliminary Quantitative Risk Assessment. However, OSHA implemented all risk models in its own life table analysis so that the use of background lung cancer rates and assumptions regarding length of exposure and lifetime were constant across each of the models, and so OSHA could estimate lung cancer risks associated with exposure to specific levels of silica of interest to the Agency.

The Steenland et al. (2001a) study consisted of a pooled exposure-response analysis and risk assessment based on raw data obtained for ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths). The cohorts in this pooled analysis include U.S. gold miners (Steenland and Brown, 1995a), U.S. diatomaceous earth workers (Checkoway et al., 1997), Australian gold miners (deKlerk and Musk, 1998), Finnish granite workers (Koskela et al., 1994), South African gold miners (Hnizdo et al., 1997), U.S. industrial sand employees (Steenland et al., 2001b), Vermont granite workers (Costello and Graham, 1988), and Chinese pottery workers, tin miners, and tungsten miners (Chen et al., 1992). The investigators used a nested case-control design with cases and controls matched for race, sex, age (within five years) and study; 100 controls were matched for each case. An extensive exposure assessment for this pooled analysis was developed and published by Mannetje et al. (2002a). Exposure measurement data were available for all 10 cohorts and included measurements of particle counts, total dust mass, respirable dust mass, and, for one cohort, respirable quartz. Cohort-specific conversion factors were used to estimate cumulative exposures to respirable crystalline silica. A case-control analysis of silicosis mortality (Mannetje et al., 2002b) showed a strong positive exposure-response trend, indicating that cumulative exposure estimates for the cohorts were not subject to random misclassification errors of such a magnitude so as to obscure observing an exposure-response relationship between silica and silicosis despite the variety of dust measurement metrics relied upon and the need to make assumptions to convert the data to a single exposure metric (*i.e.,* mass concentration of respirable crystalline silica). In effect, the known relationship between exposure to respirable silica and silicosis served as a positive control to assess the validity of exposure estimates. Quantitative assessment of lung cancer risks were based on use of a log-linear model (log RR = βx, where x represents the exposure variable and β the coefficient to be estimated) with a 15-year exposure lag providing the best fit. Models based on untransformed or log-transformed cumulative dose metrics provided an acceptable fit to the pooled data, with the model using untransformed cumulative dose providing a slightly better fit. However, there was substantial heterogeneity among the exposure-response coefficients derived from the individual cohorts when untransformed cumulative dose was used, which could result in one or a few of the cohorts unduly influencing the pooled exposure-response coefficient. For this reason, the authors preferred the use of log-transformed cumulative exposure in the model to derive the pooled coefficient since heterogeneity was substantially reduced.

OSHA's implementation of this model is based on a re-analysis conducted by Steenland and Bartow (Toxichemica, 2004), which corrected small errors in the assignment of exposure estimates in the original analysis. In addition, subsequent to the Toxichemica report, and in response to suggestions made by external peer reviewers, Steenland and Bartow conducted additional analyses based on use of a linear relative risk model having the general form RR = 1 + βx, as well as a categorical analysis (personal communication, Steenland 2010). The linear model was implemented with both untransformed and log-transformed cumulative exposure metrics, and was also implemented as a 2-piece spline model.

The categorical analysis indicates that, for the pooled data set, lung cancer relative risks increase steeply at low exposures, after which the rate of increase in relative risk declines and the exposure-response curve becomes flat (*see* Figure II–2 of the Preliminary Quantitative Risk Assessment). Use of either the linear relative risk or log-linear relative risk model with untransformed cumulative exposure (with or without a 15-year lag) failed to capture this initial steep slope, resulting in an underestimate of the relative risk compared to that suggested by the categorical analysis. In contrast, use of log-transformed cumulative exposure with the linear or log-linear model, and use of the 2-piece linear spline model with untransformed exposure, better reflected the initial rise and subsequent leveling out of the exposure-response curve, with the spline model fitting somewhat better than either the linear or log-linear models (all models incorporated a 15-year exposure lag). Of the three models that best reflect the shape of the underlying exposure-response curve suggested by the categorical analysis, there is no clear rationale to prefer one over the other. Use of log-transformed cumulative exposure in either the linear or log-linear models has the advantage of reducing heterogeneity among the 10 pooled studies, lessening the likelihood that the pooled coefficient would be overtly influenced by outliers; however, use of a log-transformed exposure metric complicates comparing results with those from other risk analyses considered by OSHA that are based on untransformed exposure metrics. Since all three of these models yield comparable estimates of risk the choice of model is not critical for the purpose of assessing significance of the risk, and therefore OSHA believes that the risk estimates derived from the pooled study are best represented as a range of estimates based on all three of these models.

From these models, the estimated lung cancer risk associated with 45 years of exposure to 0.1 mg/m^3 (about equal to the current general industry PEL) is between 22 and 29 deaths per 1,000 workers. The estimated risk associated with exposure to silica concentrations in the range of 0.25 and 0.5 mg/m^3 (about equal to the current construction and shipyard PELs) is between 27 and 38 deaths per 1,000. At the proposed PEL of 0.05 mg/m^3, the estimated excess risk ranges from 18 to 26 deaths per 1,000, and, at the proposed action level of 0.025 mg/m^3, from 9 to 23 deaths per 1,000.

As previously discussed, the exposure-response coefficients derived from each of the 10 cohorts exhibited significant heterogeneity; risk estimates based on the coefficients derived from the individual studies for untransformed cumulative exposure varied by almost two orders of magnitude, with estimated risks associated with exposure over a working lifetime to the current general industry PEL ranging from a low of 0.8 deaths per 1,000 (from the Chinese pottery worker study) to a high of 69 deaths per 1,000 (from the South African miner study). It is possible that the differences seen in the slopes of the exposure-response relationships reflect physical differences in the nature of crystalline silica particles generated in these workplaces and/or the presence of different substances on the crystal surfaces that could mitigate or enhance their toxicity (*see* Section V, Health Effects Summary). It may also be that exposure estimates for some cohorts were subject to systematic misclassification errors resulting in under- or over-estimation of exposures due to the use of assumptions and conversion factors that were necessary to estimate mass respirable crystalline silica concentrations from exposure samples analyzed as particle counts or total and respirable dust mass. OSHA believes that, given the wide range of risk estimates derived from these 10 studies, use of log-transformed cumulative exposure or the 2-piece spline model is a reasonable approach for deriving a single summary statistic that represents the lung cancer risk across the range of workplaces and exposure conditions represented by the studies. However, use of these approaches results in a non-linear exposure-response and suggests that the relative risk of silica-related lung cancer begins to attenuate at cumulative exposures in the range of those represented by the current PELs. Although such exposure-response relationships have been described for some carcinogens (for example, from metabolic saturation or a healthy worker survivor effect, *see* Staynor et al., 2003), OSHA is not aware of any specific evidence that would suggest that such a result is biologically plausible for silica, except perhaps the possibility that lung cancer risks increase more slowly with increasing exposure because of competing risks from other silica-related diseases. Attenuation of the exposure-response can also result from misclassification of exposure estimates for the more highly-exposed cohort members (Staynor et al., 2003). OSHA's evaluation of individual cohort studies discussed below indicates that, with the exception of the Vermont granite cohort, attenuation of exposure-related lung cancer response has not been directly observed.

In addition to the pooled cohort study, OSHA's Preliminary Quantitative Risk Assessment presents risk estimates derived from four individual studies where investigators presented either lung cancer risk estimates or exposure-response coefficients. Two of these studies, one on diatomaceous earth workers (Rice et al., 2001) and one on Vermont granite workers (Attfield and Costello, 2004), were included in the 10-cohort pooled study (Steenland et al., 2001a; Toxichemica, 2004). The other two were of British coal miners (Miller et al., 2007; Miller and MacCalman, 2010) and North American industrial sand workers (Hughes et al., 2001).

Rice et al. (2001) presents an exposure-response analysis of the diatomaceous worker cohort studied by Checkoway et al. (1993, 1996, 1997), who found a significant relationship between exposure to respirable cristobalite and increased lung cancer mortality. The cohort consisted of 2,342 white males employed for at least one year between 1942 and 1987 in a California diatomaceous earth mining and processing plant. The cohort was followed until 1994, and included 77 lung cancer deaths. The risk analysis relied on an extensive job-specific exposure assessment developed by Sexias et al. (1997), which included use of over 6,000 samples taken during the period 1948 through 1988. The mean cumulative exposure for the cohort was 2.16 mg/m^3-years for respirable crystalline silica dust. Rice et al. (2001) evaluated several model forms for the exposure-response analysis and found exposure to respirable cristobalite to be a significant predictor of lung cancer mortality with the best-fitting model being a linear relative risk model (with a 15-year exposure lag). From this model, the estimates of the excess risk of lung cancer mortality are 34, 17, and 9 deaths per 1,000 workers for 45-years of exposure to 0.1, 0.05, and 0.025 mg/m^3, respectively. For exposures in the range of the current construction and shipyard PELs over 45 years, estimated risks lie in a range between 81 and 152 deaths per 1,000 workers.

Somewhat higher risk estimates are derived from the analysis presented by Attfield and Costello (2004) of Vermont granite workers. This study involved a cohort of 5,414 male granite workers who were employed in the Vermont granite industry between 1950 and 1982 and who were followed through 1994. Workers' cumulative exposures were estimated by Davis et al. (1983) based on historical exposure data collected in six environmental surveys conducted between 1924 and 1977. A categorical analysis showed an increasing trend of lung cancer risk ratios with increasing exposure, and Poisson regression was used to evaluate several exposure-response models with varying exposure lags and use of either untransformed or log-transformed exposure metrics. The best-fitting model was based on use of a 15-year lag, use of untransformed cumulative exposure, and omission of the highest exposure group. The investigators believed that the omission of the highest exposure group was appropriate since: (1) The underlying exposure data for the high-exposure group was weaker than for the others; (2) there was a greater likelihood that competing causes of death and misdiagnoses of causes of death attenuated the lung cancer death rate in the highest exposure group; (3) all of the remaining groups comprised 85 percent of the deaths in the cohort and showed a strong linear increase in lung cancer mortality with increasing exposure; and (4) the exposure-response relationship seen in the lower exposure groups was more relevant given that the exposures of these groups were within the range of current occupational standards. OSHA's use of the exposure coefficient from this analysis in a log-linear relative risk model yielded a risk estimate of 60 deaths per 1,000 workers for 45 years of exposure to the current general industry PEL of 0.1 mg/m^3, 25 deaths per 1,000 for 45 years of exposure to the proposed PEL of 0.05 mg/m^3, and 11 deaths per 1,000 for 45 years of exposure at the proposed action level of 0.025 mg/m^3. Estimated risks associated with 45 years of exposure at the current construction PEL range from 250 to 653 deaths per 1,000.

Hughes et al. (2001) conducted a nested case-control study of 95 lung cancer deaths from a cohort of 2,670 industrial sand workers in the U.S. and Canada studied by McDonald et al. (2001). (This cohort overlaps with the cohort studied by Steenland and Sanderson (2001), which was included in the 10-cohort pooled study by Steenland et al., 2001a). Both categorical analyses and conditional logistic regression were used to examine relationships with cumulative exposure, log of cumulative exposure, and average exposure. Exposure levels over time were estimated via a job-exposure matrix developed for this study (Rando et al., 2001). The 50th percentile (median) exposure level of cases and controls for lung cancer were 0.149 and 0.110 mg/m³ respirable crystalline silica, respectively, slightly above the current OSHA general industry standard. There did not appear to be substantial misclassification of exposures, as evidenced by silicosis mortality showing a positive exposure-response trend with cumulative exposure and average exposure concentration. Statistically significant positive exposure-response trends for lung cancer were found for both cumulative exposure (lagged 15 years) and average exposure concentration, but not for duration of employment, after controlling for smoking. There was no indication of an interaction effect of smoking and cumulative silica exposure. Hughes et al. (2001) reported the exposure coefficients for both lagged and unlagged cumulative exposure; there was no significant difference between the two (0.13 per mg/m³-year for lagged vs. 0.14 per mg/m³-year for unlagged). Use of the coefficient from Hughes et al. (2001) that incorporated a 15-year lag generates estimated cancer risks of 34, 15, and 7 deaths per 1,000 for 45 years exposure to the current general industry PEL of 0.1, the proposed PEL of 0.05 mg/m³, and the proposed action level of 0.025 mg/m³ respirable silica, respectively. For 45 years of exposure to the construction PEL, estimated risks range from 120 to 387 deaths per 1,000 workers.

Miller and MacCalman (2010, also reported in Miller et al., 2007) extended the follow-up of a previously published cohort mortality study (Miller and Buchanan, 1997). The follow-up study included 17,800 miners from 10 coal mines in the U.K. who were followed through the end of 2005; observation in the original study began in 1970. By 2005, there were 516,431 person years of observation, an average of 29 years per miner, with 10,698 deaths from all causes. Exposure estimates of cohort members were not updated from the earlier study since the mines closed in the 1980s; however, some of these men might have had additional exposure at other mines or facilities. An analysis of cause-specific mortality was performed using external controls; it demonstrated that lung cancer mortality was statistically significantly elevated for coal miners exposed to silica. An analysis using internal controls was performed via Cox proportional hazards regression methods, which allowed for each individual miner's measurements of age and smoking status, as well as the individual's detailed dust and quartz time-dependent exposure measurements. From the Cox regression, Miller and MacCalman (2009) estimated that cumulative exposure of 5 g-h/m³ respirable quartz (incorporating a 15-year lag) was associated with a relative risk of 1.14 for lung cancer. This cumulative exposure is about equivalent to 45 years of exposure to 0.055 mg/m³ respirable quartz, or a cumulative exposure of 2.25 mg/m³-yr, assuming 2,000 hours of exposure per year. OSHA applied this slope factor in a log-relative risk model and estimated the lifetime lung cancer mortality risk to be 13 per 1,000 for 45 years of exposure to 0.1 mg/m³ respirable crystalline silica. For the proposed PEL of 0.05 mg/m³ and proposed action level of 0.025 mg/m³, the lifetime risks are estimated to be 6 and 3 deaths per 1,000, respectively. The range of risks estimated to result from 45 years of exposure to the current construction and shipyard PELs is from 37 to 95 deaths per 1,000 workers.

The analysis from the Miller and MacCalman (2009) study yields risk estimates that are lower than those obtained from the other cohort studies described above. Possible explanations for this include: (1) Unlike the studies on diatomaceous earth workers and granite workers, the mortality analysis of the coal miners was adjusted for smoking; (2) lung cancer risks might have been lower among the coal miners due to high competing mortality risks observed in the cohort (mortality was significantly increased for several diseases, including tuberculosis, chronic bronchitis, and non-malignant respiratory disease); and (3) the lower risk estimates derived from the coal miner study could reflect an actual difference in the cancer potency of the quartz dust in the coal mines compared to that present in the work environments studied elsewhere. OSHA believes that the risk estimates derived from this study are credible. In terms of design, the cohort was based on union rolls with very good participation rates and good reporting. The study group was the largest of any of the individual cohort studies reviewed here (over 17,000 workers) and there was an average of nearly 30 years of follow-up, with about 60 percent of the cohort having died by the end of follow-up. Just as important were the high quality and detail of the exposure measurements, both of total dust and quartz.

b. Summary of Risk Estimates for Silicosis and Other Chronic Lung Disease Mortality

OSHA based its quantitative assessment of silicosis mortality risks on a pooled analysis conducted by Mannetje et al. (2002b) of data from six of the ten epidemiological studies in the Steenland et al. (2001a) pooled analysis of lung cancer mortality. Cohorts included in the silicosis study were U.S. diatomaceous earth workers (Checkoway et al., 1997); Finnish granite workers (Koskela et al., 1994); U.S. granite workers (Costello and Graham, 1988); U.S. industrial sand workers (Steenland and Sanderson, 2001); U.S. gold miners (Steenland and Brown, 1995b); and Australian gold miners (deKlerk and Musk, 1998). These six cohorts contained 18,634 subjects and 170 silicosis deaths, where silicosis mortality was defined as death from silicosis (ICD–9 502, n=150) or from unspecified pneumoconiosis (ICD–9 505, n = 20). Analysis of exposure-response was performed in a categorical analysis where the cohort was divided into cumulative exposure deciles and Poisson regression was used to estimate silicosis rate ratios for each category, adjusted for age, calendar period, and study. Exposure-response was examined in more detail using a nested case-control design and logistic regression. Although Mannetje et al. (2002b) estimated silicosis risks at the current OSHA PEL from the Poisson regression, a subsequent analysis based on the case-control design was conducted by Steenland and Bartow (Toxichemica, 2004), which resulted in slightly lower estimates of risk. Based on the Toxichemica analysis, OSHA estimates that the lifetime risk (over 85 years) of silicosis mortality associated with 45 years of exposure to the current general industry PEL of 0.1 mg/m³ is 11 deaths per 1,000 workers. Exposure for 45 years to the proposed PEL of 0.05 mg/m³ and action level of 0.025 mg/m³ results in an estimated 7 and 4 silicosis deaths per 1,000, respectively. Lifetime risks associated with exposure at the current construction and shipyard PELs range from 17 to 22 deaths per 1,000 workers.

To study non-malignant respiratory diseases, of which silicosis is one, Park et al. (2002) analyzed the California diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994. The authors quantified the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Less than 25 percent of the LDOC deaths in the analysis were coded as silicosis or other pneumoconiosis (15 of 67). As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis. Exposure-response relationships were explored using both Poisson regression models and Cox's proportional hazards models fit to the same series of relative rate exposure-response models that were evaluated by Rice et al. (2001) for lung cancer (*i.e.,* log-linear, log-square root, log-quadratic, linear relative rate, a power function, and a shape function). Relative or excess rates were modeled using internal controls and adjusting for age, calendar time, ethnicity (Hispanic versus white), and time since first entry into the cohort, or using age- and calendar time-adjusted external standardization to U.S. population mortality rates. There were no LDOC deaths recorded among workers having cumulative exposures above 32 mg/m³-years, causing the response to level off or decline in the highest exposure range; possible explanations considered included survivor selection, depletion of susceptible populations in high dust areas, and/or a higher degree of misclassification of exposures in the earlier years where exposure data were lacking and when exposures were presumably the highest. Therefore, Park et al. (2002) performed exposure-response analyses that restricted the dataset to observations where cumulative exposures were below 10 mg/m³-years, a level more than four times higher than that resulting from 45 years of exposure to the current general industry PEL for cristobalite (which is about 0.05 mg/m³), as well as analyses using the full dataset. Among the models based on the restricted dataset, the best-fitting model with a single exposure term was the linear relative rate model using external adjustment.

OSHA's estimates of the lifetime chronic lung disease mortality risk based on this model are substantially higher than those that OSHA derived from the Mannetje et al. (2002b) silicosis analysis. For the current general industry PEL of 0.1 mg/m³, exposure for 45 years is estimated to result in 83 deaths per 1,000 workers. At the proposed PEL of 0.05 mg/m³ and action level of 0.025 mg/m³, OSHA estimates the lifetime risk from 45 years of exposure to be 43 and 22 deaths per 1,000, respectively. The range of risks associated with exposure at the construction and shipyard PELs over a working lifetime is from 188 to 321 deaths per 1,000 workers. It should be noted that the Mannetje study (2002b) was not adjusted for smoking while the Park study (2002) had data on smoking habits for about one-third of the workers who died from LDOC and about half of the entire cohort. The Poisson regression on which the risk model is based was partially stratified on smoking. Furthermore, analyses without adjustment for smoking suggested to the authors that smoking was acting as a negative confounder.

c. Summary of Risk Estimates for Renal Disease Mortality

OSHA's analysis of the health effects literature included several studies that have demonstrated that exposure to crystalline silica increases the risk of renal and autoimmune disease (*see* Section V, Health Effects Summary). Studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease, sub-clinical renal changes, end-stage renal disease morbidity, chronic renal disease mortality, and Wegener's granulomatosis. A strong exposure-response association for renal disease mortality and silica exposure has also been demonstrated.

OSHA's assessment of the renal disease risks that result from exposure to respirable crystalline silica are based on an analysis of pooled data from three cohort studies (Steenland et al., 2002a). The combined cohort for the pooled analysis (Steenland et al., 2002a) consisted of 13,382 workers and included industrial sand workers (Steenland et al., 2001b), U.S. gold miners (Steenland and Brown, 1995a), and Vermont granite workers (Costello and Graham, 1998). Exposure data were available for 12,783 workers and analyses conducted by the original investigators demonstrated monotonically increasing exposure-response trends for silicosis, indicating that exposure estimates were not likely subject to significant random misclassification. The mean duration of exposure, cumulative exposure, and concentration of respirable silica for the combined cohort were 13.6 years, 1.2 mg/m³-years, and 0.07 mg/m³, respectively. There were highly statistically significant trends for increasing renal disease mortality with increasing cumulative exposure for both multiple cause analysis of mortality ($p<0.000001$) and underlying cause analysis ($p = 0.0007$). Exposure-response analysis was also conducted as part of a nested case-control study, which showed statistically significant monotonic trends of increasing risk with increasing exposure again for both multiple cause ($p = 0.004$ linear trend, 0.0002 log trend) and underlying cause ($p = 0.21$ linear trend, 0.03 log trend) analysis. The authors found that use of log-cumulative dose in a log relative risk model fit the pooled data better than cumulative exposure, average exposure, or lagged exposure. OSHA's estimates of renal disease mortality risk, which are based on the log relative risk model with log cumulative exposure, are 39 deaths per 1,000 for 45 years of exposure at the current general industry PEL of 0.1 mg/m³, 32 deaths per 1,000 for exposure at the proposed PEL of 0.05 mg/m³, and 25 deaths per 1,000 at the proposed action level of 0.025 mg/m³. OSHA also estimates that 45 years of exposure at the current construction and shipyard PELs would result in a renal disease mortality risk ranging from 52 to 63 deaths per 1,000 workers.

d. Summary of Risk Estimates for Silicosis Morbidity

OSHA's Preliminary Quantitative Risk Assessment reviewed several cross-sectional studies designed to characterize relationships between exposure to respirable crystalline silica and development of silicosis as determined by chest radiography. Several of these studies could not provide information on exposure or length of employment prior to disease onset. Others did have access to sufficient historical medical data to retrospectively determine time of disease onset but included medical examination at follow up of primarily active workers with little or no post-employment follow-up. Although OSHA presents silicosis risk estimates that were reported by the investigators of these studies, OSHA believes that such estimates are likely to understate lifetime risk of developing radiological silicosis; in fact, the risk estimates reported in these studies are generally lower than those derived from studies that included retired workers in follow up medical examinations.

Therefore, OSHA believes that the most useful studies for characterizing lifetime risk of silicosis morbidity are retrospective cohort studies that included a large proportion of retired workers in the cohort and that were able to evaluate disease status over time, including post-retirement. OSHA identified studies of six cohorts for which the inclusion of retirees was deemed sufficient to adequately characterize silicosis morbidity risks well past employment (Hnizdo and Sluis-Cremer, 1993; Steenland and Brown, 1995b; Miller et al., 1998; Buchanan et al., 2003; Chen et al., 2001; Chen et al., 2005). Study populations included five mining cohorts and a Chinese pottery worker cohort. Except for the Chinese studies (Chen et al., 2001; Chen et al., 2005), chest radiographs were interpreted in accordance with the ILO system described earlier in this section, and x-ray films were read by panels of B-readers. In the Chinese studies, films were evaluated using a Chinese system of classification that is analogous to the ILO system. In addition, the Steenland and Brown (1995b) study of U.S. gold miners included silicosis mortality as well as morbidity in its analysis. OSHA's estimates of silicosis morbidity risks are based on implementing the various exposure-response models reported by the investigators; these are considered to be cumulative risk models in the sense that they represent the risk observed in the cohort at the time of the last medical evaluation and do not reflect all of the risk that may become manifest over a lifetime. With the exception of a coal miner study (Buchanan et al., 2003), risk estimates reflect the risk that a worker will acquire an abnormal chest x-ray classified as ILO major category 1 or greater; the coal miner study evaluated the risk of acquiring an abnormal chest x-ray classified as major category 2 or higher.

For miners exposed to freshly cut crystalline silica, the estimated risk of developing lesions consistent with an ILO classification of category 1 or greater is estimated to range from 120 to 773 cases per 1,000 workers exposed at the current general industry PEL of 0.1 mg/m^3 for 45 years. For 45 years of exposure to the proposed PEL of 0.05 mg/m^3, the range in estimated risk is from 20 to 170 cases per 1,000 workers. The risk predicted from exposure to the proposed action level of 0.025 mg/m^3 ranges from 5 to 40 cases per 1,000. From the coal miner study of Buchanan et al. (2003), the estimated risks of acquiring an abnormal chest x-ray classified as ILO category 2 or higher are 301, 55, and 21 cases per 1,000 workers exposed for 45 years to 0.1, 0.05, and 0.025 mg/m^3, respectively. These estimates are within the range of risks obtained from the other mining studies. At exposures at or above 0.25 mg/m^3 for 45 years (equivalent to the current construction and shipyard PELs), the risk of acquiring an abnormal chest x-ray approaches unity. Risk estimates based on the pottery cohort are 60, 20, and 5 cases per 1,000 workers exposed for 45 years to 0.1, 0.05, and 0.025 mg/m^3, respectively, which is generally below the range of risks estimated from the other studies and may reflect a lower toxicity of quartz particles in that work environment due to the presence of alumino-silicates on the particle surfaces. According to Chen et al. (2005), adjustment of the exposure metric to reflect the unoccluded surface area of silica particles resulted in an exposure-response of pottery workers that was similar to the mining cohorts. The finding of a reduced silicosis risk among pottery workers is consistent with other studies of clay and brick industries that have reported finding a lower prevalence of silicosis compared to that experienced in other industry sectors (Love et al., 1999; Hessel, 2006; Miller and Soutar, 2007) as well as a lower silicosis risk per unit of cumulative exposure (Love et al., 1999; Miller and Soutar, 2007).

3. Significance of Risk and Risk Reduction

The Supreme Court's benzene decision of 1980, discussed above in this section, states that ''before he can promulgate *any* permanent health or safety standard, the Secretary [of Labor] is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices.'' Benzene, 448 U.S. at 642. While making it clear that it is up to the Agency to determine what constitutes a significant risk, the Court offered general guidance on the level of risk OSHA might determine to be significant.

> It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.

Benzene, 448 U.S. at 655. The Court further stated that the determination of significant risk is not a mathematical straitjacket and that ''the Agency has no duty to calculate the exact probability of harm.'' *Id.*

In this section, OSHA presents its preliminary findings with respect to the significance of the risks summarized above, and the potential of the proposed standard to reduce those risks. Findings related to mortality risk will be presented first, followed by silicosis morbidity risks.

a. Mortality Risks

OSHA's Preliminary Quantitative Risk Assessment (and the Summary of the Preliminary Quantitative Risk Assessment in section VI) presents risk estimates for four causes of excess mortality: Lung cancer, silicosis, non-malignant respiratory disease (including silicosis and COPD), and renal disease. Table VII–2 presents the estimated excess lifetime risks (*i.e.,* to age 85) of these fatal diseases associated with various levels of crystalline silica exposure allowed under the current rule, based on OSHA's risk assessment and assuming 45 years of occupational exposure to crystalline silica.

TABLE VII–2—EXPECTED EXCESS DEATHS PER 1,000 WORKERS

Fatal health outcome	Current general industry PEL (0.1 mg/m^3)	Current construction/ shipyard PEL (0.25–0.5 mg/m^3)	Proposed PEL (0.05 mg/m^3)
Lung Cancer:			
10-cohort pooled analysis	22–29	27–38	18–26
Single cohort study-lowest estimate	13	37–95	6
Single cohort study-highest estimate	60	250–653	25
Silicosis	11	17–22	7
Non-Malignant Respiratory Disease (including silicosis)	83	188–321	43

TABLE VII–2—EXPECTED EXCESS DEATHS PER 1,000 WORKERS—Continued

Fatal health outcome	Current general industry PEL (0.1 mg/m³)	Current construction/ shipyard PEL (0.25–0.5 mg/m³)	Proposed PEL (0.05 mg/m³)
Renal Disease	39	52–63	32

The purpose of the OSH Act, as stated in Section 6(b), is to ensure ''that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.'' 29 U.S.C. 655(b)(5). Assuming a 45-year working life, as OSHA has done in significant risk determinations for previous standards, the Agency preliminarily finds that the excess risk of disease mortality related to exposure to respirable crystalline silica at levels permitted by current OSHA standards is clearly significant. The Agency's estimate of such risk falls well above the level of risk the Supreme Court indicated a reasonable person might consider unacceptable. *Benzene,* 448 U.S. at 655. For lung cancer, OSHA estimates the range of risk at the current general industry PEL to be between 13 and 60 deaths per 1,000 workers. The estimated risk for silicosis mortality is lower, at 11 deaths per 1,000 workers; however, the estimated lifetime risk for non-malignant respiratory disease mortality, including silicosis, is about 8-fold higher than that for silicosis alone, at 83 deaths per 1,000. OSHA believes that the estimate for non-malignant respiratory disease mortality is better than the estimate for silicosis mortality at capturing the total respiratory disease burden associated with exposure to crystalline silica dust. The former captures deaths related to COPD, for which there is strong evidence of a causal relationship with exposure to silica, and is also more likely to capture those deaths where silicosis was a contributing factor but where the cause of death was misclassified. Finally, there is an estimated lifetime risk of renal disease mortality of 39 deaths per 1,000. Exposure for 45 years at levels of respirable crystalline silica in the range of the current limits for construction and shipyards result in even higher risk estimates, as presented in Table VII–2.

To further demonstrate significant risk, OSHA compares the risk from currently permissible crystalline silica exposures to risks found across a broad variety of occupations. The Agency has used similar occupational risk comparisons in the significant risk determination for substance-specific standards promulgated since the benzene decision. This approach is supported by evidence in the legislative record, with regard to Section 6(b)(5) of the Act (29 U.S.C. 655(b)(5)), that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not ''to establish a utopia free from any hazards'' or to address risks comparable to those that exist in virtually any occupation or workplace. 116 Cong. Rec. 37614 (1970), Leg. Hist. 480–82. It is also consistent with Section 6(g) of the OSH Act, which states: ''In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments.'' 29 U.S.C. 655(g).

Fatal injury rates for most U.S. industries and occupations may be obtained from data collected by the Bureau of Labor Statistics. Table VII–3 shows annual fatality rates per 1,000 employees for several industries for 2007, as well as projected fatalities per 1,000 employees assuming exposure to workplace hazards for 45 years based on these annual rates (BLS, 2010). While it is difficult to meaningfully compare aggregate industry fatality rates to the risks estimated in the quantitative risk assessment for crystalline silica, which address one specific hazard (inhalation exposure to respirable crystalline silica) and several health outcomes (lung cancer, silicosis, NMRD, renal disease mortality), these rates provide a useful frame of reference for considering risk from inhalation exposure to crystalline silica. For example, OSHA's estimated range of 6–60 excess lung cancer deaths per 1,000 workers from regular occupational exposure to respirable crystalline silica in the range of 0.05—0.1 mg/m³ is roughly comparable to, or higher than, the expected risk of fatal injuries over a working life in high-risk occupations such as mining and construction (*see* Table VII–3). Regular exposures at higher levels, including the current construction and shipyard PELs for respirable crystalline silica, are expected to cause substantially more deaths per 1,000 workers from lung cancer (ranging from 37 to 653 per 1,000) than result from occupational injuries in most private industry. At the proposed PEL of 0.05 mg/m³ respirable crystalline silica, the Agency's estimate of excess lung cancer mortality, from 6 to 26 deaths per 1,000 workers, is still 3- to10-fold or more higher than private industry's average fatal injury rate, given the same employment time, and substantially exceeds those rates found in lower-risk industries such as finance and educational and health services.

TABLE VII–3—FATAL INJURIES PER 1000 EMPLOYEES, BY INDUSTRY OR SECTOR

	Over 1 year	Over 45 years
All Private Industry	0.043	1.9
Mining (General)	0.214	9.6
Construction	0.108	4.8
Manufacturing	0.024	1.1
Wholesale Trade	0.045	2.0
Transportation and Warehousing	0.165	7.4
Financial Activities	0.012	0.5
Educational and Health Services	0.008	0.4

Source: BLS (2010).

Because there is little available information on the incidence of occupational cancer across all industries, risk from crystalline silica exposure cannot be compared with overall risk from other workplace carcinogens. However, OSHA's previous risk assessments provide estimates of risk from exposure to certain carcinogens. These risk assessments, as with the current assessment for crystalline silica, were based on animal or human data of reasonable or high quality and used the best information then available. Table VII–4 shows the Agency's best estimates of cancer risk from 45 years of occupational exposure to several carcinogens, as published in the preambles to final rules promulgated since the benzene decision in 1980. These risks were judged by the Agency to be significant.

TABLE VII–4—SELECTED OSHA RISK ESTIMATES FOR PRIOR AND CURRENT PELS

[Excess Cancers per 1000 workers]

Standard	Risk at prior PEL	Risk at current PEL	**Federal Register** date
Ethylene Oxide	63–109 per 1000	1.2–2.3 per 1000	June 22, 1984.
Asbestos	64 per 1000	6.7 per 1000	June 20, 1986.
Benzene	95 per 1000	10 per 1000	September 11, 1987.
Formaldehyde	0.4–6.2 per 1000	0.0056 per 1000	December 4, 1987.
Methylenedianiline	*6–30 per 1000	0.8 per 1000	August 10, 1992.
Cadmium	58–157 per 1000	3–15 per 1000	September 14, 1992.
1,3-Butadiene	11.2–59.4 per 1000	1.3–8.1 per 1000	November 4, 1996.
Methylene Chloride	126 per 1000	3.6 per 1000	January 10, 1997.
Chromium VI	101–351 per 1000	10–45 per 1000	February 28, 2006
Crystalline Silica:			
General Industry PEL	**13–60 per 1000	***6–26 per 1000	N/A
Construction/Shipyard PEL	**27–653 per 1000	***6–26 per 1000	

* no prior standard; reported risk is based on estimated exposures at the time of the rulemaking
** estimated excess lung cancer risks at the current PEL
*** estimated excess lung cancer risks at the proposed new PEL

The estimated excess lung cancer risks associated with respirable crystalline silica at the current general industry PEL, 13–60 deaths per 1,000 workers, are comparable to, and in some cases higher than, the estimated excess cancer risks for many other workplace carcinogens for which OSHA made a determination of significant risk (*see* Table VII–4, ''Selected OSHA Risk Estimates for Prior and Current PELs''). The estimated excess lung cancer risks associated with exposure to the current construction and shipyard PELs are even higher. The estimated risk from lifetime occupational exposure to respirable crystalline silica at the proposed PEL is 6–26 excess lung cancer deaths per 1,000 workers, a range still higher than the risks from exposure to many other carcinogens regulated by OSHA (*see* Table VII–4, ''Selected OSHA Risk Estimates for Prior and Current PELs'').

OSHA's preliminary risk assessment also shows that reduction of the current PELs to the proposed level of 0.05 mg/m^3 will result in substantial reduction in risk, although quantification of that reduction is subject to model uncertainty. Risk models that reflect attenuation of the risk with increasing exposure, such as those relating risk to a log transformation of cumulative exposure, will result in lower estimates of risk reduction compared to linear risk models. Thus, for lung cancer risks, the assessment based on the 10-cohort pooled analysis by Steenland et al. (2001; also Toxichemica, 2004; Steenland 2010) suggests risk will be reduced by about 14 percent from the current general industry PEL and by 28–41 percent from the current construction/shipyard PEL (based on the midpoint of the ranges of estimated risk derived from the three models used for the pooled cohort data). These risk reduction estimates, however, are much lower than those derived from the single cohort studies (Rice et al., 2001; Attfield and Costello, 2004; Hughes et al., 2001; Miller and MacCalman, 2009), which used linear or log-linear relative risk models with untransformed cumulative exposure as the dose metric. These single cohort studies suggest that reducing the current PELs to the proposed PEL will reduce lung cancer risk by more than 50 percent in general industry and by more than 80 percent in construction and shipyards.

For silicosis mortality, OSHA's assessment indicates that risk will be reduced by 36 percent and by 58–68 percent as a result of reducing the current general industry and construction/shipyard PELs, respectively. Non-malignant respiratory disease mortality risks will be reduced by 48 percent and by 77–87 percent from reducing the general industry and construction/shipyard PELs, respectively, to the proposed PEL. There is also a substantial reduction in renal disease mortality risks; an 18-percent reduction associated with reducing the general industry PEL and a 38- to 49-percent reduction associated with reducing the construction/shipyard PEL.

Thus, OSHA believes that the proposed PEL of 0.05 mg/m^3 respirable crystalline silica will substantially reduce the risk of material health impairments associated with exposure to silica. However, even at the proposed PEL, as well as the action level of 0.025 mg/m^3, the risk posed to workers with 45 years of regular exposure to respirable crystalline silica is greater than 1 per 1,000 workers and is still clearly significant.

b. Silicosis Morbidity Risks

OSHA's Preliminary Risk Assessment characterizes the risk of developing lung fibrosis as detected by chest x-ray. For 45 years of exposure at the current general industry PEL, OSHA estimates that the risk of developing lung fibrosis consistent with an ILO category 1+ degree of small opacity profusion ranges from 60 to 773 cases per 1,000. For exposure at the construction and shipyard PELs, the risk approaches unity. The wide range of risk estimates derived from the underlying studies relied on for the risk assessment may reflect differences in the relative toxicity of quartz particles in different workplaces; nevertheless, OSHA believes that each of these risk estimates clearly represent a significant risk of developing fibrotic lesions in the lung. Exposure to the proposed PEL of 0.05 mg/m^3 respirable crystalline silica for 45 years yields an estimated risk of between 20 and 170 cases per 1,000 for developing fibrotic lesions consistent with an ILO category of 1+. These risk estimates indicate that promulgation of the proposed PEL would result in a reduction in risk by about two-thirds or more, which the Agency believes is a substantial reduction of the risk of developing abnormal chest x-ray findings consistent with silicosis.

One study of coal miners also permitted the agency to evaluate the risk of developing lung fibrosis consistent with an ILO category 2+ degree of profusion of small opacities (Buchanan et al., 2003). This level of profusion has been shown to be associated with a higher prevalence of lung function decrement and an increased rate of early mortality (Ng et al., 1987a; Begin et al., 1998; Moore et al., 1988; Ng et al., 1992a; Infante-Rivard et al., 1991). From this study, OSHA estimates that the risk associated with 45 years of exposure to the current general industry PEL is 301 cases per 1,000 workers, again a clearly significant risk. Exposure to the proposed PEL of 0.05 mg/m³ respirable crystalline silica for 45 years yields an estimated risk of 55 cases per 1,000 for developing lesions consistent with an ILO category 2+ degree of small opacity profusion. This represents a reduction in risk of over 80 percent, again a clearly substantial reduction of the risk of developing radiologic silicosis consistent with ILO category 2+ degree of small opacity profusion.

As is the case for other health effects addressed in the preliminary risk assessment (*i.e.,* lung cancer, silicosis morbidity defined as ILO 1+ level of profusion), there is some evidence that this risk will vary according to the nature of quartz particles present in different workplaces. In particular, risk may vary depending on whether quartz is freshly fractured during work operations and the co-existence of other minerals and substances that could alter the biological activity of quartz. Using medical and exposure data taken from a cohort of heavy clay workers first studied by Love et al. (1999), Miller and Soutar (2007) compared the silicosis prevalence within the cohort to that predicted by the exposure-response model derived by Buchanan et al. (2003) and used by OSHA to estimate the risk of radiologic silicosis with a classification of ILO 2+. They found that the model predicted about a 4-fold higher prevalence of workers having an abnormal x-ray than was actually seen in the clay cohort (31 cases predicted vs. 8 observed). Unlike the coal miner study, the clay worker cohort included only active workers and not retirees (Love et al., 1999); however, Miller and Soutar believed this could not explain the magnitude of the difference between the model prediction and observed silicosis prevalence in the clay worker cohort. OSHA believes that the result obtained by Miller and Soutar (2007) likely does reflect differences in the toxic potency of quartz particles in different work settings. Nevertheless, even if the risk estimates predicted by the model derived from the coal worker study were reduced substantially, even by more than a factor of 10, the resulting risk estimate would still reflect the presence of a significant risk.

The Preliminary Quantitative Risk Assessment also discusses the question of a threshold exposure level for silicosis. There is little quantitative data available with which to estimate a threshold exposure level for silicosis or any of the other silica-related diseases addressed in the risk assessment. The risk assessment discussed one study that perhaps provides the best information. This is an analysis by Kuempel et al. (2001) who used a rat-based toxicokinetic/toxicodynamic model along with a human lung deposition/clearance model to estimate a minimum lung burden necessary to cause the initial inflammatory events that can lead to lung fibrosis and an indirect genotoxic cause of lung cancer. They estimated that the threshold effect level of lung burden associated with this inflammation (M_{crit}) is the equivalent of exposure to 0.036 mg/m³ for 45 years; thus, exposures below this level would presumably not lead to an excess lung cancer risk (based on an indirect genotoxic mechanism) nor to silicosis, at least in the ''average individual.'' This might suggest that exposures to a concentration of silica at the proposed action level would not be associated with a risk of silicosis, and possibly not of lung cancer. However, OSHA does not believe that the analysis by Kuemple et al. is definitive with respect to a threshold for silica-related disease. First, since the critical quartz burden is a mean value derived from the model, the authors estimated that a 45-year exposure to a concentration as low as 0.005 mg/m³, or 5 times below the proposed action level, would result in a lung quartz burden that was equal to the 95-percent lower confidence limit on M_{crit}. Due to the statistical uncertainty in Kuemple et al.'s estimate of critical lung burden, OSHA cannot rule out the existence of a threshold lung burden that is below that resulting from exposure to the proposed action level. In addition, with respect to silica-related lung cancer, if at least some of the risk is from a direct genotoxic mechanism (*see* section II.F of the Health Effects Literature Review), then this threshold value is not relevant to the risk of lung cancer. Supporting evidence comes from Steenland and Deddens (2002), who found that, for the 10-cohort pooled data set, a risk model that incorporated a threshold did fit better than a no-threshold model, but the estimated threshold was very low, 0.010 mg/m³ (10 μg/m³). OSHA acknowledges that a threshold exposure level might lie within the range of the proposed action level, as suggested by the work of Kuempel et al. (2001) and that this possibility adds uncertainty to the estimated risks associated with exposure to the action level. However, OSHA believes that available information cannot firmly establish a threshold exposure level for silica-related effects, and there is no empirical evidence that a threshold exists at or above the proposed PEL of 0.05 mg/m³ for respirable crystalline silica.

VIII. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

A. Introduction and Summary

OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this proposed respirable crystalline silica rule and evaluates regulatory alternatives to the proposed rule. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full PEA has been placed in OSHA rulemaking docket OSHA–2010–0034. This rule is an economically significant regulatory action under Sec. 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order.

The purpose of the PEA is to:

- Identify the establishments and industries potentially affected by the proposed rule;

• Estimate current exposures and the technologically feasible methods of controlling these exposures;
• Estimate the benefits resulting from employers coming into compliance with the proposed rule in terms of reductions in cases of silicosis, lung cancer, other forms of chronic obstructive pulmonary disease, and renal failure;
• Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the proposed rule;
• Assess the economic feasibility of the proposed rule for affected industries; and
• Assess the impact of the proposed rule on small entities through an Initial Regulatory Flexibility Analysis (IRFA), to include an evaluation of significant regulatory alternatives to the proposed rule that OSHA has considered.

The Preliminary Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Assessing the Need for Regulation
Chapter III. Profile of Affected Industries
Chapter IV. Technological Feasibility
Chapter V. Costs of Compliance
Chapter VI. Economic Impacts
Chapter VII. Benefits and Net Benefits
Chapter VIII. Regulatory Alternatives
Chapter IX. Initial Regulatory Flexibility Analysis
Chapter X. Environmental Impacts

Key findings of these chapters are summarized below and in sections VIII.B through VIII.I of this PEA summary.

Profile of Affected Industries

The proposed rule would affect employers and employees in many different industries across the economy. As described in Section VIII.C and reported in Table VIII–3 of this preamble, OSHA estimates that a total of 2.1 million employees in 550,000 establishments and 533,000 firms (entities) are potentially at risk from exposure to respirable crystalline silica. This total includes 1.8 million employees in 477,000 establishments and 486,000 firms in the construction industry and 295,000 employees in 56,000 establishments and 47,000 firms in general industry and maritime.

Technological Feasibility

As described in more detail in Section VIII.D of this preamble and in Chapter IV of the PEA, OSHA assessed, for all affected sectors, the current exposures and the technological feasibility of the proposed PEL of 50 μg/m³ and, for analytic purposes, an alternative PEL of 25 μg/m³.

Tables VIII–6 and VIII–7 in section VIII.D of this preamble summarize all the industry sectors and construction activities studied in the technological feasibility analysis and show how many operations within each can achieve levels of 50 μg/m³ through the implementation of engineering and work practice controls. The table also summarizes the overall feasibility finding for each industry sector or construction activity based on the number of feasible versus infeasible operations. For the general industry sector, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For the construction activities, OSHA has determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls (seven out of 108 operations, *see* Tables VIII–6 and VIII–7), employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

Based on the information presented in the technological feasibility analysis, the Agency believes that 50 μg/m³ is the lowest feasible PEL. An alternative PEL of 25 μg/m³ would not be feasible because the engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to levels below 25 μg/m³ in most operations most of the time. OSHA believes that an alternative PEL of 25 μg/m³ would not be feasible for many industries, and that the use of respiratory protection would be necessary in most operations most of the time to achieve compliance. Additionally, the current methods of sampling analysis create higher errors and lower precision in measurement as concentrations of silica lower than the proposed PEL are analyzed. However, the Agency preliminarily concludes that these sampling and analytical methods are adequate to permit employers to comply with all applicable requirements triggered by the proposed action level and PEL.

Costs of Compliance

As described in more detail in Section VIII.E and reported by industry in Table VIII–8 of this preamble, the total annualized cost of compliance with the proposed standard is estimated to be about $658 million. The major cost elements associated with the revisions to the standard are costs for engineering controls, including controls for abrasive blasting ($344 million); medical surveillance ($79 million); exposure monitoring ($74 million); respiratory protection ($91 million); training ($50 million) and regulated areas or access control ($19 million). Of the total cost, $511 million would be borne by firms in the construction industry and $147 million would be borne by firms in general industry and maritime.

The compliance costs are expressed as annualized costs in order to evaluate economic impacts against annual revenue and annual profits, to be able to compare the economic impact of the rulemaking with other OSHA regulatory actions, and to be able to add and track Federal regulatory compliance costs and economic impacts in a consistent manner. Annualized costs also represent a better measure for assessing the longer-term potential impacts of the rulemaking. The annualized costs were calculated by annualizing the one-time costs over a period of 10 years and applying discount rates of 7 and 3 percent as appropriate.

The estimated costs for the proposed silica standard rule include the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

OSHA's exposure profile represents the Agency's best estimate of current exposures (*i.e.,* baseline exposures). OSHA did not attempt to determine the extent to which current exposures in compliance with the current silica PELs are the result of baseline engineering controls or the result of circumstances leading to low exposures. This information is not needed to estimate the costs of (additional) engineering controls needed to comply with the proposed standard.

Because of the severe health hazards involved, the Agency expects that the estimated 15,446 abrasive blasters in the construction sector and the estimated 4,550 abrasive blasters in the maritime sector are currently wearing respirators in compliance with OSHA's abrasive blasting provisions. Furthermore, for the construction baseline, an estimated 241,269 workers, including abrasive blasters, will need to use respirators to achieve compliance with the proposed rule, and, based on the NIOSH/BLS respirator use survey (NIOSH/BLS, 2003), an estimated 56 percent of construction employers currently require such respiratory use and have respirator programs that meet OSHA's respirator standard. OSHA has not taken any costs for employers and their workers currently in compliance with the respiratory provisions in the proposed rule.

In addition, under both the general industry and construction baselines, an estimated 50 percent of employers have pre-existing training programs that address silica-related risks (as required under OSHA's hazard communication standard) and partially satisfy the proposed rule's training requirements (for costing purposes, estimated to satisfy 50 percent of the training requirements in the proposed rule). These employers will need fewer resources to achieve full compliance with the proposed rule than those employers without pre-existing training programs that address silica-related risks.

Other than respiratory protection and worker training concerning silica-related risks, OSHA did not assume baseline compliance with any ancillary provisions, even though some employers have reported that they do currently monitor silica exposure and some employers have reported conducting medical surveillance.

Economic Impacts

To assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the new requirements on entities in each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide an assessment of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts.

As described in greater detail in Section VIII.F of this preamble, the costs of compliance with the proposed rulemaking are not large in relation to the corresponding annual financial flows associated with each of the affected industry sectors. The estimated annualized costs of compliance represent about 0.02 percent of annual revenues and about 0.5 percent of annual profits, on average, across all firms in general industry and maritime, and about 0.05 percent of annual revenues and about 1.0 percent of annual profits, on average, across all firms in construction. Compliance costs do not represent more than 0.39 percent of revenues or more than 8.8 percent of profits in any affected industry in general industry or maritime, or more than 0.13 percent of revenues or more than 3 percent of profits in any affected industry in construction.

Based on its analysis of international trade effects, OSHA concluded that most or all costs arising from this proposed silica rule would be passed on in higher prices rather than absorbed in lost profits and that any price increases would result in minimal loss of business to foreign competition.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has preliminarily concluded that compliance with the requirements of the proposed rulemaking would be economically feasible in every affected industry sector.

In addition, OSHA directed Inforum—a not-for-profit corporation with over 40 years of experience in the design and application of macroeconomic models—to run its LIFT (Long-term Interindustry Forecasting Tool) model of the U.S. economy to estimate the industry and aggregate employment effects of the proposed silica rule. Inforum developed estimates of the employment impacts over the ten-year period from 2014–2023 by feeding OSHA's year-by-year and industry-by-industry estimates of the compliance costs of the proposed rule into its LIFT model. The most important Inforum result is that the proposed silica rule would have a negligible—albeit slightly positive—net effect on aggregate U.S. employment.

Based on its analysis of the costs and economic impacts associated with this rulemaking and on Inforum's estimates of associated employment and other macroeconomic impacts, OSHA preliminarily concludes that the effect of the proposed standard on employment, wages, and economic growth for the United States would be negligible.

Benefits, Net Benefits, and Cost-Effectiveness

As described in more detail in Section VIII.G of this preamble, OSHA estimated the benefits, net benefits, and incremental benefits of the proposed silica rule. That section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and benefit parameters. A full explanation of the derivation of the estimates presented there is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of its estimation of the benefits and net benefits of the proposed rule.

OSHA estimated the benefits associated with the proposed PEL of 50 μg/m^3 and, for analytical purposes to comply with OMB Circular A–4, with an alternative PEL of 100 μg/m^3 for respirable crystalline silica by applying the dose-response relationship developed in the Agency's quantitative risk assessment—summarized in Section VI of this preamble—to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile (presented in Chapter IV of the PEA) for industries with workers exposed to respirable crystalline silica, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile is summarized in Table VIII–5 in Section VIII.C of this preamble.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given current exposure levels (the "baseline"):

- Fatal cases of lung cancer,
- fatal cases of non-malignant respiratory disease (including silicosis),
- fatal cases of end-stage renal disease, and
- cases of silicosis morbidity.

Table VIII–1 provides a summary of OSHA's best estimate of the costs and benefits of the proposed rule using a discount rate of 3 percent. As shown, the proposed rule is estimated to prevent 688 fatalities and 1,585 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $637 million annually. Also as shown in Table VIII–1, the discounted monetized benefits of the proposed rule are estimated to be $5.3 billion annually, and the proposed rule is estimated to generate net benefits of $4.6 billion annually. Table VIII–1 also presents the estimated costs and benefits of the proposed rule using a discount rate of 7 percent. The estimated costs and benefits of the proposed rule, disaggregated by industry sector, were previously presented in Table SI–3 in this preamble.

TABLE VIII–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S PROPOSED SILICA STANDARD OF 50 μG/M3

Discount rate		3%	7%
Annualized Costs			
Engineering Controls (includes Abrasive Blasting)		$329,994,068	$343,818,700
Respirators		90,573,449	90,918,741
Exposure Assessment		72,504,999	74,421,757
Medical Surveillance		76,233,932	79,069,527
Training		48,779,433	50,266,744
Regulated Area or Access Control		19,243,500	19,396,743
Total Annualized Costs (point estimate)		637,329,380	657,892,211
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancers (midpoint estimate)	162		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	375		
Fatal Renal Disease	151		
Silica-Related Mortality	688	3,203,485,869	2,101,980,475
Silicosis Morbidity	1,585	1,986,214,921	1,363,727,104
Monetized Annual Benefits (midpoint estimate)		5,189,700,790	3,465,707,579
Net Benefits		4,552,371,410	2,807,815,368

Initial Regulatory Flexibility Analysis

OSHA has prepared an Initial Regulatory Flexibility Analysis (IRFA) in accordance with the requirements of the Regulatory Flexibility Act, as amended in 1996. Among the contents of the IRFA are an analysis of the potential impact of the proposed rule on small entities and a description and discussion of significant alternatives to the proposed rule that OSHA has considered. The IRFA is presented in its entirety both in Chapter IX of the PEA and in Section VIII.I of this preamble.

The remainder of this section (Section VIII) of the preamble is organized as follows:

B. The Need for Regulation
C. Profile of Affected Industry
D. Technological Feasibility
E. Costs of Compliance
F. Economic Feasibility Analysis and Regulatory Flexibility Determination
G. Benefits and Net Benefits
H. Regulatory Alternatives
I. Initial Regulatory Flexibility Analysis.

B. Need for Regulation

Employees in work environments addressed by the proposed silica rule are exposed to a variety of significant hazards that can and do cause serious injury and death. As described in Chapter II of the PEA in support of the proposed rule, the risks to employees are excessively large due to the existence of various types of market failure, and existing and alternative methods of overcoming these negative consequences—such as workers' compensation systems, tort liability options, and information dissemination programs—have been shown to provide insufficient worker protection.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA concludes that, in the case of silica exposure, the proposed mandatory standards represent the best choice for reducing the risks to employees. In addition, rulemaking is necessary in this case in order to replace older existing standards with updated, clear, and consistent health standards.

C. Profile of Affected Industries

1. Introduction

Chapter III of the PEA presents profile data for industries potentially affected by the proposed silica rule. The discussion below summarizes the findings in that chapter. As a first step, OSHA identifies the North American Industrial Classification System (NAICS) industries, both in general industry and maritime and in the construction sector, with potential worker exposure to silica. Next, OSHA provides summary statistics for the affected industries, including the number of affected entities and establishments, the number of at-risk workers, and the average revenue for affected entities and establishments. [3] Finally, OSHA presents silica exposure profiles for at-risk workers. These data are presented by sector and job category. Summary data are also provided for the number of workers in each affected industry who are currently exposed above the proposed silica PEL of 50 μg/m³, as well as above an alternative PEL of 100 μg/m³ for economic analysis purposes.

The methodological basis for the industry and at-risk worker data presented here comes from ERG (2007a, 2007b, 2008a, and 2008b). The actual data presented here comes from the technological feasibility analyses presented in Chapter IV of the PEA and from ERG (2013), which updated ERG's earlier spreadsheets to reflect the most recent industry data available. The technological feasibility analyses identified the job categories with potential worker exposure to silica. ERG (2007a, 2007b) matched the BLS Occupational Employment Survey (OES) occupational titles in NAICS industries with the at-risk job categories and then calculated the percentages of production employment represented by each at-risk job title.[4] These percentages were then used to project the number of employees in the at-risk job categories by NAICS industry. OSHA welcomes additional information and data that might help improve the accuracy and usefulness of the industry profile presented here and in Chapter III of the PEA.

2. Selection of NAICS Industries for Analysis

The technological feasibility analyses presented in Chapter IV of the PEA identify the general industry and maritime sectors and the construction activities potentially affected by the proposed silica standard.

[3] An establishment is a single physical location at which business is conducted or services or industrial operations are performed. An entity is an aggregation of all establishments owned by a parent company within an industry with some annual payroll.

[4] Production employment includes workers in building and grounds maintenance; forestry, fishing, and farming; installation and maintenance; construction; production; and material handling occupations.

a. General Industry and Maritime

Employees engaged in various activities in general industry and maritime routinely encounter crystalline silica as a molding material, as an inert mineral additive, as a refractory material, as a sandblasting abrasive, or as a natural component of the base materials with which they work. Some industries use various forms of silica for multiple purposes. As a result, employers are challenged to limit worker exposure to silica in dozens of job categories throughout the general industry and maritime sectors.

Job categories in general industry and maritime were selected for analysis based on data from the technical industrial hygiene literature, evidence from OSHA Special Emphasis Program (SEP) results, and, in several cases, information from ERG site visit reports. These data sources provided evidence of silica exposures in numerous sectors. While the available data are not entirely comprehensive, OSHA believes that silica exposures in other sectors are quite limited.

The 25 industry subsectors in the overall general industry and maritime sectors that OSHA identified as being potentially affected by the proposed silica standard are as follows:

- Asphalt Paving Products
- Asphalt Roofing Materials
- Industries with Captive Foundries
- Concrete Products
- Cut Stone
- Dental Equipment and Supplies
- Dental Laboratories
- Flat Glass
- Iron Foundries
- Jewelry
- Mineral Processing
- Mineral Wool
- Nonferrous Sand Casting Foundries
- Non-Sand Casting Foundries
- Other Ferrous Sand Casting Foundries
- Other Glass Products
- Paint and Coatings
- Porcelain Enameling
- Pottery
- Railroads
- Ready-Mix Concrete
- Refractories
- Refractory Repair
- Shipyards
- Structural Clay

In some cases, affected industries presented in the technological feasibility analysis have been disaggregated to facilitate the cost and economic impact analysis. In particular, flat glass, mineral wool, and other glass products are subsectors of the glass industry described in Chapter IV of the PEA, and captive foundries,[5] iron foundries, nonferrous sand casting foundries, non-sand cast foundries, and other ferrous sand casting foundries are subsectors of the overall foundries industry presented in Chapter IV of the PEA.

As described in ERG (2008b), OSHA identified the six-digit NAICS codes for these subsectors to develop a list of industries potentially affected by the proposed silica standard. Table VIII–2 presents the sectors listed above with their corresponding six-digit NAICS industries.

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[5] Captive foundries include establishments in other industries with foundry processes incidental to the primary products manufactured. ERG (2008b) provides a discussion of the methodological issues involved in estimating the number of captive foundries and in identifying the industries in which they are found.

Table VIII-2

General Industry and Martime Sectors and Industries Potentially Affected by OSHA's Proposed Silica Rule

Sector	NAICS	Industry
Asphalt Paving Products	324121	Asphalt paving mixture and block mfg
Asphalt Roofing Materials	324122	Asphalt shingle and roofing materials
Captive Foundries	331111	Iron & steel mills
	331112	Electrometallurgical ferroalloy product mfg
	331210	Iron & steel pipes & tubes mfg from purchased steel
	331221	Cold-rolled steel shape mfg
	331222	Steel wire drawing
	331314	Secondary smelting & alloying of aluminum
	331423	Secondary smelting, refining, & alloying of copper
	331492	Other nonferrous metal secondary smelting, refining, & alloying
	332111	Iron & steel forging
	332112	Nonferrous forging
	332115	Crown & closure mfg
	332116	Metal stamping
	332117	Powder metallurgy part mfg
	332211	Cutlery & flatware (except precious) mfg
	332212	Hand & edge tool mfg
	332213	Saw blade & handsaw mfg
	332214	Kitchen utensil, pot, & pan mfg
	332439	Other metal container mfg
	332510	Hardware mfg
	332611	Spring (heavy gauge) mfg
	332612	Spring (light gauge) mfg
	332618	Other fabricated wire product mfg
	332710	Machine shops
	332911	Industrial valve mfg
	332912	Fluid power valve & hose fitting mfg
	332913	Plumbing fixture fitting & trim mfg
	332919	Other metal valve & pipe fitting mfg
	332991	Ball & roller bearing mfg
	332996	Fabricated pipe & pipe fitting mfg
	332997	Industrial pattern mfg
	332998	Enameled iron & metal sanitary ware mfg
	332999	All other miscellaneous fabricated metal product mfg
	333319	Other commercial & service industry machinery mfg
	333411	Air purification equipment mfg
	333412	Industrial & commercial fan & blower mfg
	333414	Heating equipment (except warm air furnaces) mfg
	333511	Industrial mold mfg
	333512	Machine tool (metal cutting types) mfg
	333513	Machine tool (metal forming types) mfg
	333514	Special die & tool, die set, jig, & fixture mfg
	333515	Cutting tool & machine tool accessory mfg
	333516	Rolling mill machinery & equipment mfg
	333518	Other metalworking machinery mfg
	333612	Speed changer, industrial high-speed drive, & gear mfg
	333613	Mechanical power transmission equipment mfg
	333911	Pump & pumping equipment mfg
	333912	Air & gas compressor mfg
	333991	Power-driven handtool mfg
	333992	Welding & soldering equipment mfg
	333993	Packaging machinery mfg
	333994	Industrial process furnace & oven mfg
	333995	Fluid power cylinder & actuator mfg
	333996	Fluid power pump & motor mfg
	333997	Scale & balance (except laboratory) mfg
	333999	All other miscellaneous general-purpose machinery mfg
	334518	Watch, clock, & part mfg
	336111	Automobile mfg
	336112	Light truck & utility vehicle mfg
	336120	Heavy duty truck mfg
	336211	Motor vehicle body mfg
	336212	Truck trailer mfg

Table VIII-2
General Industry and Martime Sectors and Industries Potentially Affected by OSHA's Proposed Silica Rule (Continued)

Sector	NAICS	Industry
	336213	Motor home mfg
	336311	Carburetor, piston, piston ring, & valve mfg
	336312	Gasoline engine & engine parts mfg
	336322	Other motor vehicle electrical & electronic equipment mfg
	336330	Motor vehicle steering & suspension component (except spring) mfg
	336340	Motor vehicle brake system mfg
	336350	Motor vehicle transmission & power train parts mfg
	336370	Motor vehicle metal stamping
	336399	All other motor vehicle parts mfg
	336992	Military armored vehicle, tank, & tank component mfg
	337215	Showcase, partition, shelving, & locker mfg
	339914	Costume jewelry & novelty mfg
Concrete Products	327331	Concrete block & brick mfg
	327332	Concrete pipe mfg
	327390	Other concrete product mfg
	327999	All other miscellaneous nonmetallic mineral product mfg
Cut Stone	327991	Cut stone & stone product mfg
Dental Equipment and Supplies	339114	Dental equipment and supplies, manufacturing
Dental Laboratories	339116	Dental laboratories
	621210	Offices of dentists
Flat Glass	327211	Flat glass mfg
Iron Foundries	331511	Iron foundries
Jewelry	339911	Jewelry (except costume) mfg
	339913	Jewelers' material & lapidary work mfg
	339914	Costume jewelry & novelty mfg
Mineral Processing	327992	Ground or treated mineral and earth manufacturing
Mineral Wool	327993	Mineral wool mfg
Nonferrous Sand Casting Foundries	331524	Aluminum foundries (except die-casting)
	331525	Copper foundries (except die-casting)
	331528	Other nonferrous foundries (except die-casting)
Non-Sand Casting Foundries	331512	Steel investment foundries
	331524	Aluminum foundries (except die-casting)
	331525	Copper foundries (except die-casting)
	331528	Other nonferrous foundries (except die-casting)
Other Ferrous Sand Casting Foundries	331513	Steel foundries (except investment)
Other Glass Products	327212	Other pressed & blown glass & glassware mfg
	327213	Glass container mfg
Paint and Coatings	325510	Paint & coating mfg [e]
Porcelain Enameling	332812	Metal coating and allied services
	332998	Enameled iron & metal sanitary ware mfg
	335211	Electric housewares and household fans
	335221	Household cooking appliance manufactruing
	335222	Household refrigerator and home freezer manufacturing
	332323	Ornamental and architectural metal work
	335224	Household laundry equipment manufacturing
	335228	Other major household appliance manufacturing
	339950	Sign manufacturing
Pottery	327111	Vitreous china plumbing fixture & bathroom accessories mfg
	327112	Vitreous china, fine earthenware, & other pottery product mfg
	327113	Porcelain electrical supply mfg
Railraods	482110	Rail transportation
Ready-Mix Concrete	327320	Ready-mix concrete mfg
Refractories	327124	Clay refractory mfg
	327125	Nonclay refractory mfg
Refractory Repair	423840	Industrial supplies - wholesale
Shipyards	336611	Ship building & repairing
	336612	Boat building
Structural Clay	327121	Brick & structural clay tile mfg
	327122	Ceramic wall & floor tile mfg
	327123	Other structural clay product mfg

Source: ERG, 2013

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b. Construction

The construction sector is an integral part of the nation's economy, accounting for almost 6 percent of total employment. Establishments in this industry are involved in a wide variety of activities, including land development and subdivision, homebuilding, construction of nonresidential buildings and other structures, heavy construction work (including roadways and bridges), and a myriad of special trades such as plumbing, roofing, electrical, excavation, and demolition work.

Construction activities were selected for analysis based on historical data of recorded samples of construction worker exposures from the OSHA Integrated Management Information System (IMIS) and the National Institute for Occupational Safety and Health (NIOSH). In addition, OSHA reviewed the industrial hygiene literature across the full range of construction activities, and focused on dusty operations where silica sand was most likely to be fractured or abraded by work operations. These physical processes have been found to cause the silica exposures that pose the greatest risk of silicosis for workers.

The 12 construction activities, by job category, that OSHA identified as being potentially affected by the proposed silica standard are as follows:

- Abrasive Blasters
- Drywall Finishers
- Heavy Equipment Operators
- Hole Drillers Using Hand-Held Drills
- Jackhammer and Impact Drillers
- Masonry Cutters Using Portable Saws
- Masonry Cutters Using Stationary Saws
- Millers Using Portable or Mobile Machines
- Rock and Concrete Drillers
- Rock-Crushing Machine Operators and Tenders
- Tuckpointers and Grinders
- Underground Construction Workers

As shown in ERG (2008a) and in Chapter IV of the PEA, these construction activities occur in the following construction industries, accompanied by their four-digit NAICS codes:[6 7]

- 2361 Residential Building Construction
- 2362 Nonresidential Building Construction
- 2371 Utility System Construction
- 2372 Land Subdivision
- 2373 Highway, Street, and Bridge Construction
- 2379 Other Heavy and Civil Engineering Construction
- 2381 Foundation, Structure, and Building Exterior Contractors
- 2382 Building Equipment Contractors
- 2383 Building Finishing Contractors
- 2389 Other Specialty Trade Contractors

Characteristics of Affected Industries

Table VIII–3 provides an overview of the industries and estimated number of workers affected by the proposed rule. Included in Table VIII–3 are summary statistics for each of the affected industries, subtotals for construction and for general industry and maritime, and grand totals for all affected industries combined.

The first five columns in Table VIII–3 identify each industry in which workers are routinely exposed to respirable crystalline silica (preceded by the industry's NAICS code) and the total number of entities, establishments, and employees for that industry. Note that not all entities, establishments, and employees in these affected industries necessarily engage in activities involving silica exposure.

The next three columns in Table VIII–3 show, for each affected industry, OSHA's estimate of the number of affected entities, establishments, and workers—that is, the number of entities and establishments in which workers are actually exposed to silica and the total number of workers exposed to silica. Based on ERG (2007a, 2007b), OSHA's methodology focused on estimation of the number of affected workers. The number of affected establishments was set equal to the total number of establishments in an industry (based on Census data) unless the number of affected establishments would exceed the number of affected employees in the industry. In that case, the number of affected establishments in the industry was set equal to the number of affected employees, and the number of affected entities in the industry was reduced so as to maintain the same ratio of entities to establishments in the industry.[8]

[6] ERG and OSHA used the four-digit NAICS codes for the construction sector both because the BLS's Occupational Employment Statistics survey only provides data at this level of detail and because, unlike the case in general industry and maritime, job categories in the construction sector are task-specific, not industry-specific. Furthermore, as far as economic impacts are concerned, IRS data on profitability are reported only at the four-digit NAICS code level of detail.

[7] In addition, some public employees in state and local governments are exposed to elevated levels of respirable crystalline silica. These exposures are included in the construction sector because they are the result of construction activities.

[8] OSHA determined that removing this assumption would have a negligible impact on total costs and would reduce the cost and economic impact on the average affected establishment or entity.

TABLE VIII–3—CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR SILICA—ALL ENTITIES

NAICS	Industry	Total entities [a]	Total estab-lish-ments [a]	Total employ-ment [a]	Total affected entities [b]	Total affected establish-ments [b]	Total affected employment [b]	Total FTE affected employees [b]	Total revenues ($1,000) [c]	Revenues per entity	Revenues per establishment
	Construction										
236100	Residential Building Construction	197,600	198,912	966,198	54,973	55,338	55,338	27,669	$374,724,410	$1,896,379	$1,883,870
236200	Nonresidential Building Construction	43,634	44,702	741,978	43,634	44,702	173,939	34,788	313,592,140	7,186,876	7,015,170
237100	Utility System Construction	20,236	21,232	496,628	20,236	21,232	217,070	96,181	98,129,343	4,849,246	4,621,766
237200	Land Subdivision	12,383	12,469	77,406	6,466	6,511	6,511	3,255	24,449,519	1,974,442	1,960,824
237300	Highway, Street, and Bridge Construction	11,081	11,860	325,182	11,081	11,860	204,899	66,916	96,655,241	8,722,610	8,149,683
237900	Other Heavy and Civil Engineering Construction	5,326	5,561	90,167	5,326	5,561	46,813	18,835	19,456,230	3,653,066	3,498,693
238100	Foundation, Structure, and Building Exterior Contractors	116,836	117,456	1,167,986	116,836	117,456	559,729	111,946	157,513,197	1,348,156	1,341,040
238200	Building Equipment Contractors	179,051	182,368	1,940,281	19,988	20,358	20,358	10,179	267,537,377	1,494,196	1,467,019
238300	Building Finishing Contractors	132,219	133,343	975,335	119,000	120,012	120,012	60,006	112,005,298	847,120	839,979
238900	Other Specialty Trade Contractors	73,922	74,446	557,638	73,922	74,446	274,439	137,219	84,184,953	1,138,835	1,130,819
999000	State and local governments [d]	14,397	N/A	5,762,939	14,397	NA	170,068	85,034	N/A	N/A	N/A
	Subtotals—Construction	806,685	802,349	13,101,738	485,859	477,476	1,849,175	652,029	1,548,247,709	1,954,148	1,929,644
	General Industry and Maritime										
324121	Asphalt paving mixture and block manufacturing	480	1,431	14,471	480	1,431	5,043	....	8,909,030	18,560,480	6,225,737
324122	Asphalt shingle and roofing materials	121	224	12,631	121	224	4,395	....	7,168,591	59,244,556	32,002,640
325510	Paint and coating manufacturing [e]	1,093	1,344	46,209	1,093	1,344	3,285	....	24,113,682	22,061,923	17,941,728
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	31	41	5,854	31	41	2,802	....	818,725	26,410,479	19,968,899
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	728	731	9,178	728	731	4,394	....	827,296	1,136,395	1,131,731
327113	Porcelain electrical supply mfg	110	125	6,168	110	125	2,953	....	951,475	8,649,776	7,611,802
327121	Brick and structural clay mfg	104	204	13,509	104	204	5,132	....	2,195,641	21,111,931	10,762,945
327122	Ceramic wall and floor tile mfg	180	193	7,094	180	193	2,695	....	1,217,597	6,764,429	6,308,794
327123	Other structural clay product mfg	45	49	1,603	45	49	609	....	227,406	5,053,461	4,640,933
327124	Clay refractory manufacturing	108	129	4,475	108	129	1,646	....	955,377	8,846,082	7,406,022
327125	Nonclay refractory manufacturing	81	105	5,640	81	105	2,075	....	1,453,869	17,948,999	13,846,371
327211	Flat glass manufacturing	56	83	11,003	56	83	271	....	3,421,674	61,101,328	41,224,993
327212	Other pressed and blown glass and glassware manufacturing	457	499	20,625	457	499	1,034	....	3,395,635	7,430,274	6,804,880
327213	Glass container manufacturing	32	72	14,392	32	72	722	....	4,365,673	136,427,289	60,634,351
327320	Ready-mixed concrete manufacturing	2,470	6,064	107,190	2,470	6,064	43,920	....	27,904,708	11,297,453	4,601,700
327331	Concrete block and brick mfg	599	951	22,738	599	951	10,962	....	5,127,518	8,560,131	5,391,712
327332	Concrete pipe mfg	194	385	14,077	194	385	6,787	....	2,861,038	14,747,620	7,431,268
327390	Other concrete product mfg	1,934	2,281	66,095	1,934	2,281	31,865	....	10,336,178	5,344,456	4,531,424
327991	Cut stone and stone product manufacturing	1,885	1,943	30,633	1,885	1,943	12,085	....	3,507,209	1,860,588	1,805,048
327992	Ground or treated mineral and earth manufacturing	171	271	6,629	171	271	5,051	....	2,205,910	12,900,061	8,139,891
327993	Mineral wool manufacturing	195	321	19,241	195	321	1,090	....	5,734,226	29,406,287	17,863,633
327999	All other misc. nonmetallic mineral product mfg	350	465	10,028	350	465	4,835	....	2,538,560	7,253,028	5,459,268
331111	Iron and steel mills	686	805	108,592	523	614	614	....	53,496,748	77,983,597	66,455,587
331112	Electrometallurgical ferroalloy product manufacturing	22	22	2,198	12	12	12	....	1,027,769	46,716,774	46,716,774
331210	Iron and steel pipe and tube manufacturing from purchased steel.	186	240	21,543	94	122	122	....	7,014,894	37,714,484	29,228,725
331221	Rolled steel shape manufacturing	150	170	10,857	54	61	61	....	4,494,254	29,961,696	26,436,790
331222	Steel wire drawing	232	288	14,669	67	83	83	....	3,496,143	15,069,584	12,139,387
331314	Secondary smelting and alloying of aluminum	119	150	7,381	33	42	42	....	4,139,263	34,783,724	27,595,088
331423	Secondary smelting, refining, and alloying of copper	29	31	1,278	7	7	7	....	765,196	26,386,082	24,683,755
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	195	217	9,383	48	53	53	....	3,012,985	15,451,203	13,884,721
331511	Iron foundries	457	527	59,209	457	527	22,111	....	9,753,093	21,341,560	18,506,818
331512	Steel investment foundries	115	132	16,429	115	132	5,934	....	2,290,472	19,917,147	17,352,060
331513	Steel foundries (except investment)	208	222	17,722	208	222	6,618	....	3,640,441	17,502,121	16,398,383
331524	Aluminum foundries (except die-casting)	441	466	26,565	441	466	9,633	....	3,614,233	8,195,541	7,755,866
331525	Copper foundries (except die-casting)	251	256	6,120	251	256	2,219	....	747,437	2,977,835	2,919,674
331528	Other nonferrous foundries (except die-casting)	119	124	4,710	119	124	1,708	....	821,327	6,901,910	6,623,607
332111	Iron and steel forging	358	398	26,596	135	150	150	....	5,702,872	15,929,811	14,328,825
332112	Nonferrous forging	67	77	8,814	43	50	50	....	2,080,000	31,044,783	27,012,993
332115	Crown and closure manufacturing	50	59	3,243	15	18	18	....	905,206	18,104,119	15,342,473
332116	Metal stamping	1,556	1,641	64,724	347	366	366	....	10,418,233	6,695,523	6,348,710
332117	Powder metallurgy part manufacturing	111	129	8,362	41	47	47	....	1,178,698	10,618,900	9,137,193
332211	Cutlery and flatware (except precious) manufacturing	138	141	5,779	32	33	33	....	1,198,675	8,686,049	8,501,240
332212	Hand and edge tool manufacturing	1,056	1,155	36,622	189	207	207	....	6,382,593	6,044,123	5,526,055
332213	Saw blade and handsaw manufacturing	127	136	7,304	39	41	41	....	1,450,781	11,423,474	10,667,509
332214	Kitchen utensil, pot, and pan manufacturing	64	70	3,928	20	22	22	....	1,226,230	19,159,850	17,517,577
332323	Ornamental and architectural metal work	2,408	2,450	39,947	53	54	54	....	6,402,565	2,658,873	2,613,292
332439	Other metal container manufacturing	364	401	15,195	78	86	86	....	2,817,120	7,739,340	7,025,236

332510	Hardware manufacturing	734	828	45,282	227	256	256		9,268,800	12,627,793	11,194,203
332611	Spring (heavy gauge) manufacturing	109	113	4,059	22	23	23		825,444	7,572,882	7,304,815
332612	Spring (light gauge) manufacturing	270	340	15,336	69	87	87		2,618,283	9,697,344	7,700,832
332618	Other fabricated wire product manufacturing	1,103	1,198	36,364	189	205	205		5,770,701	5,231,823	4,816,946
332710	Machine shops	21,135	21,356	266,597	1,490	1,506	1,506		32,643,382	1,544,518	1,528,534
332812	Metal coating and allied services	2,363	2,599	56,978	2,363	2,599	4,695		11,010,624	4,659,595	4,236,485
332911	Industrial valve manufacturing	394	488	38,330	175	216	216		8,446,768	21,438,497	17,308,951
332912	Fluid power valve and hose fitting manufacturing	306	381	35,519	161	201	201		8,044,008	26,287,608	21,112,882
332913	Plumbing fixture fitting and trim manufacturing	126	144	11,513	57	65	65		3,276,413	26,003,281	22,752,871
332919	Other metal valve and pipe fitting manufacturing	240	268	18,112	91	102	102		3,787,626	15,781,773	14,132,931
332991	Ball and roller bearing manufacturing	107	180	27,197	91	154	154		6,198,871	57,933,374	34,438,172
332996	Fabricated pipe and pipe fitting manufacturing	711	765	27,201	143	154	154		4,879,023	6,862,198	6,377,808
332997	Industrial pattern manufacturing	459	461	5,281	30	30	30		486,947	1,060,887	1,056,285
332998	Enameled iron and metal sanitary ware manufacturing	72	76	5,655	72	76	96		1,036,508	14,395,940	13,638,259
332999	All other miscellaneous fabricated metal product manufacturing.	3,043	3,123	72,201	397	408	408		12,944,345	4,253,811	4,144,843
333319	Other commercial and service industry machinery manufacturing.	1,253	1,349	53,012	278	299	299		12,744,730	10,171,373	9,447,539
333411	Air purification equipment manufacturing	303	351	14,883	72	84	84		2,428,159	8,013,727	6,917,833
333412	Industrial and commercial fan and blower manufacturing	142	163	10,506	52	59	59		1,962,040	13,817,181	12,037,053
333414	Heating equipment (except warm air furnaces) manufacturing	377	407	20,577	108	116	116		4,266,536	11,317,071	10,482,888
333511	Industrial mold manufacturing	2,084	2,126	39,917	221	226	226		4,963,915	2,381,917	2,334,861
333512	Machine tool (metal cutting types) manufacturing	514	530	17,220	94	97	97		3,675,264	7,150,320	6,934,461
333513	Machine tool (metal forming types) manufacturing	274	285	8,556	46	48	48		1,398,993	5,105,812	4,908,746
333514	Special die and tool, die set, jig, and fixture manufacturing	3,172	3,232	57,576	319	325	325		7,232,706	2,280,172	2,237,842
333515	Cutting tool and machine tool accessory manufacturing	1,482	1,552	34,922	188	197	197		4,941,932	3,334,637	3,184,235
333516	Rolling mill machinery and equipment manufacturing	70	73	3,020	17	17	17		652,141	9,316,299	8,933,437
333518	Other metalworking machinery manufacturing	362	383	12,470	67	70	70		2,605,582	7,197,740	6,803,086
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	197	226	12,374	61	70	70		2,280,825	11,577,790	10,092,145
333613	Mechanical power transmission equipment manufacturing	196	231	15,645	75	88	88		3,256,010	16,612,294	14,095,280
333911	Pump and pumping equipment manufacturing	413	490	30,764	147	174	174		7,872,517	19,061,785	16,066,362
333912	Air and gas compressor manufacturing	272	318	21,417	104	121	121		6,305,944	23,183,616	19,830,011
333991	Power-driven handtool manufacturing	137	150	8,714	45	49	49		3,115,514	22,740,979	20,770,094
333992	Welding and soldering equipment manufacturing	250	275	15,853	82	90	90		4,257,678	17,030,713	15,482,466
333993	Packaging machinery manufacturing	583	619	21,179	113	120	120		4,294,579	7,366,345	6,937,931
333994	Industrial process furnace and oven manufacturing	312	335	10,720	56	61	61		1,759,938	5,640,828	5,253,548
333995	Fluid power cylinder and actuator manufacturing	269	319	19,887	95	112	112		3,991,832	14,839,523	12,513,579
333996	Fluid power pump and motor manufacturing	146	178	13,631	63	77	77		3,019,188	20,679,367	16,961,728
333997	Scale and balance (except laboratory) manufacturing	95	102	3,748	20	21	21		694,419	7,309,671	6,808,027
333999	All other miscellaneous general purpose machinery manufacturing.	1,630	1,725	52,454	280	296	296		9,791,511	6,007,062	5,676,238
334518	Watch, clock, and part manufacturing	104	106	2,188	12	12	12		491,114	4,722,250	4,633,151
335211	Electric housewares and household fans	99	105	7,425	20	22	22		2,175,398	21,973,717	20,718,076
335221	Household cooking appliance manufacturing	116	125	16,033	43	47	47		4,461,008	38,456,968	35,688,066
335222	Household refrigerator and home freezer manufacturing	18	26	17,121	18	26	50		4,601,594	255,644,105	176,984,380
335224	Household laundry equipment manufacturing	17	23	16,269	17	23	47		4,792,444	281,908,445	208,367,112
335228	Other major household appliance manufacturing	39	45	12,806	32	37	37		4,549,859	116,663,058	101,107,984
336111	Automobile manufacturing	167	181	75,225	167	181	425		87,308,106	522,803,033	482,365,229
336112	Light truck and utility vehicle manufacturing	63	94	103,815	63	94	587		139,827,543	2,219,484,812	1,487,527,055
336120	Heavy duty truck manufacturing	77	95	32,122	77	95	181		17,387,065	225,806,042	183,021,739
336211	Motor vehicle body manufacturing	728	820	47,566	239	269	269		11,581,029	15,908,007	14,123,206
336212	Truck trailer manufacturing	353	394	32,260	163	182	182		6,313,133	17,884,229	16,023,179
336213	Motor home manufacturing	79	91	21,533	79	91	122		5,600,569	70,893,283	61,544,718
336311	Carburetor, piston, piston ring, and valve manufacturing	102	116	10,537	52	60	60		2,327,226	22,815,945	20,062,296
336312	Gasoline engine and engine parts manufacturing	810	876	66,112	345	373	373		30,440,351	37,580,680	34,749,259
336322	Other motor vehicle electrical and electronic equipment manufacturing.	643	697	62,016	323	350	350		22,222,133	34,560,082	31,882,544
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	214	257	39,390	185	223	223		10,244,934	47,873,524	39,863,557
336340	Motor vehicle brake system manufacturing	188	241	33,782	149	191	191		11,675,801	62,105,323	48,447,306
336350	Motor vehicle transmission and power train parts manufacturing.	432	535	83,756	382	473	473		31,710,273	73,403,409	59,271,538
336370	Motor vehicle metal stamping	635	781	110,578	508	624	624		24,461,822	38,522,554	31,321,154
336399	All other motor vehicle parts manufacturing	1,189	1,458	149,251	687	843	843		42,936,991	36,111,851	29,449,239
336611	Ship building and repair	575	635	87,352	575	635	2,798		14,650,189	25,478,589	23,071,163
336612	Boat building	1,066	1,129	54,705	1,066	1,129	1,752		10,062,908	9,439,876	8,913,116
336992	Military armored vehicle, tank, and tank component manufacturing.	47	57	6,899	32	39	39		2,406,966	51,212,047	42,227,477
337215	Showcase, partition, shelving, and locker manufacturing	1,647	1,733	59,080	317	334	334		8,059,533	4,893,462	4,650,625
339114	Dental equipment and supplies manufacturing	740	763	15,550	399	411	411		3,397,252	4,590,881	4,452,493
339116	Dental laboratories	7,028	7,261	47,088	7,028	7,261	33,214		3,852,293	548,135	530,546
339911	Jewelry (except costume) manufacturing	1,760	1,777	25,280	1,760	1,777	7,813		6,160,238	3,500,135	3,466,650
339913	Jewelers' materials and lapidary work manufacturing	261	264	5,199	261	264	1,607		934,387	3,580,028	3,539,346
339914	Costume jewelry and novelty manufacturing	590	590	6,775	590	590	1,088		751,192	1,273,206	1,273,206

TABLE VIII–3—CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR SILICA—ALL ENTITIES—Continued

NAICS	Industry	Total entities [a]	Total estab-lish-ments [a]	Total employ-ment [a]	Total affected entities [b]	Total affected establish-ments [b]	Total affected employment [b]	Total FTE affected employees [b]	Total revenues ($1,000) [c]	Revenues per entity	Revenues per establishment
339950	Sign manufacturing	6,291	6,415	89,360	487	496	496		11,299,429	1,796,126	1,761,407
423840	Industrial supplies, wholesalers	7,016	10,742	111,198	250	383	383		19,335,522	2,755,918	1,799,993
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	16,895		N/A	N/A	N/A
621210	Dental offices	119,471	124,553	817,396	7,655	7,980	7,980		88,473,742	740,546	710,330
	Subtotals—General Industry and maritime	219,203	238,942	4,406,990	47,007	56,121	294,886		1,101,555,989	5,025,278	4,610,140
	Totals—All Industries	1,025,888	1,041,291	17,508,728	532,866	533,597	2,144,061	652,029	$2,649,803,698	$2,619,701	$2,544,729

a U.S. Census Bureau, Statistics of U.S. Businesses, 2006.

[b] OSHA estimates of employees potentially exposed to silica and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees.

[c] Estimates based on 2002 receipts and payroll data from U.S. Census Bureau, Statistics of U.S. Businesses, 2002, and payroll data from the U.S. Census Bureau, Statistics of U.S. Businesses, 2006. Receipts are not reported for 2006, but were estimated assuming the ratio of receipts to payroll remained unchanged from 2002 to 2006.

[d] State-plan states only. State and local governments are included under the construction sector because the silica risks for public employees are the result of construction-related activities.

[e] OSHA estimates that only one-third of the entities and establishments in this industry, as reported above, use silica-containing inputs.

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG, 2013.

As shown in Table VIII–3, OSHA estimates that a total of 533,000 entities (486,000 in construction; 47,000 in general industry and maritime), 534,000 establishments (477,500 in construction; 56,100 in general industry and maritime), and 2.1 million workers (1.8 million in construction; 0.3 million in general industry and maritime) would be affected by the proposed silica rule. Note that only slightly more than 50 percent of the entities and establishments, and about 12 percent of the workers in affected industries, actually engage in activities involving silica exposure.[9]

The ninth column in Table VIII–3, with data only for construction, shows for each affected NAICS construction industry the number of full-time-equivalent (FTE) affected workers that corresponds to the total number of affected construction workers in the previous column.[10] This distinction is necessary because affected construction workers may spend large amounts of time working on tasks with no risk of silica exposure. As shown in Table VIII–3, the 1.8 million affected workers in construction converts to approximately 652,000 FTE affected workers. In contrast, OSHA based its analysis of the affected workers in general industry and maritime on the assumption that they were engaged full time in activities with some silica exposure.

[9] It should be emphasized that these percentages vary significantly depending on the industry sector and, within an industry sector, depending on the NAICS industry. For example, about 14 percent of the workers in construction, but only 7 percent of workers in general industry, actually engage in activities involving silica exposure. As an example within construction, about 63 percent of workers in highway, street, and bridge construction, but only 3 percent of workers in state and local governments, actually engage in activities involving silica exposure.

[10] FTE affected workers becomes a relevant variable in the estimation of control costs in the construction industry. The reason is that, consistent with the costing methodology, control costs depend only on how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. For the derivation of FTEs, see Tables IV–8 and IV–22 and the associated text in ERG (2007a).

The last three columns in Table VIII–3 show combined total revenues for all entities (not just affected entities) in each affected industry, and the average revenue per entity and per establishment in each affected industry. Because OSHA did not have data to distinguish revenues for affected entities and establishments in any industry, average revenue per entity and average revenue per affected entity (as well as average revenue per establishment and average revenue per affected establishment) are estimated to be equal in value.

Silica Exposure Profile of At-Risk Workers

The technological feasibility analyses presented in Chapter IV of the PEA contain data and discussion of worker exposures to silica throughout industry. Exposure profiles, by job category, were developed from individual exposure measurements that were judged to be substantive and to contain sufficient accompanying description to allow interpretation of the circumstance of each measurement. The resulting exposure profiles show the job categories with current overexposures to silica and, thus, the workers for whom silica controls would be implemented under the proposed rule.

Chapter IV of the PEA includes a section with a detailed description of the methods used to develop the exposure profile and to assess the technological feasibility of the proposed standard. That section documents how OSHA selected and used the data to establish the exposure profiles for each operation in the affected industry sectors, and discusses sources of uncertainly including the following:

- Data Selection—OSHA discusses how exposure samples with sample durations of less than 480 minutes (an 8-hour shift) are used in the analysis.
- Use of IMIS data—OSHA discusses the limitations of data from its Integrated Management Information System.
- Use of analogous information—OSHA discusses how information from one industry or operation is used to describe exposures in other industries or operations with similar characteristics.
- Non-Detects—OSHA discusses how exposure data that is identified as ''less than the LOD (limit of detection)'' is used in the analysis.

OSHA seeks comment on the assumptions and data selection criteria the Agency used to develop the exposure profiles shown in Chapter IV of the PEA.

Table VIII–4 summarizes, from the exposure profiles, the total number of workers at risk from silica exposure at any level, and the distribution of 8-hour TWA respirable crystalline silica exposures by job category for general industry and maritime sectors and for construction activities. Exposures are grouped into the following ranges: less than 25 μg/m^3; ≥ 25 μg/m^3 and ≤ 50 μg/m^3; > 50 μg/m^3 and ≤ 100 μg/m^3; > 100 μg/m^3 and ≤ 250 μg/m^3; and greater than 250 μg/m^3. These frequencies represent the percentages of production employees in each job category and sector currently exposed at levels within the indicated range.

Table VIII–5 presents data by NAICS code—for each affected general, maritime, and construction industry—on the estimated number of workers currently at risk from silica exposure, as well as the estimated number of workers at risk of silica exposure at or above 25 μg/m^3, above 50 μg/m^3, and above 100 μg/m^3. As shown, an estimated 1,026,000 workers (851,000 in construction; 176,000 in general industry and maritime) currently have silica exposures at or above the proposed action level of 25 μg/m^3; an estimated 770,000 workers (648,000 in construction; 122,000 in general industry and maritime) currently have silica exposures above the proposed PEL of 50 μg/m^3; and an estimated 501,000 workers (420,000 in construction; 81,000 in general industry and maritime) currently have silica exposures above 100 μg/m^3—an alternative PEL investigated by OSHA for economic analysis purposes.

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Table VIII-4
Distribution of Silica Exposures by Sector and Job Category or Activity

Sector	Job Category/Activity	Silica Exposure Range <25 μg/m³	25-50 μg/m³	50-100 μg/m³	100-250 μg/m³	>250 μg/m³	Total
Construction							
	Abrasive Blasters	18.6%	11.9%	16.9%	20.3%	32.2%	100.0%
	Drywall Finishers	86.7%	6.7%	6.7%	0.0%	0.0%	100.0%
	Heavy Equipment Operators	79.2%	8.3%	8.3%	4.2%	0.0%	100.0%
	Hole Drillers Using Hand-Held Drills	14.3%	28.6%	35.7%	14.3%	7.1%	100.0%
	Jackhammer and Impact Drillers	18.3%	8.3%	15.6%	24.8%	33.0%	100.0%
	Masonry Cutters Using Portable Saws	24.2%	9.9%	12.1%	38.5%	15.4%	100.0%
	Masonry Cutters Using Stationary Saws	21.4%	25.0%	25.0%	3.6%	25.0%	100.0%
	Millers Using Portable or Mobile Machines	54.3%	20.0%	20.0%	2.9%	2.9%	100.0%
	Rock and Concrete Drillers	35.9%	17.9%	17.9%	17.9%	10.3%	100.0%
	Rock-Crushing Machine Operators and Tenders	0.0%	0.0%	0.0%	20.0%	80.0%	100.0%
	Tuckpointers and Grinders	10.0%	8.5%	11.9%	18.4%	51.2%	100.0%
	Underground Construction Workers	59.3%	18.5%	11.1%	7.4%	3.7%	100.0%
General Industry/Maritime							
Asphalt Paving Products	Front-end loader operator	50.0%	0.0%	50.0%	0.0%	0.0%	100.0%
	Maintenance worker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Plant operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Asphalt Roofing Materials	Material handler	0.0%	28.6%	42.9%	28.6%	0.0%	100.0%
	Production operator	0.0%	60.0%	20.0%	20.0%	0.0%	100.0%
Captive Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Concrete Products	Abrasive blasting operator	13.3%	6.7%	20.0%	26.7%	33.3%	100.0%
	Finishing operator	45.9%	16.2%	10.8%	16.2%	10.8%	100.0%
	Forming Line operator	83.3%	7.1%	7.1%	2.4%	0.0%	100.0%
	Material handler	41.9%	22.6%	19.4%	9.7%	6.5%	100.0%
	Mixer Operator	46.2%	15.4%	0.0%	30.8%	7.7%	100.0%
	Packaging operator	33.3%	0.0%	33.3%	16.7%	16.7%	100.0%
Cut Stone	Abrasive blasting ops	14.3%	28.6%	14.3%	14.3%	28.6%	100.0%
	Fabricator	16.7%	33.3%	8.3%	25.0%	16.7%	100.0%
	Machine operator	11.8%	17.6%	23.5%	35.3%	11.8%	100.0%
	Sawyer	17.4%	26.1%	39.1%	17.4%	0.0%	100.0%
	Splitter/chipper	17.2%	13.8%	20.7%	48.3%	0.0%	100.0%
Dental Equipment	Production operator	33.3%	0.0%	33.3%	33.3%	0.0%	100.0%
Dental Laboratories	Dental technician	83.9%	12.9%	3.2%	0.0%	0.0%	100.0%
Flat Glass	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Iron Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Jewelry	Jewelry workers	37.5%	18.8%	12.5%	18.8%	12.5%	100.0%
Mineral Processing	Production worker	0.0%	82.4%	11.8%	5.9%	0.0%	100.0%
Mineral Wool	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Nonferrous Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%

Table VIII-4
Distribution of Silica Exposures by Sector and Job Category or Activity
(Continued)

Sector	Job Category/Activity	<25 μg/m³	25-50 μg/m³	50-100 μg/m³	100-250 μg/m³	>250 μg/m³	Total
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Non-Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Other Ferrous Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Other Glass Products	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Paint and Coatings	Material handler	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Mixer operator	80.0%	0.0%	0.0%	0.0%	20.0%	100.0%
Porcelain Enameling	Enamel preparer	33.3%	33.3%	33.3%	0.0%	0.0%	100.0%
	Porcelain applicator	52.2%	13.0%	21.7%	0.0%	13.0%	100.0%
Pottery	Coatings operator	18.9%	10.8%	16.2%	32.4%	21.6%	100.0%
	Coatings preparer	5.3%	5.3%	31.6%	26.3%	31.6%	100.0%
	Finishing operator	15.4%	34.6%	19.2%	30.8%	0.0%	100.0%
	Forming Line operator	25.6%	40.0%	14.4%	20.0%	0.0%	100.0%
	Material handler	38.1%	19.0%	19.0%	9.5%	14.3%	100.0%
Railroads	Ballast dumper	50.0%	26.9%	7.7%	7.7%	7.7%	100.0%
	Machine operator	21.0%	38.0%	23.0%	11.0%	7.0%	100.0%
Ready mix	Batch operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Maintenance operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Material handler	75.0%	0.0%	25.0%	0.0%	0.0%	100.0%
	Quality control technician	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Truck driver	0.0%	0.0%	0.0%	0.0%	100.0%	100.0%
Refractories	Ceramic fiber furnace operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Finishing operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Forming operator	45.5%	27.3%	13.6%	13.6%	0.0%	100.0%
	Material handler	33.3%	22.2%	22.2%	18.5%	3.7%	100.0%
	Packaging operator	50.0%	41.7%	0.0%	8.3%	0.0%	100.0%
Refractory Repair	Production operator	20.0%	40.0%	20.0%	20.0%	0.0%	100.0%
Shipyards	Abrasive blasters	0.0%	28.6%	14.3%	14.3%	42.9%	100.0%
Structural Clay	Forming line operator/Coatings blender	10.0%	10.0%	50.0%	30.0%	0.0%	100.0%
	Forming line operator/Formers	27.0%	16.2%	16.2%	29.7%	10.8%	100.0%
	Forming Line operator/Pug mill operator	0.0%	14.3%	14.3%	28.6%	42.9%	100.0%
	Grinding operator	21.4%	7.1%	21.4%	28.6%	21.4%	100.0%
	Material handler/Loader operator	42.9%	0.0%	28.6%	28.6%	0.0%	100.0%
	Material handler/post-production	70.3%	16.2%	10.8%	2.7%	0.0%	100.0%
	Material handler/production	30.0%	20.0%	30.0%	15.0%	5.0%	100.0%

Source: Technological feasibility analysis in Chapter IV of the PEA.

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TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))

NAICS	Industry	Number of establish-ments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
Construction								
236100	Residential Building Construction	198,912	966,198	55,338	32,260	24,445	14,652	7,502
236200	Nonresidential Building Construction	44,702	741,978	173,939	83,003	63,198	39,632	20,504
237100	Utility System Construction	21,232	496,628	217,070	76,687	53,073	28,667	9,783
237200	Land Subdivision	12,469	77,406	6,511	1,745	1,172	560	186

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
237300	Highway, Street, and Bridge Construction.	11,860	325,182	204,899	58,441	39,273	19,347	7,441
237900	Other Heavy and Civil Engineering Construction.	5,561	90,167	46,813	12,904	8,655	4,221	1,369
238100	Foundation, Structure, and Building Exterior Contractors.	117,456	1,167,986	559,729	396,582	323,119	237,537	134,355
238200	Building Equipment Contractors	182,368	1,940,281	20,358	6,752	4,947	2,876	1,222
238300	Building Finishing Contractors	133,343	975,335	120,012	49,202	37,952	24,662	14,762
238900	Other Specialty Trade Contractors	74,446	557,638	274,439	87,267	60,894	32,871	13,718
999000	State and local governments [d]	NA	5,762,939	170,068	45,847	31,080	15,254	5,161
Subtotals—Construction.		802,349	13,101,738	1,849,175	850,690	647,807	420,278	216,003
General Industry and Maritime								
324121	Asphalt paving mixture and block manufacturing.	1,431	14,471	5,043	48	48	0	0
324122	Asphalt shingle and roofing materials	224	12,631	4,395	4,395	1,963	935	0
325510	Paint and coating manufacturing	1,344	46,209	3,285	404	404	404	404
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	41	5,854	2,802	2,128	1,319	853	227
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	731	9,178	4,394	3,336	2,068	1,337	356
327113	Porcelain electrical supply mfg	125	6,168	2,953	2,242	1,390	898	239
327121	Brick and structural clay mfg	204	13,509	5,132	3,476	2,663	1,538	461
327122	Ceramic wall and floor tile mfg	193	7,094	2,695	1,826	1,398	808	242
327123	Other structural clay product mfg	49	1,603	609	412	316	182	55
327124	Clay refractory manufacturing	129	4,475	1,646	722	364	191	13
327125	Nonclay refractory manufacturing	105	5,640	2,075	910	459	241	17
327211	Flat glass manufacturing	83	11,003	271	164	154	64	45
327212	Other pressed and blown glass and glassware manufacturing.	499	20,625	1,034	631	593	248	172
327213	Glass container manufacturing	72	14,392	722	440	414	173	120
327320	Ready-mixed concrete manufacturing	6,064	107,190	43,920	32,713	32,110	29,526	29,526
327331	Concrete block and brick mfg	951	22,738	10,962	5,489	3,866	2,329	929
327332	Concrete pipe mfg	385	14,077	6,787	3,398	2,394	1,442	575
327390	Other concrete product mfg	2,281	66,095	31,865	15,957	11,239	6,769	2,700
327991	Cut stone and stone product manufacturing.	1,943	30,633	12,085	10,298	7,441	4,577	1,240
327992	Ground or treated mineral and earth manufacturing.	271	6,629	5,051	5,051	891	297	0
327993	Mineral wool manufacturing	321	19,241	1,090	675	632	268	182
327999	All other misc. nonmetallic mineral product mfg.	465	10,028	4,835	2,421	1,705	1,027	410
331111	Iron and steel mills	805	108,592	614	456	309	167	57
331112	Electrometallurgical ferroalloy product manufacturing.	22	2,198	12	9	6	3	1
331210	Iron and steel pipe and tube manufacturing from purchased steel.	240	21,543	122	90	61	33	11
331221	Rolled steel shape manufacturing	170	10,857	61	46	31	17	6
331222	Steel wire drawing	288	14,669	83	62	42	23	8
331314	Secondary smelting and alloying of aluminum.	150	7,381	42	31	21	11	4
331423	Secondary smelting, refining, and alloying of copper.	31	1,278	7	5	4	2	1
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	217	9,383	53	39	27	14	5
331511	Iron foundries	527	59,209	22,111	16,417	11,140	6,005	2,071
331512	Steel investment foundries	132	16,429	5,934	4,570	3,100	1,671	573
331513	Steel foundries (except investment)	222	17,722	6,618	4,914	3,334	1,797	620
331524	Aluminum foundries (except die-casting)	466	26,565	9,633	7,418	5,032	2,712	931
331525	Copper foundries (except die-casting)	256	6,120	2,219	1,709	1,159	625	214
331528	Other nonferrous foundries (except die-casting).	124	4,710	1,708	1,315	892	481	165
332111	Iron and steel forging	398	26,596	150	112	76	41	14
332112	Nonferrous forging	77	8,814	50	37	25	13	5
332115	Crown and closure manufacturing	59	3,243	18	14	9	5	2
332116	Metal stamping	1,641	64,724	366	272	184	99	34
332117	Powder metallurgy part manufacturing	129	8,362	47	35	24	13	4
332211	Cutlery and flatware (except precious) manufacturing.	141	5,779	33	24	16	9	3
332212	Hand and edge tool manufacturing	1,155	36,622	207	154	104	56	19
332213	Saw blade and handsaw manufacturing	136	7,304	41	31	21	11	4
332214	Kitchen utensil, pot, and pan manufacturing.	70	3,928	22	17	11	6	2

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establish-ments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
332323	Ornamental and architectural metal work.	2,450	39,947	54	26	19	7	7
332439	Other metal container manufacturing	401	15,195	86	64	43	23	8
332510	Hardware manufacturing	828	45,282	256	190	129	69	24
332611	Spring (heavy gauge) manufacturing	113	4,059	23	17	12	6	2
332612	Spring (light gauge) manufacturing	340	15,336	87	64	44	24	8
332618	Other fabricated wire product manufacturing.	1,198	36,364	205	153	104	56	19
332710	Machine shops	21,356	266,597	1,506	1,118	759	409	141
332812	Metal coating and allied services	2,599	56,978	4,695	2,255	1,632	606	606
332911	Industrial valve manufacturing	488	38,330	216	161	109	59	20
332912	Fluid power valve and hose fitting manufacturing.	381	35,519	201	149	101	55	19
332913	Plumbing fixture fitting and trim manufacturing.	144	11,513	65	48	33	18	6
332919	Other metal valve and pipe fitting manufacturing.	268	18,112	102	76	51	28	10
332991	Ball and roller bearing manufacturing	180	27,197	154	114	77	42	14
332996	Fabricated pipe and pipe fitting manufacturing.	765	27,201	154	114	77	42	14
332997	Industrial pattern manufacturing	461	5,281	30	22	15	8	3
332998	Enameled iron and metal sanitary ware manufacturing.	76	5,655	96	56	38	16	11
332999	All other miscellaneous fabricated metal product manufacturing.	3,123	72,201	408	303	205	111	38
333319	Other commercial and service industry machinery manufacturing.	1,349	53,012	299	222	151	81	28
333411	Air purification equipment manufacturing	351	14,883	84	62	42	23	8
333412	Industrial and commercial fan and blower manufacturing.	163	10,506	59	44	30	16	6
333414	Heating equipment (except warm air furnaces) manufacturing.	407	20,577	116	86	59	32	11
333511	Industrial mold manufacturing	2,126	39,917	226	168	114	61	21
333512	Machine tool (metal cutting types) manufacturing.	530	17,220	97	72	49	26	9
333513	Machine tool (metal forming types) manufacturing.	285	8,556	48	36	24	13	5
333514	Special die and tool, die set, jig, and fixture manufacturing.	3,232	57,576	325	241	164	88	30
333515	Cutting tool and machine tool accessory manufacturing.	1,552	34,922	197	146	99	54	18
333516	Rolling mill machinery and equipment manufacturing.	73	3,020	17	13	9	5	2
333518	Other metalworking machinery manufacturing.	383	12,470	70	52	35	19	7
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	226	12,374	70	52	35	19	7
333613	Mechanical power transmission equipment manufacturing.	231	15,645	88	66	44	24	8
333911	Pump and pumping equipment manufacturing.	490	30,764	174	129	88	47	16
333912	Air and gas compressor manufacturing	318	21,417	121	90	61	33	11
333991	Power-driven handtool manufacturing	150	8,714	49	37	25	13	5
333992	Welding and soldering equipment manufacturing.	275	15,853	90	67	45	24	8
333993	Packaging machinery manufacturing	619	21,179	120	89	60	32	11
333994	Industrial process furnace and oven manufacturing.	335	10,720	61	45	31	16	6
333995	Fluid power cylinder and actuator manufacturing.	319	19,887	112	83	57	31	11
333996	Fluid power pump and motor manufacturing.	178	13,631	77	57	39	21	7
333997	Scale and balance (except laboratory) manufacturing.	102	3,748	21	16	11	6	2
333999	All other miscellaneous general purpose machinery manufacturing.	1,725	52,454	296	220	149	80	28
334518	Watch, clock, and part manufacturing	106	2,188	12	9	6	3	1
335211	Electric housewares and household fans.	105	7,425	22	10	8	3	3
335221	Household cooking appliance manufacturing.	125	16,033	47	22	16	6	6
335222	Household refrigerator and home freezer manufacturing.	26	17,121	50	24	17	7	7
335224	Household laundry equipment manufacturing.	23	16,269	47	23	17	6	6
335228	Other major household appliance manufacturing.	45	12,806	37	18	13	5	5
336111	Automobile manufacturing	181	75,225	425	316	214	115	40

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
336112	Light truck and utility vehicle manufacturing.	94	103,815	587	436	296	159	55
336120	Heavy duty truck manufacturing	95	32,122	181	135	91	49	17
336211	Motor vehicle body manufacturing	820	47,566	269	200	135	73	25
336212	Truck trailer manufacturing	394	32,260	182	135	92	50	17
336213	Motor home manufacturing	91	21,533	122	90	61	33	11
336311	Carburetor, piston, piston ring, and valve manufacturing.	116	10,537	60	44	30	16	6
336312	Gasoline engine and engine parts manufacturing.	876	66,112	373	277	188	101	35
336322	Other motor vehicle electrical and electronic equipment manufacturing.	697	62,016	350	260	176	95	33
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	257	39,390	223	165	112	60	21
336340	Motor vehicle brake system manufacturing.	241	33,782	191	142	96	52	18
336350	Motor vehicle transmission and power train parts manufacturing.	535	83,756	473	351	238	128	44
336370	Motor vehicle metal stamping	781	110,578	624	464	315	170	58
336399	All other motor vehicle parts manufacturing.	1,458	149,251	843	626	425	229	79
336611	Ship building and repair	635	87,352	2,798	2,798	1,998	1,599	1,199
336612	Boat building	1,129	54,705	1,752	1,752	1,252	1,001	751
336992	Military armored vehicle, tank, and tank component manufacturing.	57	6,899	39	29	20	11	4
337215	Showcase, partition, shelving, and locker manufacturing.	1,733	59,080	334	248	168	91	31
339114	Dental equipment and supplies manufacturing.	763	15,550	411	274	274	137	0
339116	Dental laboratories	7,261	47,088	33,214	5,357	1,071	0	0
339911	Jewelry (except costume) manufacturing.	1,777	25,280	7,813	4,883	3,418	2,442	977
339913	Jewelers' materials and lapidary work manufacturing.	264	5,199	1,607	1,004	703	502	201
339914	Costume jewelry and novelty manufacturing.	590	6,775	1,088	685	479	338	135
339950	Sign manufacturing	6,415	89,360	496	249	172	57	57
423840	Industrial supplies, wholesalers	10,742	111,198	383	306	153	77	0
482110	Rail transportation	NA	NA	16,895	11,248	5,629	2,852	1,233
621210	Dental offices	124,553	817,396	7,980	1,287	257	0	0
Subtotals—General Industry and Maritime.		238,942	4,406,990	294,886	175,801	122,472	80,731	48,956
Totals		1,041,291	17,508,728	2,144,061	1,026,491	770,280	501,009	264,959

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Table III–5 and the technological feasibility analysis presented in Chapter IV of the PEA.

D. Technological Feasibility Analysis of the Proposed Permissible Exposure Limit to Crystalline Silica Exposures

Chapter IV of the Preliminary Economic Analysis (PEA) provides the technological feasibility analysis that guided OSHA's selection of the proposed PEL, consistent with the requirements of the Occupational Safety and Health Act (''OSH Act''), 29 U.S.C. 651 et seq. Section 6(b)(5) of the OSH Act requires that OSHA ''set the standard which most adequately assures, *to the extent feasible,* on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity.'' 29 U.S.C. 655(b)(5) (emphasis added). The Court of Appeals for the D.C. Circuit has clarified the Agency's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance:

> OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators . . . Insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility. Rather, in such operations firms will remain responsible for installing engineering and work practice controls to the extent feasible, and for using them to reduce . . . exposure as far as these controls can do so.

United Steelworkers of America, AFL–CIO–CIC v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980).

Additionally, the D.C. Circuit has explained that ''[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time. . . .'' *American Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 990 (D.C. Cir. 1991).

To demonstrate the limits of feasibility, OSHA's analysis examines the technological feasibility of the proposed PEL of 50 μg/m³, as well as the technological feasibility of an alternative PEL of 25 μg/m³. In total, OSHA analyzed technological feasibility in 108 operations in general industry, maritime, and construction industries. This analysis addresses two different aspects of technological feasibility: (1) The extent to which engineering controls can reduce and maintain exposures; and (2) the capability of existing sampling and analytical methods to measure silica exposures. The discussion below summarizes the findings in Chapter IV of the PEA (*see* Docket No. OSHA–2010–0034).

Methodology

The technological feasibility analysis relies on information from a wide variety of sources. These sources include published literature, OSHA inspection reports, NIOSH reports and engineering control feasibility studies, and information from other federal agencies, state agencies, labor organizations, industry associations, and other groups. OSHA has limited the analysis to job categories that are associated with substantial direct silica exposure. The technological feasibility analyses group the general industry and maritime workplaces into 23 industry sectors.[11] The Agency has divided each industry sector into specific job categories on the basis of common materials, work processes, equipment, and available exposure control methods. OSHA notes that these job categories are intended to represent job functions; actual job titles and responsibilities might differ depending on the facility.

OSHA has organized the construction industry by grouping workers into 12 general construction activities. The Agency organized construction workers into general activities that create silica exposures rather than organizing them by job titles because construction workers often perform multiple activities and job titles do not always coincide with the sources of exposure. In organizing construction worker activity this way, OSHA was able to create a more accurate exposure profile and apply control methods to workers who perform these activities in any segment of the construction industry.

The exposure profiles include silica exposure data only for workers in the United States. Information on international exposure levels is occasionally referenced for perspective or in discussions of control options. It is important to note that the vast majority of crystalline silica encountered by workers in the United States is in the quartz form, and the terms crystalline silica and quartz are often used interchangeably. Unless specifically indicated otherwise, all silica exposure data, samples, and results discussed in the technological feasibility analysis refer to measurements of personal breathing zone (PBZ) respirable crystalline silica.

In general and maritime industries, the exposure profiles in the technological feasibility analysis consist mainly of full-shift samples, collected over periods of 360 minutes or more. By using full-shift sampling results, OSHA minimizes the number of results that are less than the limit of detection (LOD) and eliminates the ambiguity associated with the LOD for low air volume samples. Thus, results that are reported in the original data source as below the LOD are included without contributing substantial uncertainty regarding their relationship to the proposed PEL. This is particularly important for general industry samples, which on average have lower silica levels than typical results for many tasks in the construction industry.

In general and maritime industries, the exposure level for the period sampled is assumed to have continued over any unsampled portion of the worker's shift. OSHA has preliminarily determined that this sample criterion is valid because workers in these industries are likely to work at the same general task or same repeating set of tasks over most of their shift; thus, unsampled periods generally are likely to be similar to the sampled periods.

In the construction industry, much of the data analyzed for the defined activities consisted of full-shift samples collected over periods of 360 minutes or more. Construction workers are likely to spend a shift working at multiple discrete tasks, independent of occupational titles, and do not normally engage in those discrete tasks for the entire duration of a shift. Therefore, the Agency occasionally included partial-shift samples (periods of less than 360 minutes), but has limited the use of partial-shift samples with results below the LOD, giving preference to data covering a greater part of the workers' shifts.

OSHA believes that the partial-shift samples were collected for the entire duration of the task and that the exposure to silica ended when the task was completed. Therefore, OSHA assumes that the exposure to silica was zero for the remaining unsampled time. OSHA understands that this may not always be the case, and that there may be activities other than the sampled tasks that affect overall worker exposures, but the documentation regarding these factors is insufficient to use in calculating a time-weighted average. It is important to note, however, that the Agency has identified to the best of its ability the construction activities that create significant exposures to respirable crystalline silica.

In cases where exposure information from a specific job category is not available, OSHA has based that portion of the exposure profile on surrogate data from one or more similar job categories in related industries. The surrogate data is selected based on strong similarities of raw materials, equipment, worker activities, and exposure duration between the job categories. When used, OSHA has clearly identified the surrogate data and the relationship between the industries or job categories.

1. Feasibility Determination of Sampling and Analytical Methods

As part of its technological feasibility analysis, OSHA examined the capability of currently available sampling methods and sensitivity[12] and precision of currently available analytical methods to measure respirable crystalline silica (please refer to the ''Feasibility of Measuring Respirable Crystalline Silica Exposures at The Proposed PEL'' section in Chapter IV of the PEA). The Agency understands that several commercially available personal sampling cyclones exist that can be operated at flow rates that conform to the ISO/CEN particle size selection criteria with an acceptable level of bias. Some of these sampling devices are the Dorr-Oliver, Higgens-Dowel, BGI GK 2.69, and the SKC G–3 cyclones. Bias against the ISO/CEN criteria will fall within ±20 percent, and often is within ±10 percent.

Additionally, the Agency preliminarily concludes that all of the mentioned cyclones are capable of allowing a sufficient quantity of quartz to be collected from atmospheric concentrations as low as 25 μg/m³ to exceed the limit of quantification for the OSHA ID–142 analytical method, provided that a sample duration is at least 4 hours. Furthermore, OSHA believes that these devices are also capable of collecting more than the minimum amount of cristobalite at the proposed PEL and action level

[11] Note that OSHA's technological feasibility analysis contains 21 general industry sections. The number is expanded to 23 in this summary because Table VIII.D–1 describes the foundry industry as three different sectors (ferrous, nonferrous, and non-sand casting foundries) to provide a more detailed analysis of exposures.

[12] Note that sensitivity refers to the smallest quantity that can be measured with a specified level of accuracy, expressed either as the limit of detection or limit of quantification.

necessary for quantification with OSHA's method ID–142 for a full shift. One of these cyclones (GK 2.69) can also collect an amount of cristobalite exceeding OSHA's limit of quantification (LOQ) with a 4-hour sample at the proposed PEL and action level.

Regarding analytical methods to measure silica, OSHA investigated the sensitivity and precision of available methods. The Agency preliminarily concludes that the X-Ray Diffraction (XRD) and Infrared Spectroscopy (IR) methods of analysis are both sufficiently sensitive to quantify levels of quartz and cristobalite that would be collected on air samples taken from concentrations at the proposed PEL and action level. Available information shows that poor inter-laboratory agreement and lack of specificity render colorimetric spectrophotometry (another analytical method) inferior to XRD or IR techniques. As such, OSHA is proposing not to permit employers to rely on exposure monitoring results based on analytical methods that use colorimetric methods.

For the OSHA XRD Method ID–142 (revised December 1996), precision is ±23 percent at a working range of 50 to 160 μg crystalline silica, and the SAE (sampling and analytical error) is ±19 percent. The NIOSH and MSHA XRD and IR methods report a similar degree of precision. OSHA's Salt Lake Technical Center (SLTC) evaluated the precision of ID–142 at lower filter loadings and has shown an acceptable level of precision is achieved at filter loadings of approximately 40 μg and 20 μg corresponding to the amounts collected from full-shift sampling at the proposed PEL and action level, respectively. This analysis showed that at filter loadings corresponding to the proposed PEL, the precision and SAE for quartz are ±17 and ±14 percent, respectively. For cristobalite, the precision and SAE are ±19 and ±16 percent, respectively. These results indicate that employers can have confidence in sampling results for the purpose of assessing compliance with the PEL and identifying when additional engineering and work practice controls and/or respiratory protection are needed.

For example, given an SAE for quartz of 0.14 at a filter load of 40 μg, employers can be virtually certain that the PEL is not exceeded where exposures are less than 43 μg/m^3, which represents the lower 95-percent confidence limit (*i.e.,* 50 μg/m^3 minus 50*0.14). At 43 μg/m^3, a full-shift sample that collects 816 L of air will result in a filter load of 35 μg of quartz, or more than twice the LOQ for Method ID–142. Thus, OSHA believes that the method is sufficiently sensitive and precise to allow employers to distinguish between operations that have sufficient dust control to comply with the PEL from those that do not. Finally, OSHA's analysis of PAT data indicates that most laboratories achieve good agreement in results for samples having filter loads just above 40 μg quartz (49–70 μg).

At the proposed action level, the study by SLTC found the precision and SAE of the method for quartz at 20 μg to be ±19 and ±16 percent, respectively. For cristobalite, the precision and SAE at 20 μg were also ±19 and ±16 percent, respectively. OSHA believes that these results show that Method ID–142 can achieve a sufficient degree of precision for the purpose of identifying those operations where routine exposure monitoring should be conducted.

However, OSHA also believes that limitations in the characterization of the precision of the analytical method in this range of filter load preclude the Agency from proposing a PEL of 25 μg/m^3 at this time. First, the measurement error increases by about 4 to 5 percent for a full-shift sample taken at 25 μg/m^3 compared to one taken at 50 μg/m^3, and the error would be expected to increase further as filter loads approach the limit of detection. Second, for an employer to be virtually certain that an exposure to quartz did not exceed 25 μg/m^3 as an exposure limit, the exposure would have to be below 21 μg/m^3 given the SAE of ±16 percent calculated from the SLTC study. For a full-shift sample of 0.816 L of air, only about 17 μg of quartz would be collected at 21 μg/m^3, which is near the LOQ for Method ID–142 and at the maximum acceptable LOD that would be required by the proposed rule. Thus, given a sample result that is below a laboratory's reported LOD, employers might not be able to rule out whether a PEL of 25 μg/m^3 was exceeded.

Finally, there are no available data that describe the total variability seen between laboratories at filter loadings in the range of 20 μg crystalline silica since the lowest filter loading used in PAT samples is about 50 μg. Given these considerations, OSHA believes that a PEL of 50 μg/m^3 is more appropriate in that employers will have more confidence that sampling results are properly informing them where additional dust controls and respiratory protection is needed.

Based on the evaluation of the nationally recognized sampling and analytical methods for measuring respirable crystalline silica presented in the section titled "Feasibility of Measuring Respirable Crystalline Silica Exposures at The Proposed PEL" in Chapter IV of the PEA, OSHA preliminarily concludes that it is technologically feasible to reliably measure exposures of workers at the proposed PEL of 50 μg/m^3 and action level of 25 μg/m^3. OSHA notes that the sampling and analytical error is larger at the proposed action level than that for the proposed PEL. In the "Issues" section of this preamble (*see* Provisions of the Standards—Exposure Assessment), OSHA solicits comments on whether measurements of exposures at the proposed action level and PEL are sufficiently precise to permit employers to adequately determine when additional exposure monitoring is necessary under the standard, when to provide workers with the required medical surveillance, and when to comply with all other requirements of the proposed standard. OSHA also solicits comments on the appropriateness of specific requirements in the proposed standard for laboratories that perform analyses of respirable crystalline silica samples to reduce the variability between laboratories.

2. Feasibility Determination of Control Technologies

The Agency has conducted a feasibility analysis for each of the identified 23 general industry sectors and 12 construction industry activities that are potentially affected by the proposed silica standard. Additionally, the Agency identified 108 operations within those sectors/activities and developed exposure profiles for each operation, except for two industries, engineered stone products and landscape contracting industries. For these two industries, data satisfying OSHA's criteria for inclusion in the exposure profile were unavailable (refer to the Methodology section in Chapter 4 of the PEA for criteria). However, the Agency obtained sufficient information in both of these industries to make feasibility determinations (*see* Chapter IV Sections C.7 and C.11 of the PEA). Each feasibility analysis contains a description of the applicable operations, the baseline conditions for each operation (including the respirable silica samples collected), additional controls necessary to reduce exposures, and final feasibility determinations for each operation.

3. Feasibility Findings for the Proposed Permissible Exposure Limit of 50 μg/m^3

Tables VIII–6 and VIII–7 summarize all the industry sectors and construction activities studied in the technological feasibility analysis and show how many operations within each can achieve levels of 50 μg/m³ through the implementation of engineering and work practice controls. The tables also summarize the overall feasibility finding for each industry sector or construction activity based on the number of feasible versus not feasible operations. For the general industry sector, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For the construction activities, OSHA has determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls (seven out of 108 operations, *see* Tables VIII–6 and VIII–7), employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

4. Feasibility Findings for an Alternative Permissible Exposure Limit of 25 μg/m³

Based on the information presented in the technological feasibility analysis, OSHA believes that engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to PELs lower than 50 μg/m³. The Agency believes that a proposed PEL of 25 μg/m³, for example, would not be feasible for many industries, and to use respiratory protection would have to be required in most operations and most of the time to achieve compliance.

However, OSHA has data indicating that an alternative PEL of 25 μg/m³ has already been achieved in several industries (*e.g.* asphalt paving products, dental laboratories, mineral processing, and paint and coatings manufacturing in general industry, and drywall finishers and heavy equipment operators in construction). In these industries, airborne respirable silica concentrations are inherently low because either small amounts of silica containing materials are handled or these materials are not subjected to high energy processes that generate large amounts of respirable dust.

For many of the other industries, OSHA believes that engineering and work practice controls will not be able to reduce and maintain exposures to an alternative PEL of 25 μg/m³ in most operations and most of the time. This is especially the case in industries that use silica containing material in substantial quantities and industries with high energy operations. For example, in general industry, the ferrous foundry industry would not be able to comply with an alternative PEL of 25 μg/m³ without widespread respirator use. In this industry, silica containing sand is transported, used, and recycled in significant quantities to create castings, and as a result, workers can be exposed to high levels of silica in all steps of the production line. Additionally, some high energy operations in foundries create airborne dust that causes high worker exposures to silica. One of these operations is the shakeout process, where operators monitor equipment that separates castings from mold materials by mechanically vibrating or tumbling the casting. The dust generated from this process causes elevated silica exposures for shakeout operators and often contributes to exposures for other workers in a foundry. For small, medium, and large castings, exposure information with engineering controls in place show that exposures below 50 μg/m³ can be consistently achieved, but exposures above an alternative PEL of 25 μg/m³ still occur. With engineering controls in place, exposure data for these operations range from 13 μg/m³ to 53 μg/m³, with many of the reported exposures above 25 μg/m³.

In the construction industry, OSHA estimates that an alternative PEL of 25 μg/m³ would be infeasible in most operations because most of them are high energy operations that produce significant levels of dust, causing workers to have elevated exposures, and available engineering controls would not be able to maintain exposures at or below the alternative PEL most of the time. For example, jackhammering is a high energy operation that creates a large volume of silica containing dust, which disburses rapidly in highly disturbed air. OSHA estimates that the exposure levels of most workers operating jackhammers outdoors will be reduced to less that 100 μg/m³ as an 8-hour TWA, by using either wet methods or LEV paired with a suitable vacuum.

OSHA believes that typically, the majority of jackhammering is performed for less than four hours of a worker's shift, and in these circumstances the Agency estimates that most workers will experience levels below 50 μg/m³. Jackhammer operators who work indoors or with multiple jackhammers will achieve similar results granted that the same engineering controls are used and that fresh air circulation is provided to prevent accumulation of respirable dust in a worker's vicinity. OSHA does not have any data indicating that these control strategies would reduce exposures of most workers to levels of 25 μg/m³ or less.

5. Overall Feasibility Determination

Based on the information presented in the technological feasibility analysis, the Agency believes that 50 μg/m³ is the lowest feasible PEL. An alternative PEL of 25 μg/m³ would not be feasible because the engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to levels below 25 μg/m³ in most operations most of the time. OSHA believes that an alternative PEL of 25 μg/m³ would not be feasible for many industries, and that the use of respiratory protection would be necessary in most operations most of the time to achieve compliance. Additionally, the current methods of sampling analysis create higher errors and lower precision in measurement as concentrations of silica lower than the proposed PEL are analyzed. However, the Agency preliminarily concludes that these sampling and analytical methods are adequate to permit employers to comply with all applicable requirements triggered by the proposed action level and PEL.

TABLE VIII–6—SUMMARY OF TECHNOLOGICAL FEASIBILITY OF CONTROL TECHNOLOGIES IN GENERAL AND MARITIME INDUSTRIES AFFECTED BY SILICA EXPOSURES

Industry sector	Total number of affected operations	Number of operations for which the proposed PEL is achievable with engineering controls and work practice controls	Number of operations for which the proposed PEL is *NOT* achievable with engineering controls and work practice controls	Overall feasibility finding for industry sector
Asphalt Paving Products	3	3	0	Feasible.
Asphalt Roofing Materials	2	2	0	Feasible.
Concrete Products	6	5	1	Feasible.
Cut Stone	5	5	0	Feasible.
Dental Equipment and Suppliers	1	1	0	Feasible.
Dental Laboratories	1	1	0	Feasible.
Engineered Stone Products	1	1	0	Feasible.
Foundries: Ferrous*	12	12	0	Feasible.
Foundries: Nonferrous*	12	12	0	Feasible.
Foundries: Non-Sand Casting*	11	11	0	Feasible.
Glass	2	2	0	Feasible.
Jewelry	1	1	0	Feasible.
Landscape Contracting	1	1	0	Feasible.
Mineral Processing	1	1	0	Feasible.
Paint and Coatings	2	2	0	Feasible.
Porcelain Enameling	2	2	0	Feasible.
Pottery	5	5	0	Feasible.
Railroads	5	5	0	Feasible.
Ready-Mix Concrete	5	4	1	Feasible.
Refractories	5	5	0	Feasible.
Refractory Repair	1	1	0	Feasible.
Shipyards (Maritime Industry)	2	1	1	Feasible.
Structural Clay	3	3	0	Feasible.
Totals	89	96.6%	3.4%	

* Section 8 of the Technological Feasibility Analysis includes four subsectors of the foundry industry. Each subsector includes its own exposure profile and feasibility analysis in that section. This table lists three of those four subsectors individually based on the difference in casting processes used and subsequent potential for silica exposure. The table does not include captive foundries because the captive foundry operations are incorporated into the larger manufacturing process of the parent foundry.

TABLE VIII–7—SUMMARY OF TECHNOLOGICAL FEASIBILITY OF CONTROL TECHNOLOGIES IN CONSTRUCTION ACTIVITIES AFFECTED BY SILICA EXPOSURES

Construction activity	Total number of affected operations	Number of operations for which the proposed PEL is achievable with engineering controls and work practice controls	Number of operations for which the proposed PEL is *NOT* achievable with engineering controls and work practice controls	Overall feasibility finding for activity
Abrasive Blasters	2	0	2	Not Feasible.
Drywall Finishers	1	1	0	Feasible.
Heavy Equipment Operators	1	1	0	Feasible.
Hole Drillers Using Hand-Held Drills	1	1	0	Feasible.
Jackhammer and Impact Drillers	1	1	0	Feasible.
Masonry Cutters Using Portable Saws	3	3	0	Feasible.
Masonry Cutters Using Stationary Saws	1	1	0	Feasible.
Millers Using Portable and Mobile Machines	3	3	0	Feasible.
Rock and Concrete Drillers	1	1	0	Feasible.
Rock-Crushing Machine Operators and Tenders	1	1	0	Feasible.
Tuckpointers and Grinders	3	1	2	Not Feasible.
Underground Construction Workers	1	1	0	Feasible.
Totals	19	78.9%	21.1%	

E. Costs of Compliance

Chapter V of the PEA in support of the proposed silica rule provides a detailed assessment of the costs to establishments in all affected industry sectors of reducing worker exposures to silica to an eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 50 μg/m³ and of complying with the proposed standard's ancillary requirements. The discussion below summarizes the findings in the PEA cost chapter. OSHA's preliminary cost assessment is based on the Agency's technological feasibility analysis presented in Chapter IV of the PEA (2013); analyses of the costs of the proposed standard conducted by OSHA's contractor, Eastern Research Group (ERG, 2007a, 2007b, and 2013); and the comments submitted to the docket as part of the SBREFA panel process.

OSHA estimates that the proposed rule will cost $657.9 million per year in 2009 dollars. Costs originally estimated for earlier years were adjusted to 2009 dollars using the appropriate price indices. All costs are annualized using a discount rate of 7 percent. (A sensitivity analysis using discount rates of 3 percent and 0 percent is presented in the discussion of net benefits.) One-time costs are annualized over 10-year annualization period, and capital goods are annualized over the life of the equipment. OSHA has historically annualized one-time costs over at least a 10-year period, which approximately reflects the average life of a business in the United States. (The Agency has chosen a longer annualization period under special circumstances, such as when a rule involves longer and more complex phase-in periods. In general, a longer annualization period, in such cases, will tend to reduce annualized costs slightly.)

The estimated costs for the proposed silica standard rule include the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

Table VIII–8 provides the annualized costs of the proposed rule by cost category for general industry, maritime, and construction. As shown in Table VIII–8, of the total annualized costs of the proposed rule, $132.5 million would be incurred by general industry, $14.2 million by maritime, and $511.2 million by construction.

Table VIII–9 shows the annualized costs of the proposed rule by cost category and by industry for general industry and maritime, and Table VIII–10 shows the annualized costs similarly disaggregated for construction. These tables show that engineering control costs represent 69 percent of the costs of the proposed standard for general industry and maritime and 47 percent of the costs of the proposed standard for construction. Considering other leading cost categories, costs for exposure assessment and respirators represent, respectively, 20 percent and 5 percent of the costs of the proposed standard for general industry and maritime; costs for respirators and medical surveillance represent, respectively, 16 percent and 15 percent of the costs of the proposed standard for construction.

While the costs presented here represent the Agency's best estimate of the costs to industry of complying with the proposed rule under static conditions (that is, using existing technology and the current deployment of workers), OSHA recognizes that the actual costs could be somewhat higher or lower, depending on the Agency's possible overestimation or underestimation of various cost factors. In Chapter VII of the PEA, OSHA provides a sensitivity analysis of its cost estimates by modifying certain critical unit cost factors. Beyond the sensitivity analysis, however, OSHA believes its cost estimates may significantly overstate the actual costs of the proposed rule because, in response to the rule, industry may be able to take two types of actions to reduce compliance costs.

First, in construction, 53 percent of the estimated costs of the proposed rule (all costs except engineering controls) vary directly with the number of workers exposed to silica. However, as shown in Table VIII–3 of this preamble, almost three times as many construction workers would be affected by the proposed rule as would the number of full-time-equivalent construction workers necessary to do the work. This is because most construction workers currently do work involving silica exposure for only a portion of their workday. In response to the proposed rule, many employers are likely to assign work so that fewer construction workers perform tasks involving silica exposure; correspondingly, construction work involving silica exposure will tend to become a full-time job for some construction workers.[13] Were this approach fully implemented in construction, the actual cost of the proposed rule would decline by over 25 percent, or by $180 million annually, to under $480 million annually.[14]

Second, the costs presented here do not take into account the likely development and dissemination of cost-reducing compliance technology in response to the proposed rule.[15] One possible example is the development of safe substitutes for silica sand in abrasive blasting operations, repair and replacement of refractory materials, foundry operations, and the railroad transportation industry. Another is expanded uses of automated processes, which would allow workers to be isolated from the points of operation that involve silica exposure (such as tasks between the furnace and the pouring machine in foundries and at sand transfer stations in structural clay production facilities). Yet another example is the further development and use of bags with valves that seal effectively when filled, thereby preventing product leakage and worker exposure (for example, in mineral processing and concrete products industries). Probably the most pervasive and significant technological advances, however, will likely come from the integration of compliant control technology into production equipment as standard equipment. Such advances would both increase the effectiveness and reduce the costs of silica controls retrofitted to production equipment. Possible examples include local exhaust ventilation (LEV) systems attached to portable tools used by grinders and tuckpointers; enclosed operator cabs equipped with air filtration and air conditioning in industries that mechanically transfer silica or silica-containing materials; and machine-integrated wet dust suppression systems used, for example, in road milling operations. Of course, all the possible technological advances in response to the proposed rule and their effects on costs are difficult to predict.[16]

OSHA has decided at this time not to create a more dynamic and predictive analysis of possible cost-reducing

[13] There are numerous instances of job reassignments and job specialties arising in response to OSHA regulation. For example, asbestos removal and confined space work in construction have become activities performed by well-trained specialized employees, not general laborers (whose only responsibility is to identify the presence of asbestos or a confined space situation and then to notify the appropriate specialist).

[14] OSHA expected that such a structural change in construction work assignments would not have a significant effect on the benefits of the proposed rule. As discussed in Chapter VII of the PEA, the benefits of the proposed rule are relatively insensitive to changes in average occupational tenure or how total silica exposure in an industry is distributed among individual workers.

[15] Evidence of such technological responses to regulation is widespread (see for example Ashford, Ayers, and Stone (1985), OTA (1995), and OSHA's regulatory reviews of existing standards under § 610 of the Regulatory Flexibility Act (''610 lookback reviews'')).

[16] A dramatic example from OSHA's 610 lookback review of its 1984 ethylene oxide (EtO) standard is the use of EtO as a sterilant. OSHA estimated the costs of add-on controls for EtO sterilization, but in response to the standard, improved EtO sterilizers with built-in controls were developed and widely disseminated at about half the cost of the equipment with add-on controls. (See OSHA, 2005.) Lower-cost EtO sterilizers with built-in controls did not exist, and their development had not been predicted by OSHA, at the time the final rule was published in 1984.

technological advances or worker specialization because the technological and economic feasibility of the proposed rule can easily be demonstrated using existing technology and employment patterns. However, OSHA believes that actual costs, if future developments of this type were fully accounted for, would be lower than those estimated here.

OSHA invites comment on this discussion concerning the costs of the proposed rule.

TABLE VIII–8—ANNUALIZED COMPLIANCE COSTS FOR EMPLOYERS IN GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

[2009 dollars]

Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas or access control	Total
General Industry	$88,442,480	$6,914,225	$29,197,633	$2,410,253	$2,952,035	$2,580,728	$132,497,353
Maritime	12,797,027	NA	671,175	646,824	43,865	70,352	14,229,242
Construction	242,579,193	84,004,516	44,552,948	76,012,451	47,270,844	16,745,663	511,165,616
Total	343,818,700	90,918,741	74,421,757	79,069,527	50,266,744	19,396,743	657,892,211

U.S. Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2007a, 2007b, and 2013).

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
324121	Asphalt paving mixture and block manufacturing.	$179,111	$2,784	$8,195	$962	$49,979	$1,038	$242,070
324122	Asphalt shingle and roofing materials	2,194,150	113,924	723,761	39,364	43,563	42,495	3,157,257
325510	Paint and coating manufacturing	0	23,445	70,423	8,179	33,482	8,752	144,281
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	1,128,859	76,502	369,478	26,795	29,006	28,554	1,659,194
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,769,953	119,948	579,309	42,012	45,479	44,770	2,601,471
327113	Porcelain electrical supply mfg	1,189,482	80,610	389,320	28,234	30,564	30,087	1,748,297
327121	Brick and structural clay mfg	6,966,654	154,040	554,322	53,831	51,566	57,636	7,838,050
327122	Ceramic wall and floor tile mfg	3,658,389	80,982	306,500	28,371	27,599	30,266	4,132,107
327123	Other structural clay product mfg	826,511	18,320	72,312	6,417	6,302	6,838	936,699
327124	Clay refractory manufacturing	304,625	21,108	124,390	7,393	17,043	7,878	482,438
327125	Nonclay refractory manufacturing	383,919	26,602	156,769	9,318	21,479	9,929	608,017
327211	Flat glass manufacturing	227,805	8,960	29,108	3,138	2,800	3,344	275,155
327212	Other pressed and blown glass and glassware manufacturing.	902,802	34,398	111,912	12,048	10,708	12,839	1,084,706
327213	Glass container manufacturing	629,986	24,003	78,093	8,374	7,472	8,959	756,888
327320	Ready-mixed concrete manufacturing	7,029,710	1,862,221	5,817,205	652,249	454,630	695,065	16,511,080
327331	Concrete block and brick mfg	2,979,495	224,227	958,517	78,536	113,473	83,692	4,437,939
327332	Concrete pipe mfg	1,844,576	138,817	593,408	48,621	70,250	51,813	2,747,484
327390	Other concrete product mfg	8,660,830	651,785	2,786,227	228,290	329,844	243,276	12,900,251
327991	Cut stone and stone product manufacturing.	5,894,506	431,758	1,835,498	151,392	126,064	161,080	8,600,298
327992	Ground or treated mineral and earth manufacturing.	3,585,439	51,718	867,728	18,134	52,692	19,295	4,595,006
327993	Mineral wool manufacturing	897,980	36,654	122,015	12,852	11,376	13,675	1,094,552
327999	All other misc. nonmetallic mineral product mfg.	1,314,066	98,936	431,012	34,691	50,435	36,911	1,966,052
331111	Iron and steel mills	315,559	17,939	72,403	6,129	5,836	6,691	424,557
331112	Electrometallurgical ferroalloy product manufacturing.	6,375	362	1,463	124	118	135	8,577
331210	Iron and steel pipe and tube manufacturing from purchased steel.	62,639	3,552	14,556	1,239	1,222	1,328	84,537
331221	Rolled steel shape manufacturing	31,618	1,793	7,348	625	617	670	42,672
331222	Steel wire drawing	42,648	2,419	9,911	843	832	904	57,557
331314	Secondary smelting and alloying of aluminum.	21,359	1,213	4,908	419	406	453	28,757
331423	Secondary smelting, refining, and alloying of copper.	3,655	207	857	72	71	78	4,940
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	27,338	1,551	6,407	539	531	580	36,946
331511	Iron foundries	11,372,127	645,546	2,612,775	223,005	216,228	241,133	15,310,815
331512	Steel investment foundries	3,175,862	179,639	739,312	62,324	58,892	67,110	4,283,138
331513	Steel foundries (except investment)	3,403,790	193,194	794,973	67,027	65,679	72,174	4,596,837
331524	Aluminum foundries (except die-casting).	5,155,172	291,571	1,220,879	101,588	97,006	108,935	6,975,150
331525	Copper foundries (except die-casting)	1,187,578	67,272	309,403	23,668	23,448	25,095	1,636,463

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
331528	Other nonferrous foundries (except die-casting).	914,028	51,701	212,778	17,937	16,949	19,314	1,232,708
332111	Iron and steel forging	77,324	4,393	19,505	1,538	1,555	1,640	105,955
332112	Nonferrous forging	25,529	1,451	6,440	508	513	541	34,982
332115	Crown and closure manufacturing	9,381	532	2,236	186	186	199	12,720
332116	Metal stamping	188,102	10,676	45,595	3,734	3,736	3,988	255,832
332117	Powder metallurgy part manufacturing	24,250	1,375	5,727	481	479	514	32,828
332211	Cutlery and flatware (except precious) manufacturing.	16,763	952	4,229	333	337	355	22,970
332212	Hand and edge tool manufacturing	106,344	6,041	26,356	2,110	2,118	2,255	145,223
332213	Saw blade and handsaw manufacturing.	21,272	1,209	5,090	418	411	451	28,851
332214	Kitchen utensil, pot, and pan manufacturing.	11,442	650	2,886	228	230	243	15,678
332323	Ornamental and architectural metal work.	28,010	1,089	4,808	383	572	406	35,267
332439	Other metal container manufacturing	44,028	2,502	11,106	876	885	934	60,330
332510	Hardware manufacturing	131,574	7,476	33,190	2,617	2,646	2,790	180,292
332611	Spring (heavy gauge) manufacturing	11,792	670	2,974	235	237	250	16,158
332612	Spring (light gauge) manufacturing	44,511	2,529	11,228	885	895	944	60,992
332618	Other fabricated wire product manufacturing.	105,686	6,005	26,659	2,102	2,125	2,241	144,819
332710	Machine shops	774,529	44,074	211,043	15,533	16,157	16,423	1,077,759
332812	Metal coating and allied services	2,431,996	94,689	395,206	33,145	48,563	35,337	3,038,935
332911	Industrial valve manufacturing	111,334	6,316	25,894	2,197	2,159	2,361	150,261
332912	Fluid power valve and hose fitting manufacturing.	103,246	5,863	24,854	2,040	2,021	2,189	140,213
332913	Plumbing fixture fitting and trim manufacturing.	33,484	1,901	8,060	661	655	710	45,472
332919	Other metal valve and pipe fitting manufacturing.	52,542	2,984	12,648	1,038	1,028	1,114	71,354
332991	Ball and roller bearing manufacturing	79,038	4,488	19,027	1,561	1,547	1,676	107,338
332996	Fabricated pipe and pipe fitting manufacturing.	78,951	4,483	19,006	1,560	1,545	1,674	107,219
332997	Industrial pattern manufacturing	15,383	874	3,703	304	301	326	20,891
332998	Enameled iron and metal sanitary ware manufacturing.	46,581	2,225	9,304	774	969	831	60,684
332999	All other miscellaneous fabricated metal product manufacturing.	209,692	11,915	53,603	4,181	4,256	4,446	288,093
333319	Other commercial and service industry machinery manufacturing.	154,006	8,741	37,161	3,053	3,046	3,266	209,273
333411	Air purification equipment manufacturing.	43,190	2,453	10,037	847	823	916	58,265
333412	Industrial and commercial fan and blower manufacturing.	30,549	1,735	7,099	599	582	648	41,212
333414	Heating equipment (except warm air furnaces) manufacturing.	59,860	3,399	13,911	1,174	1,141	1,269	80,754
333511	Industrial mold manufacturing	116,034	6,597	30,348	2,317	2,375	2,460	160,131
333512	Machine tool (metal cutting types) manufacturing.	49,965	2,839	12,313	988	985	1,059	68,151
333513	Machine tool (metal forming types) manufacturing.	24,850	1,411	6,157	495	500	527	33,940
333514	Special die and tool, die set, jig, and fixture manufacturing.	167,204	9,513	44,922	3,346	3,458	3,545	231,988
333515	Cutting tool and machine tool accessory manufacturing.	101,385	5,764	26,517	2,025	2,075	2,150	139,916
333516	Rolling mill machinery and equipment manufacturing.	8,897	506	2,327	178	182	189	12,279
333518	Other metalworking machinery manufacturing.	36,232	2,060	9,476	724	742	768	50,002
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	35,962	2,043	8,308	702	674	763	48,452
333613	Mechanical power transmission equipment manufacturing.	45,422	2,581	10,493	886	852	963	61,197
333911	Pump and pumping equipment manufacturing.	89,460	5,077	21,139	1,767	1,746	1,897	121,086
333912	Air and gas compressor manufacturing	62,241	3,534	14,975	1,230	1,219	1,320	84,518
333991	Power-driven handtool manufacturing	25,377	1,441	6,105	501	497	538	34,459
333992	Welding and soldering equipment manufacturing.	46,136	2,622	10,882	904	879	978	62,401
333993	Packaging machinery manufacturing	61,479	3,491	15,004	1,219	1,218	1,304	83,714
333994	Industrial process furnace and oven manufacturing.	31,154	1,768	7,694	620	626	661	42,523
333995	Fluid power cylinder and actuator manufacturing.	57,771	3,280	13,532	1,137	1,113	1,225	78,057
333996	Fluid power pump and motor manufacturing.	39,598	2,247	9,296	782	772	840	53,535

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
333997	Scale and balance (except laboratory) manufacturing.	10,853	616	2,688	216	218	230	14,822
333999	All other miscellaneous general purpose machinery manufacturing.	152,444	8,657	36,677	3,012	2,985	3,232	207,006
334518	Watch, clock, and part manufacturing	6,389	363	1,596	127	129	135	8,740
335211	Electric housewares and household fans.	11,336	437	1,641	149	203	163	13,928
335221	Household cooking appliance manufacturing.	24,478	944	3,543	321	438	352	30,077
335222	Household refrigerator and home freezer manufacturing.	26,139	1,009	3,784	343	468	376	32,118
335224	Household laundry equipment manufacturing.	24,839	958	3,596	326	444	357	30,521
335228	Other major household appliance manufacturing.	19,551	754	2,830	256	350	281	24,023
336111	Automobile manufacturing	218,635	12,444	49,525	4,203	3,914	4,636	293,357
336112	Light truck and utility vehicle manufacturing.	301,676	17,170	68,335	5,799	5,400	6,397	404,778
336120	Heavy duty truck manufacturing	93,229	5,303	21,179	1,800	1,692	1,977	125,181
336211	Motor vehicle body manufacturing	138,218	7,849	32,738	2,722	2,674	2,931	187,131
336212	Truck trailer manufacturing	93,781	5,325	21,786	1,841	1,791	1,989	126,512
336213	Motor home manufacturing	62,548	3,557	14,284	1,212	1,147	1,326	84,073
336311	Carburetor, piston, piston ring, and valve manufacturing.	30,612	1,739	7,044	598	576	649	41,219
336312	Gasoline engine and engine parts manufacturing.	192,076	10,910	44,198	3,753	3,616	4,073	258,625
336322	Other motor vehicle electrical and electronic equipment manufacturing.	180,164	10,233	41,457	3,520	3,392	3,820	242,586
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	114,457	6,504	26,216	2,228	2,128	2,427	153,960
336340	Motor vehicle brake system manufacturing.	98,118	5,573	22,578	1,917	1,847	2,080	132,114
336350	Motor vehicle transmission and power train parts manufacturing.	243,348	13,832	55,796	4,730	4,510	5,160	327,377
336370	Motor vehicle metal stamping	321,190	18,237	73,408	6,282	6,057	6,810	431,985
336399	All other motor vehicle parts manufacturing.	433,579	24,628	99,769	8,472	8,162	9,194	583,803
336611	Ship building and repair	7,868,944	NA	412,708	397,735	26,973	43,259	8,749,619
336612	Boat building	4,928,083	NA	258,467	249,089	16,892	27,092	5,479,624
336992	Military armored vehicle, tank, and tank component manufacturing.	20,097	1,142	4,786	394	383	426	27,227
337215	Showcase, partition, shelving, and locker manufacturing.	171,563	9,741	41,962	3,405	3,412	3,638	233,720
339114	Dental equipment and supplies manufacturing.	272,308	15,901	48,135	5,524	4,157	5,930	351,955
339116	Dental laboratories	103,876	62,183	892,167	21,602	335,984	23,193	1,439,004
339911	Jewelry (except costume) manufacturing.	260,378	198,421	876,676	69,472	81,414	73,992	1,560,353
339913	Jewelers' materials and lapidary work manufacturing.	53,545	40,804	180,284	14,287	16,742	15,216	320,878
339914	Costume jewelry and novelty manufacturing.	54,734	27,779	122,885	9,726	11,337	10,359	236,821
339950	Sign manufacturing	227,905	9,972	44,660	3,491	5,173	3,718	294,919
423840	Industrial supplies, wholesalers	97,304	8,910	60,422	3,149	4,199	3,315	177,299
482110	Rail transportation	0	327,176	1,738,398	110,229	154,412	121,858	2,452,073
621210	Dental offices	24,957	14,985	251,046	5,286	87,408	5,572	389,256
	Total	101,239,507	6,914,225	29,868,808	3,057,076	2,995,900	2,651,079	146,726,595

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–10—ANNUALIZED COMPLIANCE COSTS FOR CONSTRUCTION EMPLOYERS AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas and access control	Total
236100	Residential Building Construction	$14,610,121	$2,356,507	$1,949,685	$2,031,866	$1,515,047	$825,654	$23,288,881
236200	Nonresidential Building Construction	16,597,147	7,339,394	4,153,899	6,202,842	4,349,517	1,022,115	39,664,913
237100	Utility System Construction	30,877,799	2,808,570	4,458,900	2,386,139	5,245,721	941,034	46,718,162
237200	Land Subdivision	676,046	59,606	128,183	51,327	173,183	22,443	1,110,789
237300	Highway, Street, and Bridge Construction.	16,771,688	2,654,815	3,538,146	2,245,164	4,960,966	637,082	30,807,861

TABLE VIII–10—ANNUALIZED COMPLIANCE COSTS FOR CONSTRUCTION EMPLOYERS AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas and access control	Total
237900	Other Heavy and Civil Engineering Construction.	4,247,372	430,127	825,247	367,517	1,162,105	131,843	7,164,210
238100	Foundation, Structure, and Building Exterior Contractors.	66,484,670	59,427,878	17,345,127	50,179,152	14,435,854	8,034,530	215,907,211
238200	Building Equipment Contractors	3,165,237	366,310	394,270	316,655	526,555	133,113	4,902,138
238300	Building Finishing Contractors	34,628,392	2,874,918	2,623,763	5,950,757	3,156,004	1,025,405	50,259,239
238900	Other Specialty Trade Contractors	43,159,424	4,044,680	5,878,597	4,854,336	7,251,924	2,815,017	68,003,978
999000	State and Local Governments [c]	11,361,299	1,641,712	3,257,131	1,426,696	4,493,968	1,157,427	23,338,234
	Total—Construction	242,579,193	84,004,516	44,552,948	76,012,451	47,270,844	16,745,663	511,165,616

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

1. Unit Costs, Other Cost Parameters, and Methodological Assumptions by Major Provision

Below, OSHA summarizes its methodology for estimating unit and total costs for the major provisions required under the proposed silica standard. For a full presentation of the cost analysis, see Chapter V of the PEA and ERG (2007a, 2007b, 2011, 2013). OSHA invites comment on all aspects of its preliminary cost analysis.

a. Engineering Controls

Engineering controls include such measures as local exhaust ventilation, equipment hoods and enclosures, dust suppressants, spray booths and other forms of wet methods, high efficient particulate air (HEPA) vacuums, and control rooms.

Following ERG's (2011) methodology, OSHA estimated silica control costs on a per-worker basis, allowing the costs to be related directly to the estimates of the number of overexposed workers. OSHA then multiplied the estimated control cost per worker by the numbers of overexposed workers for both the proposed PEL of 50 μg/m^3 and the alternative PEL of 100 μg/m^3, introduced for economic analysis purposes. The numbers of workers needing controls (*i.e.,* workers overexposed) are based on the exposure profiles for at-risk occupations developed in the technological feasibility analysis in Chapter IV of the PEA and estimates of the number of workers employed in these occupations developed in the industry profile in Chapter III of the PEA. This worker-based method is necessary because, even though the Agency has data on the number of firms in each affected industry, on the occupations and industrial activities with worker exposure to silica, on exposure profiles of at-risk occupations, and on the costs of controlling silica exposure for specific industrial activities, OSHA does not have a way to match up these data at the firm level. Nor does OSHA have facility-specific data on worker exposure to silica or even facility-specific data on the level of activity involving worker exposure to silica. Thus, OSHA could not directly estimate per-affected-facility costs, but instead, first had to estimate aggregate compliance costs and then calculate the average per-affected-facility costs by dividing aggregate costs by the number of affected facilities.

In general, OSHA viewed the extent to which exposure controls are already in place to be reflected in the distribution of overexposures among the affected workers. Thus, for example, if 50 percent of workers in a given occupation are found to be overexposed relative to the proposed silica PEL, OSHA judged this equivalent to 50 percent of facilities lacking the relevant exposure controls. The remaining 50 percent of facilities are expected either to have installed the relevant controls or to engage in activities that do not require that the exposure controls be in place. OSHA recognizes that some facilities might have the relevant controls in place but are still unable, for whatever reason, to achieve the PEL under consideration. ERG's review of the industrial hygiene literature and other source materials (as noted in ERG, 2007b), however, suggest that the large majority of overexposed workers lack relevant controls. Thus, OSHA has generally assumed that overexposures occur due to the absence of suitable controls. This assumption results in an overestimate of costs since, in some cases, employers may merely need to upgrade or better maintain existing controls or to improve work practices rather than to install and maintain new controls.

There are two situations in which the proportionality assumption may oversimplify the estimation of the costs of the needed controls. First, some facilities may have the relevant controls in place but are still unable, for whatever reason, to achieve the PEL under consideration for all employees. ERG's review of the industrial hygiene literature and other source materials (as noted in ERG, 2007b, pg. 3–4), however, suggest that the large majority of overexposed workers lack relevant controls. Thus, OSHA has generally assumed that overexposures occur due to the absence of suitable controls. This assumption could, in some cases, result in an overestimate of costs where employers merely need to upgrade or better maintain existing controls or to improve work practices rather than to install and maintain new controls. Second, there may be situations where facilities do not have the relevant controls in place but nevertheless have only a fraction of all affected employees above the PEL. If, in such situations, an employer would have to install all the controls necessary to meet the PEL, OSHA may have underestimated the control costs. However, OSHA believes that, in general, employers could come into compliance by such methods as checking the work practices of the employee who is above the PEL or installing smaller amounts of LEV at costs that would be more or less proportional to the costs for all employees. Nevertheless there may be situations in which a complete set of controls would be necessary if even one employee in a work area is above the PEL. OSHA welcomes comment on the extent to which this approach may yield underestimates or overestimates of costs.

At many workstations, employers must improve ventilation to reduce silica exposures. Ventilation improvements will take a variety of forms at different workstations and in different facilities and industries. The cost of ventilation enhancements generally reflects the expense of ductwork and other equipment for the immediate workstation or individual location and, potentially, the cost of incremental capacity system-wide enhancements and increased operation costs for the heating, ventilation, and air conditioning (HVAC) system for the facility.

For a number of occupations, the technological feasibility analysis indicates that, in addition to ventilation, the use of wet methods, improved housekeeping practices, and enclosure of process equipment are needed to reduce silica exposures. The degree of incremental housekeeping depends upon how dusty the operations are and the applicability of HEPA vacuums or other equipment to the dust problem. The incremental costs for most such occupations arise due to the labor required for these additional housekeeping efforts. Because additional labor for housekeeping will be required on virtually every work shift by most of the affected occupations, the costs of housekeeping are substantial. Employers also need to purchase HEPA vacuums and must incur the ongoing costs of HEPA vacuum filters. To reduce silica exposures by enclosure of process equipment, such as in the use of conveyors near production workers in mineral processing, covers can be particularly effective where silica-containing materials are transferred (and notable quantities of dust become airborne), or, as another example, where dust is generated, such as in sawing or grinding operations.

For construction, ERG (2007a) defined silica dust control measures for each representative job as specified in Table 1 of the proposed rule. Generally, these controls involve either a dust collection system or a water-spray approach (wet method) to capture and suppress the release of respirable silica dust. Wet-method controls require a water source (*e.g.,* tank) and hoses. The size of the tank varies with the nature of the job and ranges from a small hand-pressurized tank to a large tank for earth drilling operations. Depending on the tool, dust collection methods entail vacuum equipment, including a vacuum unit and hoses, and either a dust shroud or an extractor. For example, concrete grinding operations using hand-held tools require dust shroud adapters for each tool and a vacuum. The capacity of the vacuum depends on the type and size of tool being used. Some equipment, such as concrete floor grinders, comes with a dust collection system and a port for a vacuum hose. The estimates of control costs for those jobs using dust collection methods assume that an HEPA filter will be required.

For each job, ERG estimated the annual cost of the appropriate controls and translated this cost to a daily charge. The unit costs for control equipment were based on price information collected from manufacturers and vendors. In some cases, control equipment costs were based on data on equipment rental charges.

As noted above, included among the engineering controls in OSHA's cost model are housekeeping and dust-suppression controls in general industry. For the maritime industry and for construction, abrasive blasting operations are expected to require the use of wet methods to control silica dust.

Tables V–3, V–4, V–21, V–22, and V–31 in Chapter V of the PEA and Tables V–A–1 and V–A–2 in Appendix V–A provide details on the unit costs, other unit parameters, and methodological assumptions applied by OSHA to estimate engineering control costs.

b. Respiratory Protection

OSHA's cost estimates assume that implementation of the recommended silica controls prevents workers in general industry and maritime from being exposed over the PEL in most cases. Specifically, based on its technological feasibility analysis, OSHA expects that the technical controls are adequate to keep silica exposures at or below the PEL for an alternative PEL of 100 μg/m³ (introduced for economic analysis purposes).[17] For the proposed 50 μg/m³ PEL, OSHA's feasibility analysis suggests that the controls that employers use, either because of technical limitations or imperfect implementation, might not be adequate in all cases to ensure that worker exposures in all affected job categories are at or below 50 μg/m³. For this preliminary cost analysis, OSHA estimates that ten percent of the at-risk workers in general industry would require respirators, at least occasionally, after the implementation of engineering controls to achieve compliance with the proposed PEL of 50 μg/m³. For workers in maritime, the only activity with silica exposures above the proposed PEL of 50 μg/m³ is abrasive blasting, and maritime workers engaged in abrasive blasting are already required to use respirators under the existing OSHA ventilation standard (29 CFR 1910.94(a)). Therefore, OSHA has estimated no additional costs for maritime workers to use respirators as a result of the proposed silica rule.

For construction, employers whose workers receive exposures above the PEL are assumed to adopt the appropriate task-specific engineering controls and, where required, respirators prescribed in Table 1 and under paragraph (g)(1) in the proposed standard. Respirator costs in the construction industry have been adjusted to take into account OSHA's estimate (consistent with the findings from the NIOSH Respiratory Survey, 2003) that 56 percent of establishments in the construction industry are already using respirators that would be in compliance with the proposed silica rule.

ERG (2013) used respirator cost information from a 2003 OSHA respirator study to estimate the annual cost of $570 (in 2009 dollars) for a half-mask, non-powered, air-purifying respirator and $638 per year (in 2009 dollars) for a full-face non-powered air-purifying respirator (ERG, 2003). These unit costs reflect the annualized cost of respirator use, including accessories (*e.g.,* filters), training, fit testing, and cleaning.

In addition to bearing the costs associated with the provision of respirators, employers will incur a cost burden to establish respirator programs. OSHA projects that this expense will involve an initial 8 hours for establishments with 500 or more employees and 4 hours for all other firms. After the first year, OSHA estimates that 20 percent of establishments would revise their respirator program every year, with the largest establishments (500 or more employees) expending 4 hours for program revision, and all other employers expending two hours for program revision. Consistent with the findings from the NIOSH Respiratory Survey (2003), OSHA estimates that 56 percent of establishments in the construction industry that would require respirators to achieve compliance with the proposed PEL already have a respirator program.[18] OSHA further estimates that 50 percent of firms in general industry and all maritime firms that would require

[17] As a result, OSHA expects that establishments in general industry do not currently use respirators to comply with the current OSHA PEL for quartz of approximately 100 μg/m³.

[18] OSHA's derivation of the 56 percent current compliance rate in construction, in the context of the proposed silica rule, is described in Chapter V in the PEA.

respirators to achieve compliance already have a respirator program.

c. Exposure Assessment

Most establishments wishing to perform exposure monitoring will require the assistance of an outside consulting industrial hygienist (IH) to obtain accurate results. While some firms might already employ or train qualified staff, ERG (2007b) judged that the testing protocols are fairly challenging and that few firms have sufficiently skilled staff to eliminate the need for outside consultants.

Table V–8 in the PEA shows the unit costs and associated assumptions used to estimate exposure assessment costs. Unit costs for exposure sampling include direct sampling costs, the costs of productivity losses, and recordkeeping costs, and, depending on establishment size, range from $225 to $412 per sample in general industry and maritime and from $228 to $415 per sample in construction.

For costing purposes, based on ERG (2007b), OSHA estimated that there are four workers per work area. OSHA interpreted the initial exposure assessment as requiring first-year testing of at least one worker in each distinct job classification and work area who is, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level. This may result in overestimated exposure assessment costs in construction because OSHA anticipates that many employers, aware that their operations currently expose their workers to silica levels above the PEL, will simply choose to comply with Table 1 and avoid the costs of conducting exposure assessments.

For periodic monitoring, the proposed standard provides employers an option of assessing employee exposures either under a fixed schedule (paragraph (d)(3)(i)) or a performance-based schedule (paragraph (d)(3)(ii)). Under the fixed schedule, the proposed standard requires semi-annual sampling for exposures at or above the action level and quarterly sampling for exposures above the 50 μg/m³ PEL. Monitoring must be continued until the employer can demonstrate that exposures are no longer at or above the action level. OSHA used the fixed schedule option under the frequency-of-monitoring requirements to estimate, for costing purposes, that exposure monitoring will be conducted (a) twice a year where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, and (b) four times a year where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL.

As required under paragraph (d)(4) of the proposed rule, whenever there is a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures at or above the action level or when the employer has any reason to suspect that a change may result in new or additional exposures at or above the action level, the employer must conduct additional monitoring. Based on ERG (2007a, 2007b), OSHA estimated that approximately 15 percent of workers whose initial exposure or subsequent monitoring was at or above the action level would undertake additional monitoring.

A more detailed description of unit costs, other unit parameters, and methodological assumptions for exposure assessments is presented in Chapter V of the PEA.

d. Medical Surveillance

Paragraph (h) of the proposed standard requires an initial health screening and then triennial periodic screenings for workers exposed above the proposed PEL of 50 μg/m³ for 30 days or more per year. ERG (2013) assembled information on representative unit costs for initial and periodic medical surveillance. Separate costs were estimated for current employees and for new hires as a function of the employment size (*i.e.,* 1–19, 20–499, or 500+ employees) of affected establishments. Table V–10 in the PEA presents ERG's unit cost data and modeling assumptions used by OSHA to estimate medical surveillance costs.

In accordance with the paragraph (h)(2) of the proposed rule, the initial (baseline) medical examination would consist of (1) a medical and work history, (2) a physical examination with special emphasis on the respiratory system, (3) a chest X-ray that is interpreted according to guidelines of the International Labour Organization, (4) a pulmonary function test that meets certain criteria and is administered by spirometry technician with current certification from a NIOSH-approved spirometry course, (5) testing for latent tuberculosis (TB) infection, and (6) any other tests deemed appropriate by the physician or licensed health care professional (PLHCP).

As shown in Table V–10 in the PEA, the estimated unit cost of the initial health screening for current employees in general industry and maritime ranges from approximately $378 to $397 and includes direct medical costs, the opportunity cost of worker time (*i.e.,* lost work time, evaluated at the worker's 2009 hourly wage, including fringe benefits) for offsite travel and for the initial health screening itself, and recordkeeping costs. The variation in the unit cost of the initial health screening is due entirely to differences in the percentage of workers expected to travel offsite for the health screening. In OSHA's experience, the larger the establishment the more likely it is that the selected PLHCP would provide the health screening services at the establishment's worksite. OSHA estimates that 20 percent of establishments with fewer than 20 employees, 75 percent of establishments with 20–499 employees, and 100 percent of establishments with 500 or more employees would have the initial health screening for current employees conducted onsite.

The unit cost components of the initial health screening for new hires in general industry and maritime are identical to those for existing employees with the exception that the percentage of workers expected to travel offsite for the health screening would be somewhat larger (due to fewer workers being screened annually, in the case of new hires, and therefore yielding fewer economies of onsite screening). OSHA estimates that 10 percent of establishments with fewer than 20 employees, 50 percent of establishments with 20–499 employees, and 90 percent of establishments with 500 or more employees would have the initial health screening for new hires conducted onsite. As shown in Chapter V in the PEA, the estimated unit cost of the initial health screening for new hires in general industry and maritime ranges from approximately $380 to $399.

The unit costs of medical surveillance in construction were derived using identical methods. As shown in Table V–39 of the PEA, the estimated unit costs of the initial health screening for current employees in construction range from approximately $389 to $425; the estimated unit costs of the initial health screening for new hires in construction range from approximately $394 to $429.

In accordance with paragraph (h)(3) of the proposed rule, the periodic medical examination (every third year after the initial health screening) would consist of (1) a medical and work history review and update, (2) a physical examination with special emphasis on the respiratory system, (3) a chest X-ray that meets certain standards of the International Labour Organization, (4) a pulmonary function test that meets certain criteria and is administered by a spirometry technician with current certification from a NIOSH-approved spirometry course, (5) testing for latent TB infection, if recommended by the PLHCP, and (6) any other tests deemed appropriate by the PLHCP.

The estimated unit cost of periodic health screening also includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. As shown in Table V–10 in the PEA, these triennial unit costs in general industry and maritime vary from $378 to $397. For construction, as shown in Table V–39 in the PEA, the triennial unit costs for periodic health screening vary from roughly $389 to $425. The variation in the unit cost (with or without the chest X-ray and pulmonary function test) is due entirely to differences in the percentage of workers expected to travel offsite for the periodic health screening. OSHA estimated that the share of workers traveling offsite, as a function of establishment size, would be the same for the periodic health screening as for the initial health screening for existing employees.

ERG (2013) estimated a turnover rate of 27.2 percent in general industry and maritime and 64.0 percent in construction, based on estimates of the separations rate (layoffs, quits, and retirements) provided by the Bureau of Labor Statistics (BLS, 2007). However, not all new hires would require initial medical testing. As specified in paragraph (h)(2) of the proposed rule, employees who had received a qualifying medical examination within the previous twelve months would be exempt from the initial medical examination. OSHA estimates that 25 percent of new hires in general industry and maritime and 60 percent of new hires in construction would be exempt from the initial medical examination.

Although OSHA believes that some affected establishments in general industry, maritime, and construction currently provide some medical testing to their silica-exposed employees, the Agency doubts that many provide the comprehensive health screening required under the proposed rule. Therefore for costing purposes for the proposed rule, OSHA has assumed no current compliance with the proposed health screening requirements. OSHA requests information from interested parties on the current levels and the comprehensiveness of health screening in general industry, maritime, and construction.

Finally, OSHA estimated the unit cost of a medical examination by a pulmonary specialist for those employees found to have signs or symptoms of silica-related disease or are otherwise referred by the PLHCP. OSHA estimates that a medical examination by a pulmonary specialist costs approximately $307 for workers in general industry and maritime and $333 for workers in construction. This cost includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. In all cases, OSHA anticipates that the worker will travel offsite to receive the medical examination by a pulmonary specialist.

See Chapter V in the PEA for a full discussion of OSHA's analysis of medical surveillance costs under the proposed standard.

e. Information and Training

As specified in paragraph (i) of the proposed rule and 29 CFR 1910.1200, training is required for all employees in jobs where there is potential exposure to respirable crystalline silica. In addition, new hires would require training before starting work. As previously noted, ERG (2013) provided an estimate of the new-hire rate in general industry and maritime, based on the BLS-estimated separations rate of 27.2 percent in manufacturing, and an estimate of the new-hire rate in construction, based on the BLS-estimated separations rate in construction of 64.0 percent.

OSHA estimated separate costs for initial training of current employees and for training new hires. Given that new-hire training might need to be performed frequently during the year, OSHA estimated a smaller class size for new hires. OSHA anticipates that training, in accordance with the requirements of the proposed rule, will be conducted by in-house safety or supervisory staff with the use of training modules or videos and will last, on average, one hour. ERG (2007b) judged that establishments could purchase sufficient training materials at an average cost of $2 per worker, encompassing the cost of handouts, video presentations, and training manuals and exercises. ERG (2013) included in the cost estimates for training the value of worker and trainer time as measured by 2009 hourly wage rates (to include fringe benefits). ERG also developed estimates of average class sizes as a function of establishment size. For initial training, ERG estimated an average class size of 5 workers for establishments with fewer than 20 employees, 10 workers for establishments with 20 to 499 employees, and 20 workers for establishments with 500 or more employees. For new hire training, ERG estimated an average class size of 2 workers for establishments with fewer than 20 employees, 5 workers for establishments with 20 to 499 employees, and 10 workers for establishments with 500 or more employees.

The unit costs of training are presented in Tables V–14 (for general industry/maritime) and V–43 (for construction) in the PEA. Based on ERG's work, OSHA estimated the annualized cost (annualized over 10 years) of initial training per current employee at between $3.02 and $3.57 and the annual cost of new-hire training at between $22.50 and $32.72 per employee in general industry and maritime, depending on establishment size. For construction, OSHA estimated the annualized cost of initial training per employee at between $3.68 and $4.37 and the annual cost of new hire training at between $27.46 and $40.39 per employee, depending on establishment size.

OSHA recognizes that many affected establishments currently provide training on the hazards of respirable crystalline silica in the workplace. Consistent with some estimates developed by ERG (2007a and 2007b), OSHA estimates that 50 percent of affected establishments already provide such training. However, some of the training specified in the proposed rule requires that workers be familiar with the training and medical surveillance provisions in the rule. OSHA expects that these training requirements in the proposed rule are not currently being provided. Therefore, for costing purposes for the proposed rule, OSHA has estimated that 50 percent of affected establishments currently provide their workers, and would provide new hires, with training that would comply with approximately 50 percent of the training requirements. In other words, OSHA estimates that those 50 percent of establishments currently providing training on workplace silica hazards would provide an additional 30 minutes of training to comply with the proposed rule; the remaining 50 percent of establishments would provide 60 minutes of training to comply with the proposed rule. OSHA also recognizes that many new hires may have been previously employed in the same industry, and in some cases by the same establishment, so that they might have already received (partial) silica training. However, for purposes of cost estimation, OSHA estimates that all new hires will receive the full silica training from the new employer. OSHA requests comments from interested parties on the reasonableness of these assumptions.

f. Regulated Areas and Access Control

Paragraph (e)(1) of the proposed standard requires that wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) or an access control plan in accordance with paragraph (e)(3). For costing purposes, OSHA estimated that employers in general industry and maritime would typically prefer and choose option (e)(2) and would therefore establish regulated areas when an employee's exposure to airborne concentrations of silica exceeds, or can reasonably be expected to exceed, the PEL. OSHA believes that general industry and maritime employers will prefer this option as it is expected to be the most practical alternative in fixed worksites. Requirements in the proposed rule for a regulated area include demarcating the boundaries of the regulated area (as separate from the rest of the workplace), limiting access to the regulated area, providing an appropriate respirator to each employee entering the regulated area, and providing protective clothing as needed in the regulated area.

Based on ERG (2007b), OSHA derived unit cost estimates for establishing and maintaining regulated areas to comply with these requirements and estimated that one area would be necessary for every eight workers in general industry and maritime exposed above the PEL. Unit costs include planning time (estimated at eight hours of supervisor time annually); material costs for signs and boundary markers (annualized at $63.64 in 2009 dollars); and costs of $500 annually for two disposable respirators per day to be used by authorized persons (other than those who regularly work in the regulated area) who might need to enter the area in the course of their job duties. In addition, for costing purposes, OSHA estimates that, in response to the protective work clothing requirements in regulated areas, ten percent of employees in regulated areas would wear disposable protective clothing daily, estimated at $5.50 per suit, for an annual clothing cost of $1,100 per regulated area. Tables V–16 in the PEA shows the cost assumptions and unit costs applied in OSHA's cost model for regulated areas in general industry and maritime. Overall, OSHA estimates that each regulated area would, on average, cost employers $1,732 annually in general industry and maritime.

For construction, OSHA estimated that some employers would select the (e)(2) option concerning regulated areas while other employers would prefer the (e)(3) option concerning written access control plans whenever an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Based on the respirator specifications developed by ERG (2007a) and shown in Table V–34 in the PEA, ERG derived the full-time-equivalent number of workers engaged in construction tasks where respirators are required and estimated the costs of establishing a regulated area for these workers.

Under the second option for written access control plans, the employer must include the following elements in the plan: competent person provisions; notification and demarcation procedures; multi-employer workplace procedures; provisions for limiting access; provisions for supplying respirators; and protective clothing procedures. OSHA anticipates that employers will incur costs for labor, materials, respiratory protection, and protective clothing to comply with the proposed access control plan requirements.

Table V–45 in the PEA shows the unit costs and assumptions for developing costs for regulated areas and for access control plans in construction. ERG estimated separate development and implementation costs. ERG judged that developing either a regulated area or an access control plan would take approximately 4 hours of a supervisor's time. The time allowed to set up a regulated area or an access control plan is intended to allow for the communication of access restrictions and locations at multi-employer worksites. ERG estimated a cost of $116 per job based on job frequency and the costs for hazard tape and warning signs (which are reusable). ERG estimated a labor cost of $27 per job for implementing a written access control plan (covering the time expended for revision of the access control plan for individual jobs and communication of the plan). In addition, OSHA estimated that there would be annual disposable clothing costs of $333 per crew for employers who implement either regulated areas or the access control plan option. In addition, OSHA estimated that there would be annual respirator costs of $60 per crew for employers who implement either option.

ERG aggregated costs by estimating an average crew size of four in construction and an average job length of ten days. ERG judged that employers would choose to establish regulated areas in 75 percent of the instances where either regulated areas or an access control plan is required, and that written access control plans would be established for the remaining 25 percent.

See Chapter V in the PEA for a full discussion of OSHA's analysis of costs for regulated areas and written access control plans under the proposed standard.

F. Economic Feasibility Analysis and Regulatory Flexibility Determination

Chapter VI of the PEA presents OSHA's analysis of the economic impacts of its proposed silica rule on affected employers in general industry, maritime, and construction. The discussion below summarizes the findings in that chapter.

As a first step, the Agency explains its approach for achieving the two major objectives of its economic impact analysis: (1) To establish whether the proposed rule is economically feasible for all affected industries, and (2) to determine if the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. Next, this approach is applied to industries with affected employers in general industry and maritime and then to industries with affected employers in construction. Finally, OSHA directed Inforum—a not-for-profit corporation (based at the University of Maryland) specializing in the design and application of macroeconomic models of the United States (and other countries)—to estimate the industry and aggregate employment effects of the proposed silica rule. The Agency invites comment on any aspect of the methods and data presented here or in Chapter VI of the PEA.

1. Analytic Approach

a. Economic Feasibility

The Court of Appeals for the D.C. Circuit has long held that OSHA standards are economically feasible so long as their costs do not threaten the existence of, or cause massive economic dislocations within, a particular industry or alter the competitive structure of that industry. *American Iron and Steel Institute.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991); *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1265 (D.C. Cir. 1980); *Industrial Union Department* v. *Hodgson,* 499 F.2d 467, 478 (D.C. Cir. 1974).

In practice, the economic burden of an OSHA standard on an industry—and whether the standard is economically feasible for that industry—depends on the magnitude of compliance costs incurred by establishments in that industry and the extent to which they are able to pass those costs on to their customers. That, in turn, depends, to a significant degree, on the price elasticity of demand for the products sold by establishments in that industry.

The price elasticity of demand refers to the relationship between the price charged for a product and the demand for that product: the more elastic the relationship, the less an establishment's compliance costs can be passed through to customers in the form of a price increase and the more it has to absorb compliance costs in the form of reduced profits. When demand is inelastic, establishments can recover most of the costs of compliance by raising the prices they charge; under this scenario, profit rates are largely unchanged and the industry remains largely unaffected. Any impacts are primarily on those customers using the relevant product. On the other hand, when demand is elastic, establishments cannot recover all compliance costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean reductions both in the quantity of goods and services produced and in total profits, though the profit rate may remain unchanged. In general, ''[w]hen an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *American Dental Association* v. *Secretary of Labor* (984 F.2d 823, 829 (7th Cir. 1993)).

The court's summary is in accord with microeconomic theory. In the long run, firms can remain in business only if their profits are adequate to provide a return on investment that ensures that investment in the industry will continue. Over time, because of rising real incomes and productivity increases, firms in most industries are able to ensure an adequate profit. As technology and costs change, however, the long-run demand for some products naturally increases and the long-run demand for other products naturally decreases. In the face of additional compliance costs (or other external costs), firms that otherwise have a profitable line of business may have to increase prices to stay viable. Increases in prices typically result in reduced quantity demanded, but rarely eliminate all demand for the product. Whether this decrease in the total production of goods and services results in smaller output for each establishment within the industry or the closure of some plants within the industry, or a combination of the two, is dependent on the cost and profit structure of individual firms within the industry.

If demand is perfectly inelastic (*i.e.,* the price elasticity of demand is zero), then the impact of compliance costs that are 1 percent of revenues for each firm in the industry would result in a 1 percent increase in the price of the product, with no decline in quantity demanded. Such a situation represents an extreme case, but might be observed in situations in which there were few if any substitutes for the product in question, or if the products of the affected sector account for only a very small portion of the revenue or income of its customers.

If the demand is perfectly elastic (*i.e.,* the price elasticity of demand is infinitely large), then no increase in price is possible and before-tax profits would be reduced by an amount equal to the costs of compliance (net of any cost savings—such as reduced workers' compensation insurance premiums—resulting from the proposed standard) if the industry attempted to maintain production at the same level as previously. Under this scenario, if the costs of compliance are such a large percentage of profits that some or all plants in the industry could no longer operate in the industry with hope of an adequate return on investment, then some or all of the firms in the industry would close. This scenario is highly unlikely to occur, however, because it can only arise when there are other products—unaffected by the proposed rule—that are, in the eyes of their customers, perfect substitutes for the products the affected establishments make.

A common intermediate case would be a price elasticity of demand of one (in absolute terms). In this situation, if the costs of compliance amount to 1 percent of revenues, then production would decline by 1 percent and prices would rise by 1 percent. As a result, industry revenues would remain the same, with somewhat lower production, but with similar profit rates (in most situations where the marginal costs of production net of regulatory costs would fall as well). Customers would, however, receive less of the product for their (same) expenditures, and firms would have lower total profits; this, as the court described in *American Dental Association* v. *Secretary of Labor,* is the more typical case.

A decline in output as a result of an increase in price may occur in a variety of ways: individual establishments could each reduce their levels of production; some marginal plants could close; or, in the case of an expanding industry, new entry may be delayed until demand equals supply. In many cases it will be a combination of all three kinds of reductions in output. Which possibility is most likely depends on the form that the costs of the regulation take. If the costs are variable costs (*i.e.,* costs that vary with the level of production at a facility), then economic theory suggests that any reductions in output will take the form of reductions in output at each affected facility, with few if any plant closures. If, on the other hand, the costs of a regulation primarily take the form of fixed costs (*i.e.,* costs that do not vary with the level of production at a facility), then reductions in output are more likely to take the form of plant closures or delays in new entry.

Most of the costs of this regulation, as estimated in Chapter V of the PEA, are variable costs. Almost all of the major costs of program elements, such as medical surveillance and training, will vary in proportion to the number of employees (which is a rough proxy for the amount of production). Exposure monitoring costs will vary with the number of employees, but do have some economies of scale to the extent that a larger firm need only conduct representative sampling rather than sample every employee. The costs of engineering controls in construction also vary by level of production because almost all necessary equipment can readily be rented and the productivity costs of using some of these controls vary proportionally to the level of production. Finally, the costs of operating engineering controls in general industry (the majority of the annualized costs of engineering controls in general industry) vary by the number of hours the establishment works, and thus vary by the level of production and are not fixed costs in the strictest sense.

This leaves two kinds of costs that are, in some sense, fixed costs—capital costs of engineering controls in general industry and certain initial costs that new entries to the industry will not have to bear.

Capital costs of engineering controls in general industry due to this standard are relatively small as compared to the total costs, representing less than 8 percent of total annualized costs and approximately $362 per year per affected establishment in general industry.

Some initial costs are fixed in the sense that they will only be borne by firms in the industry today—these include initial costs for general training not currently required and initial costs of medical surveillance. Both of these costs will disappear after the initial year of the standard and thus would be difficult to pass on. These costs, however, represent less than 4 percent of total costs and less than $55 per affected establishment.

As a result of these considerations, OSHA expects that it is somewhat more likely that reductions in industry output will be met by reductions in output at each affected facility rather than as a result of plant closures. However, closures of some marginal plants or poorly performing facilities are always possible.

To determine whether a rule is economically feasible, OSHA begins with two screening tests to consider minimum threshold effects of the rule under two extreme cases: (1) all costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero), and (2) all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In the former case, the immediate impact of the rule would be observed in increased industry revenues. While there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Retrospective studies of previous OSHA regulations have shown that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure,[19] particularly since most industries have at least some ability to raise prices to reflect increased costs and, as shown in the PEA, normal price variations for products typically exceed three percent a year. Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis.

In the latter case, the immediate impact of the rule would be observed in reduced industry profits. OSHA uses the ratio of annualized costs to annual profits as a second check on economic feasibility. Again, while there is no hard and fast rule, in the absence of evidence to the contrary, OSHA has historically considered a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. In the context of economic feasibility, the Agency believes this threshold level to be fairly modest, given that—as shown in the PEA—normal year-to-year variations in profit rates in an industry can exceed 40 percent or more. OSHA's choice of a threshold level of ten percent of annual profits is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs would still equal seventy-one percent of profits and thus would be affordable from profits without resort to credit markets. If the threshold level were *first-year* costs of ten percent of annual profits, firms could even more easily expect to cover first-year costs at the threshold level out of current profits without having to access capital markets and otherwise being threatened with short-term insolvency.

In general, because it is usually the case that firms would able to pass on some or all of the costs of the proposed rule, OSHA will tend to give much more weight to the ratio of industry costs to industry revenues than to the ratio of industry costs to industry profits. However, if costs exceed either the threshold percentage of revenue or the threshold percentage of profits for an industry, or if there is other evidence of a threat to the viability of an industry because of the standard, OSHA will examine the effect of the rule on that industry more closely. Such an examination would include market factors specific to the industry, such as normal variations in prices and profits, international trade and foreign competition, and any special circumstances, such as close domestic substitutes of equal cost, which might make the industry particularly vulnerable to a regulatory cost increase.

The preceding discussion focused on the economic viability of the affected industries in their entirety. However, even if OSHA found that a proposed standard did not threaten the survival of affected industries, there is still the question of whether the industries' competitive structure would be significantly altered. For this reason, OSHA also examines the differential costs by size of firm.

b. Regulatory Flexibility Screening Analysis

The Regulatory Flexibility Act (RFA), Pub. L. No. 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601), requires Federal agencies to consider the economic impact that a proposed rulemaking will have on small entities. The RFA states that whenever a Federal agency is required to publish general notice of proposed rulemaking for any proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA). 5 U.S.C. 603(a). Pursuant to section 605(b), in lieu of an IRFA, the head of an agency may certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. A certification must be supported by a factual basis. If the head of an agency makes a certification, the agency shall publish such certification in the **Federal Register** at the time of publication of general notice of proposed rulemaking or at the time of publication of the final rule. 5 U.S.C. 605(b).

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. These screening tests are similar in concept to those OSHA developed above to identify minimum threshold effects for purposes of demonstrating economic feasibility.

There are, however, two differences. First, for each affected industry, the screening tests are applied, not to all establishments, but to small entities (defined as ''small business concerns'' by SBA) and also to very small entities (defined by OSHA as entities with fewer than 20 employees). Second, although OSHA's regulatory flexibility screening test for revenues also uses a minimum threshold level of annualized costs equal to one percent of annual revenues, OSHA has established a minimum threshold level of annualized costs equal to five percent of annual profits for the average small entity or very small entity. The Agency has chosen a lower minimum threshold level for the profitability screening analysis and has applied its screening tests to both small entities and very small entities in order to ensure that certification will be made, and an IRFA will not be prepared, only if OSHA can be highly confident that a proposed rule will not have a significant economic impact on a substantial number of small entities in any affected industry.

2. Impacts in General Industry and Maritime

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed rule's projected costs of compliance would threaten the economic viability of affected industries, OSHA first compared, for each affected industry, annualized compliance costs to annual revenues and profits per (average)

[19] See OSHA's Web page, *http://www.osha.gov/dea/lookback.html#Completed,* for a link to all completed OSHA lookback reviews.

affected establishment. The results for all affected establishments in all affected industries in general industry and maritime are presented in Table VIII–11, using annualized costs per establishment for the proposed 50 μg/m^3 PEL. Shown in the table for each affected industry are total annualized costs, the total number of affected establishments, annualized costs per affected establishment, annual revenues per establishment, the profit rate, annual profits per establishment, annualized compliance costs as a percentage of annual revenues, and annualized compliance costs as a percentage of annual profits.

The annualized costs per affected establishment for each affected industry were calculated by distributing the industry-level (incremental) annualized compliance costs among all affected establishments in the industry, where costs were annualized using a 7 percent discount rate. The annualized cost of the proposed rule for the average establishment in all of general industry and maritime is estimated at $2,571 in 2009 dollars. It is clear from Table VIII–11 that the estimates of the annualized costs per affected establishment in general industry and maritime vary widely from industry to industry. These estimates range from $40,468 for NAICS 327111 (Vitreous china plumbing fixtures and bathroom accessories manufacturing) and $38,422 for NAICS 327121 (Brick and structural clay manufacturing) to $107 for NAICS 325510 (Paint and coating manufacturing) and $49 for NAICS 621210 (Dental offices).

Table VIII–11 also shows that, within the general industry and maritime sectors, there are no industries in which the annualized costs of the proposed rule exceed 1 percent of annual revenues or 10 percent of annual profits. NAICS 327123 (Other structural clay product manufacturing) has both the highest cost impact as a percentage of revenues, of 0.39 percent, and the highest cost impact as a percentage of profits, of 8.78 percent. Based on these results, even if the costs of the proposed rule were 50 percent higher than OSHA has estimated, the highest cost impact as a percentage of revenues in any affected industry in general industry or maritime would be less than 0.6 percent. Furthermore, the costs of the proposed rule would have to be more than 150 percent higher than OSHA has estimated for the cost impact as a percentage of revenues to equal 1 percent in any affected industry. For all affected establishments in general industry and maritime, the estimated annualized cost of the proposed rule is, on average, equal to 0.02 percent of annual revenue and 0.5 percent of annual profit.

TABLE VIII–11—SCREENING ANALYSIS FOR ESTABLISHMENTS IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$242,070	1,431	$169	$6,617,887	7.50	$496,420	0.00	0.03
324122	Asphalt shingle and roofing materials	3,157,257	224	14,095	34,018,437	7.50	2,551,788	0.04	0.55
325510	Paint and coating manufacturing	144,281	1,344	107	19,071,850	5.38	1,026,902	0.00	0.01
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	1,659,194	41	40,468	21,226,709	4.41	937,141	0.19	4.32
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	2,601,471	731	3,559	1,203,017	4.41	53,112	0.30	6.70
327113	Porcelain electrical supply mfg	1,748,297	125	13,986	8,091,258	4.41	357,222	0.17	3.92
327121	Brick and structural clay mfg	7,838,050	204	38,422	11,440,887	4.41	505,105	0.34	7.61
327122	Ceramic wall and floor tile mfg	4,132,107	193	21,410	6,706,175	4.41	296,072	0.32	7.23
327123	Other structural clay product mfg	936,699	49	19,116	4,933,258	4.41	217,799	0.39	8.78
327124	Clay refractory manufacturing	482,438	129	3,740	7,872,516	4.41	347,565	0.05	1.08
327125	Nonclay refractory manufacturing	608,017	105	5,791	14,718,533	4.41	649,810	0.04	0.89
327211	Flat glass manufacturing	275,155	83	3,315	43,821,692	3.42	1,499,102	0.01	0.22
327212	Other pressed and blown glass and glassware manufacturing.	1,084,706	499	2,174	7,233,509	3.42	247,452	0.03	0.88
327213	Glass container manufacturing	756,888	72	10,512	64,453,615	3.42	2,204,903	0.02	0.48
327320	Ready-mixed concrete manufacturing	16,511,080	6,064	2,723	4,891,554	6.64	324,706	0.06	0.84
327331	Concrete block and brick mfg	4,437,939	951	4,667	5,731,328	6.64	380,451	0.08	1.23
327332	Concrete pipe mfg	2,747,484	385	7,136	7,899,352	6.64	524,366	0.09	1.36
327390	Other concrete product mfg	12,900,251	2,281	5,656	4,816,851	6.64	319,747	0.12	1.77
327991	Cut stone and stone product manufacturing	8,600,298	1,943	4,426	1,918,745	5.49	105,320	0.23	4.20
327992	Ground or treated mineral and earth manufacturing	4,595,006	271	16,956	8,652,610	5.49	474,944	0.20	3.57
327993	Mineral wool manufacturing	1,094,552	321	3,410	18,988,835	5.49	1,042,303	0.02	0.33
327999	All other misc. nonmetallic mineral product mfg	1,966,052	465	4,228	5,803,139	5.49	318,536	0.07	1.33
331111	Iron and steel mills	424,557	614	692	70,641,523	4.49	3,173,209	0.00	0.02
331112	Electrometallurgical ferroalloy product manufacturing	8,577	12	692	49,659,392	4.49	2,230,694	0.00	0.03
331210	Iron and steel pipe and tube manufacturing from purchased steel.	84,537	122	694	31,069,797	4.49	1,395,652	0.00	0.05
331221	Rolled steel shape manufacturing	42,672	61	694	28,102,003	4.49	1,262,339	0.00	0.05
331222	Steel wire drawing	57,557	83	694	12,904,028	4.49	579,647	0.01	0.12
331314	Secondary smelting and alloying of aluminum	28,757	42	692	29,333,260	4.46	1,309,709	0.00	0.05
331423	Secondary smelting, refining, and alloying of copper	4,940	7	695	26,238,546	4.42	1,158,438	0.00	0.06
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	36,946	53	695	14,759,299	4.42	651,626	0.00	0.11
331511	Iron foundries	15,310,815	527	29,053	19,672,534	4.11	809,290	0.15	3.59
331512	Steel investment foundries	4,283,138	132	32,448	18,445,040	4.11	758,794	0.18	4.28
331513	Steel foundries (except investment)	4,596,837	222	20,706	17,431,292	4.11	717,090	0.12	2.89
331524	Aluminum foundries (except die-casting)	6,975,150	466	14,968	8,244,396	4.11	339,159	0.18	4.41
331525	Copper foundries (except die-casting)	1,636,463	256	6,392	3,103,580	4.11	127,675	0.21	5.01
331528	Other nonferrous foundries (except die-casting)	1,232,708	124	9,941	7,040,818	4.11	289,646	0.14	3.43
332111	Iron and steel forging	105,955	150	705	15,231,376	4.71	716,646	0.00	0.10
332112	Nonferrous forging	34,982	50	705	28,714,500	4.71	1,351,035	0.00	0.05
332115	Crown and closure manufacturing	12,720	18	697	16,308,872	4.71	767,343	0.00	0.09
332116	Metal stamping	255,832	366	700	6,748,606	4.71	317,526	0.01	0.22
332117	Powder metallurgy part manufacturing	32,828	47	696	9,712,731	4.71	456,990	0.01	0.15
332211	Cutlery and flatware (except precious) manufacturing	22,970	33	705	9,036,720	5.22	472,045	0.01	0.15
332212	Hand and edge tool manufacturing	145,223	207	702	5,874,133	5.22	306,843	0.01	0.23
332213	Saw blade and handsaw manufacturing	28,851	41	698	11,339,439	5.22	592,331	0.01	0.12
332214	Kitchen utensil, pot, and pan manufacturing	15,678	22	705	18,620,983	5.22	972,693	0.00	0.07
332323	Ornamental and architectural metal work	35,267	54	654	2,777,899	4.70	130,669	0.02	0.50
332439	Other metal container manufacturing	60,330	86	705	7,467,745	3.58	267,613	0.01	0.26
332510	Hardware manufacturing	180,292	256	705	11,899,309	5.22	621,577	0.01	0.11
332611	Spring (heavy gauge) manufacturing	16,158	23	705	7,764,934	5.22	405,612	0.01	0.17
332612	Spring (light gauge) manufacturing	60,992	87	705	8,185,896	5.22	427,602	0.01	0.16
332618	Other fabricated wire product manufacturing	144,819	205	705	5,120,358	5.22	267,469	0.01	0.26
332710	Machine shops	1,077,759	1,506	716	1,624,814	5.80	94,209	0.04	0.76
332812	Metal coating and allied services	3,038,935	2,599	1,169	4,503,334	4.85	218,618	0.03	0.53
332911	Industrial valve manufacturing	150,261	216	694	18,399,215	6.81	1,252,418	0.00	0.06

TABLE VIII–11—SCREENING ANALYSIS FOR ESTABLISHMENTS IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
332912	Fluid power valve and hose fitting manufacturing	140,213	201	698	22,442,750	6.81	1,527,658	0.00	0.05
332913	Plumbing fixture fitting and trim manufacturing	45,472	65	698	24,186,039	6.81	1,646,322	0.00	0.04
332919	Other metal valve and pipe fitting manufacturing	71,354	102	698	15,023,143	6.81	1,022,612	0.00	0.07
332991	Ball and roller bearing manufacturing	107,338	154	698	36,607,380	6.81	2,491,832	0.00	0.03
332996	Fabricated pipe and pipe fitting manufacturing	107,219	154	698	6,779,536	6.81	461,477	0.01	0.15
332997	Industrial pattern manufacturing	20,891	30	698	1,122,819	6.81	76,429	0.06	0.91
332998	Enameled iron and metal sanitary ware manufacturing.	60,684	76	798	14,497,312	6.81	986,819	0.01	0.08
332999	All other miscellaneous fabricated metal product manufacturing.	288,093	408	707	4,405,921	6.81	299,907	0.02	0.24
333319	Other commercial and service industry machinery manufacturing.	209,273	299	699	10,042,625	4.86	487,919	0.01	0.14
333411	Air purification equipment manufacturing	58,265	84	694	7,353,577	4.55	334,804	0.01	0.21
333412	Industrial and commercial fan and blower manufacturing.	41,212	59	694	12,795,249	4.55	582,559	0.01	0.12
333414	Heating equipment (except warm air furnaces) manufacturing.	80,754	116	694	11,143,189	4.55	507,342	0.01	0.14
333511	Industrial mold manufacturing	160,131	226	710	2,481,931	5.29	131,278	0.03	0.54
333512	Machine tool (metal cutting types) manufacturing	68,151	97	702	7,371,252	5.29	389,890	0.01	0.18
333513	Machine tool (metal forming types) manufacturing	33,940	48	702	5,217,940	5.29	275,994	0.01	0.25
333514	Special die and tool, die set, jig, and fixture manufacturing.	231,988	325	714	2,378,801	5.29	125,823	0.03	0.57
333515	Cutting tool and machine tool accessory manufacturing.	139,916	197	710	3,384,805	5.29	179,034	0.02	0.40
333516	Rolling mill machinery and equipment manufacturing	12,279	17	710	9,496,141	5.29	502,283	0.01	0.14
333518	Other metalworking machinery manufacturing	50,002	70	710	7,231,602	5.29	382,504	0.01	0.19
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	48,452	70	693	10,727,834	2.63	281,813	0.01	0.25
333613	Mechanical power transmission equipment manufacturing.	61,197	88	693	14,983,120	2.63	393,597	0.00	0.18
333911	Pump and pumping equipment manufacturing	121,086	174	696	17,078,357	4.58	781,566	0.00	0.09
333912	Air and gas compressor manufacturing	84,518	121	698	21,079,073	4.58	964,653	0.00	0.07
333991	Power-driven handtool manufacturing	34,459	49	698	22,078,371	4.58	1,010,384	0.00	0.07
333992	Welding and soldering equipment manufacturing	62,401	90	696	16,457,683	4.58	753,162	0.00	0.09
333993	Packaging machinery manufacturing	83,714	120	700	7,374,940	4.58	337,503	0.01	0.21
333994	Industrial process furnace and oven manufacturing	42,523	61	702	5,584,460	4.58	255,565	0.01	0.27
333995	Fluid power cylinder and actuator manufacturing	78,057	112	695	13,301,790	4.58	608,737	0.01	0.11
333996	Fluid power pump and motor manufacturing	53,535	77	695	18,030,122	4.58	825,122	0.00	0.08
333997	Scale and balance (except laboratory) manufacturing	14,822	21	702	7,236,854	4.58	331,184	0.01	0.21
333999	All other miscellaneous general purpose machinery manufacturing.	207,006	296	698	6,033,776	4.58	276,127	0.01	0.25
334518	Watch, clock, and part manufacturing	8,740	12	703	4,924,986	5.94	292,667	0.01	0.24
335211	Electric housewares and household fans	13,928	22	643	22,023,076	4.21	927,874	0.00	0.07
335221	Household cooking appliance manufacturing	30,077	47	643	37,936,003	4.21	1,598,316	0.00	0.04
335222	Household refrigerator and home freezer manufacturing.	32,118	26	1,235	188,132,355	4.21	7,926,376	0.00	0.02
335224	Household laundry equipment manufacturing	30,521	23	1,327	221,491,837	4.21	9,331,875	0.00	0.01
335228	Other major household appliance manufacturing	24,023	37	643	107,476,620	4.21	4,528,196	0.00	0.01
336111	Automobile manufacturing	293,357	181	1,621	512,748,675	2.04	10,462,470	0.00	0.02
336112	Light truck and utility vehicle manufacturing	404,778	94	4,306	1,581,224,101	2.04	32,264,364	0.00	0.01
336120	Heavy duty truck manufacturing	125,181	95	1,318	194,549,998	2.04	3,969,729	0.00	0.03
336211	Motor vehicle body manufacturing	187,131	269	696	15,012,805	2.04	306,331	0.00	0.23
336212	Truck trailer manufacturing	126,512	182	694	17,032,455	2.04	347,542	0.00	0.20
336213	Motor home manufacturing	84,073	91	924	65,421,325	2.04	1,334,901	0.00	0.07
336311	Carburetor, piston, piston ring, and valve manufacturing.	41,219	60	693	21,325,990	2.04	435,150	0.00	0.16
336312	Gasoline engine and engine parts manufacturing	258,625	373	693	36,938,061	2.04	753,709	0.00	0.09

336322	Other motor vehicle electrical and electronic equipment manufacturing.	242,586	350	693	33,890,776	2.04	691,530	0.00	0.10
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	153,960	223	692	42,374,501	2.04	864,638	0.00	0.08
336340	Motor vehicle brake system manufacturing	132,114	191	693	51,498,927	2.04	1,050,819	0.00	0.07
336350	Motor vehicle transmission and power train parts manufacturing.	327,377	473	692	63,004,961	2.04	1,285,596	0.00	0.05
336370	Motor vehicle metal stamping	431,985	624	692	33,294,026	2.04	679,354	0.00	0.10
336399	All other motor vehicle parts manufacturing	583,803	843	693	31,304,202	2.04	638,752	0.00	0.11
336611	Ship building and repair	8,749,619	635	13,779	24,524,381	5.86	1,437,564	0.06	0.96
336612	Boat building	5,479,624	1,129	4,854	9,474,540	5.86	555,376	0.05	0.87
336992	Military armored vehicle, tank, and tank component manufacturing.	27,227	39	697	44,887,321	6.31	2,832,073	0.00	0.02
337215	Showcase, partition, shelving, and locker manufacturing.	233,720	334	701	4,943,560	4.54	224,593	0.01	0.31
339114	Dental equipment and supplies manufacturing	351,955	411	856	4,732,949	10.77	509,695	0.02	0.17
339116	Dental laboratories	1,439,004	7,261	198	563,964	10.77	60,734	0.04	0.33
339911	Jewelry (except costume) manufacturing	1,560,353	1,777	878	3,685,009	5.80	213,566	0.02	0.41
339913	Jewelers' materials and lapidary work manufacturing	320,878	264	1,215	3,762,284	5.80	218,045	0.03	0.56
339914	Costume jewelry and novelty manufacturing	236,821	590	401	1,353,403	5.80	78,437	0.03	0.51
339950	Sign manufacturing	294,919	496	594	1,872,356	5.80	108,513	0.03	0.55
423840	Industrial supplies, wholesalers	177,299	383	463	1,913,371	3.44	65,736	0.02	0.70
482110	Rail transportation	2,452,073	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	389,256	7,980	49	755,073	7.34	55,429	0.01	0.09
	Total	146,726,595	56,121	2,571					

[a] Profit rates were calculated by ERG (2013) as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

b. Normal Year-to-Year Variations in Prices and Profit Rates

The United States has a dynamic and constantly changing economy in which an annual percentage increase in industry revenues or prices of one percent or more are common. Examples of year-to-year changes in an industry that could cause such an increase in revenues or prices include increases in fuel, material, real estate, or other costs; tax increases; and shifts in demand.

To demonstrate the normal year-to-year variation in prices for all the manufacturers in general industry and maritime affected by the proposed rule, OSHA developed in the PEA year-to-year producer price indices and year-to-year percentage changes in producer prices, by industry, for the years 1998–2009. For the combined affected manufacturing industries in general industry and maritime over the 12-year period, the average change in producer prices was 3.8 percent a year. For the three industries in general industry and maritime with the largest estimated potential annual cost impact as a percentage of revenue (of approximately 0.35 percent, on average), the average annual changes in producer prices in these industries over the 12-year period averaged 3.5 percent.

Based on these data, it is clear that the potential price impacts of the proposed rule in general industry and maritime are all well within normal year-to-year variations in prices in those industries. Thus, OSHA preliminarily concludes that the potential price impacts of the proposed would not threaten the economic viability of any industries in general industry and maritime.

Changes in profit rates are also subject to the dynamics of the U.S. economy. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers in general industry and maritime affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000–2006. For the combined affected manufacturing industries in general industry and maritime over the 7-year period, the average change in profit rates was 38.9 percent a year. For the 7 industries in general industry and maritime with the largest estimated potential annual cost impacts as a percentage of profit—ranging from 4 percent to 9 percent—the average annual changes in profit rates in these industries over the 7-year period averaged 35 percent.

Nevertheless, a longer-term reduction in profit rates in excess of 10 percent a year could be problematic for some affected industries and might conceivably, under sufficiently adverse circumstances, threaten an industry's economic viability. In OSHA's view, however, affected industries would generally be able to pass on most or all of the costs of the proposed rule in the form of higher prices rather than to bear the costs of the proposed rule in reduced profits. After all, it defies common sense to suggest that the demanded quantities of brick and structural clay, vitreous china, ceramic wall and floor tile, other structural clay products (such as clay sewer pipe), and the various other products manufactured by affected industries would significantly contract in response to a 0.4 percent (or lower) price increase for these products. It is of course possible that such price changes will result in some reduction in output, and the reduction in output might be met through the closure of a small percentage of the plants in the industry. However, the only realistic circumstance such that an entire industry would be significantly affected by small potential price increases would be the availability in the market of a very close or perfect substitute product not subject to OSHA regulation. The classic example, in theory, would be foreign competition. Below, OSHA examines the threat of foreign competition for affected U.S. establishments in general industry and maritime.

c. International Trade Effects

The magnitude and strength of foreign competition is a critical factor in determining the ability of firms in the U.S. to pass on (part or all of) the costs of the proposed rule. If firms are unable to do so, they would likely absorb the costs of the proposed rule out of profits, possibly resulting in the business failure of individual firms or even, if the cost impacts are sufficiently large and pervasive, causing significant dislocations within an affected industry.

In the PEA, OSHA examined how likely such an outcome is. The analysis there included a review of trade theory and empirical evidence and the estimation of impacts. Throughout, the Agency drew on ERG (2007c), which was prepared specifically to help analyze the international trade impacts of OSHA's proposed silica rule. A summary of the PEA results is presented below.

ERG (2007c) focused its analysis on eight of the industries likely to be most affected by the proposed silica rule and for which import and export data were available. ERG combined econometric estimates of the elasticity of substitution between foreign and domestic products, Annual Survey of Manufactures data, and assumptions concerning the values for key parameters to estimate the effect of a range of hypothetical price increases on total domestic production. In particular, ERG estimated the domestic production that would be replaced by imported products and the decrease in exported products that would result from a 1 percent increase in prices—under the assumption that firms would attempt to pass on all of a 1 percent increase in costs arising from the proposed rule. The sum of the increase in imports and decrease in exports represents the total loss to industry attributable to the rule. These projected losses are presented as a percentage of baseline domestic production to provide some context for evaluating the relative size of these impacts.

The effect of a 1 percent increase in the price of a domestic product is derived from the baseline level of U.S. domestic production and the baseline level of imports. The baseline ratio of import values to domestic production for the eight affected industries ranges from 0.04 for iron foundries to 0.547 for ceramic wall and floor tile manufacturing—that is, baseline import values range from 4 percent to more than 50 percent of domestic production in these eight industries. ERG's estimates of the percentage reduction in U.S. production for the eight affected industries due to increased domestic imports (arising from a 1 percent increase in the price of domestic products) range from 0.013 percent for iron foundries to 0.237 percent for cut stone and stone product manufacturing.

ERG also estimated baseline ratio of U.S. exports to consumption in the rest of the world for the sample of eight affected industries. The ratios range from 0.001 for other concrete manufacturing to 0.035 percent for nonclay refractory manufacturing. The estimated percentage reductions in U.S. production due to reduced U.S. exports (arising from a 1 percent increase in the price of domestic products) range from 0.014 percent for ceramic wall and floor tile manufacturing to 0.201 percent for nonclay refractory manufacturing.

The total percentage change in U.S. production for the eight affected industries is the sum of the loss of increased imports and the loss of exports. The total percentage reduction in U.S. production arising from a 1 percent increase in the price of domestic products range from a low of 0.085 percent for other concrete product manufacturing to a high of 0.299 percent for porcelain electrical supply manufacturing.

These estimates suggest that the proposed rule would have only modest international trade effects. It was previously hypothesized that if price increases resulted in a substantial loss of revenue to foreign competition, then the increased costs of the proposed rule would have to come out of profits. That possibility has been contradicted by the results reported in this section. The maximum loss to foreign competition in any affected industry due to a 1 percent price increase was estimated at approximately 0.3 percent of industry revenue. Because, as reported earlier in this section, the maximum cost impact of the proposed rule for any affected industry would be 0.39 percent of revenue, this means that the maximum loss to foreign competition in any affected industry as a result of the proposed rule would be 0.12 percent of industry revenue—which, even for the most affected industry, would hardly qualify as a substantial loss to foreign competition. This analysis cannot tell us whether the resulting change in revenues will lead to a small decline in the number of establishments in the industry or slightly less revenue for each establishment. However it can reasonably be concluded that revenue changes of this magnitude will not lead to the elimination of industries or significantly alter their competitive structure.

Based on the Agency's preceding analysis of economic impacts on revenues, profits, and international trade, OSHA preliminarily concludes that the annualized costs of the proposed rule are below the threshold level that could threaten the economic viability of any industry in general industry or maritime. OSHA further notes that while there would be additional costs (not attributable to the proposed rule) for some employers in general industry and maritime to come into compliance with the *current* silica standard, these costs would not affect the Agency's preliminary determination of the economic feasibility of the proposed rule.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected industries in their entirety and found that the proposed standard did not threaten the survival of these industries. Now OSHA wishes to demonstrate that the competitive structure of these industries would not be significantly altered.

To address this issue, OSHA examined the annualized costs per affected small entity and per very small entity for each affected industry in general industry and maritime. Again, OSHA used a minimum threshold level of annualized costs equal to one percent of annual revenues—and, secondarily, annualized costs equal to ten percent of annual profits—below which the Agency has concluded that the costs are unlikely to threaten the survival of small entities or very small entities or, consequently, to alter the competitive structure of the affected industries.

As shown in Table VIII–12 and Table VIII–13, the annualized cost of the proposed rule is estimated to be $2,103 for the average small entity in general industry and maritime and $616 for the average very small entity in general industry and maritime. These tables also show that there are no industries in general industry and maritime in which the annualized costs of the proposed rule for small entities or very small entities exceed one percent of annual revenues. NAICS 327111 (Vitreous china plumbing fixtures & bathroom accessories manufacturing) has the highest potential cost impact as a percentage of revenues, of 0.61 percent, for small entities, and NAICS 327112 (Vitreous china, fine earthenware, & other pottery product manufacturing) has the highest potential cost impact as a percentage of revenues, of 0.75 percent, for very small entities. Small entities in two industries in general industry and maritime—NAICS 327111 and NAICS 327123 (Other structural clay product mfg.)—have annualized costs in excess of 10 percent of annual profits (13.91 percent and 10.63 percent, respectively). NAICS 327112 is the only industry in general industry and maritime in which the annualized costs of the proposed rule for very small entities exceed ten percent of annual profits (16.92 percent).

In general, cost impacts for affected small entities or very small entities will tend to be somewhat higher, on average, than the cost impacts for the average business in those affected industries. That is to be expected. After all, smaller businesses typically suffer from diseconomies of scale in many aspects of their business, leading to less revenue per dollar of cost and higher unit costs. Small businesses are able to overcome these obstacles by providing specialized products and services, offering local service and better service, or otherwise creating a market niche for themselves. The higher cost impacts for smaller businesses estimated for this rule generally fall within the range observed in other OSHA regulations and, as verified by OSHA's lookback reviews, have not been of such a magnitude to lead to their economic failure.

TABLE VIII–12—SCREENING ANALYSIS FOR SMALL ENTITIES IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected small entities	Annualized cost per affected entity	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$140,305	431	$326	$10,428,583	7.50	$782,268	0.00	0.04
324122	Asphalt shingle and roofing materials	872,614	106	8,232	14,067,491	7.50	1,055,229	0.06	0.78
325510	Paint and coating manufacturing	71,718	1,042	69	6,392,803	5.38	344,213	0.00	0.02
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	231,845	25	9,274	1,509,677	4.41	66,651	0.61	13.91
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,854,472	717	2,586	693,637	4.41	30,623	0.37	8.45
327113	Porcelain electrical supply mfg	1,004,480	97	10,355	4,574,464	4.41	201,959	0.23	5.13
327121	Brick and structural clay mfg	3,062,272	93	32,928	9,265,846	4.41	409,079	0.36	8.05
327122	Ceramic wall and floor tile mfg	2,189,278	173	12,655	3,236,635	4.41	142,895	0.39	8.86
327123	Other structural clay product mfg	510,811	42	12,162	2,592,114	4.41	114,440	0.47	10.63
327124	Clay refractory manufacturing	212,965	96	2,218	6,026,297	4.41	266,056	0.04	0.83
327125	Nonclay refractory manufacturing	211,512	68	3,110	7,346,739	4.41	324,352	0.04	0.96
327211	Flat glass manufacturing	275,155	56	4,913	64,950,007	3.42	2,221,884	0.01	0.22
327212	Other pressed and blown glass and glassware manufacturing.	243,132	228	1,068	935,353	3.42	31,998	0.11	3.34
327213	Glass container manufacturing	57,797	24	2,408	10,181,980	3.42	348,317	0.02	0.69
327320	Ready-mixed concrete manufacturing	10,490,561	2,401	4,369	7,245,974	6.64	480,994	0.06	0.91
327331	Concrete block and brick mfg	2,862,910	567	5,049	6,318,185	6.64	419,407	0.08	1.20
327332	Concrete pipe mfg	1,441,766	181	7,966	7,852,099	6.64	521,229	0.10	1.53
327390	Other concrete product mfg	8,826,516	1,876	4,705	3,521,965	6.64	233,791	0.13	2.01
327991	Cut stone and stone product manufacturing	8,028,431	1,874	4,284	1,730,741	5.49	95,001	0.25	4.51
327992	Ground or treated mineral and earth manufacturing	2,108,649	132	15,975	6,288,188	5.49	345,160	0.25	4.63
327993	Mineral wool manufacturing	291,145	175	1,664	6,181,590	5.49	339,309	0.03	0.49
327999	All other misc. nonmetallic mineral product mfg	1,130,230	326	3,467	4,299,551	5.49	236,004	0.08	1.47
331111	Iron and steel mills	424,557	523	812	82,895,665	4.49	3,723,664	0.00	0.02
331112	Electrometallurgical ferroalloy product manufacturing	4,987	7	692	24,121,503	4.49	1,083,535	0.00	0.06
331210	Iron and steel pipe and tube manufacturing from purchased steel.	84,537	94	896	40,090,061	4.49	1,800,841	0.00	0.05
331221	Rolled steel shape manufacturing	42,672	54	787	31,848,937	4.49	1,430,651	0.00	0.05
331222	Steel wire drawing	57,557	67	862	16,018,794	4.49	719,562	0.01	0.12
331314	Secondary smelting and alloying of aluminum	15,277	20	777	18,496,524	4.46	825,857	0.00	0.09
331423	Secondary smelting, refining, and alloying of copper	4,206	6	722	20,561,614	4.42	907,800	0.00	0.08
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	18,357	25	741	9,513,728	4.42	420,033	0.01	0.18
331511	Iron foundries	5,312,382	408	13,021	5,865,357	4.11	241,290	0.22	5.40
331512	Steel investment foundries	1,705,373	101	16,885	8,489,826	4.11	349,255	0.20	4.83
331513	Steel foundries (except investment)	2,521,998	192	13,135	11,977,647	4.11	492,738	0.11	2.67
331524	Aluminum foundries (except die-casting)	4,316,135	412	10,476	4,039,244	4.11	166,167	0.26	6.30
331525	Copper foundries (except die-casting)	1,596,288	246	6,489	2,847,376	4.11	117,136	0.23	5.54
331528	Other nonferrous foundries (except die-casting)	620,344	112	5,539	2,640,180	4.11	108,612	0.21	5.10
332111	Iron and steel forging	47,376	63	756	8,310,925	4.71	391,034	0.01	0.19
332112	Nonferrous forging	13,056	17	760	21,892,338	4.71	1,030,048	0.00	0.07
332115	Crown and closure manufacturing	5,080	7	732	6,697,995	4.71	315,145	0.01	0.23
332116	Metal stamping	212,110	279	759	5,360,428	4.71	252,211	0.01	0.30
332117	Powder metallurgy part manufacturing	17,537	23	762	6,328,522	4.71	297,761	0.01	0.26
332211	Cutlery and flatware (except precious) manufacturing	10,419	14	738	2,852,835	5.22	149,022	0.03	0.50
332212	Hand and edge tool manufacturing	87,599	113	772	3,399,782	5.22	177,592	0.02	0.43
332213	Saw blade and handsaw manufacturing	9,221	12	752	5,385,465	5.22	281,317	0.01	0.27
332214	Kitchen utensil, pot, and pan manufacturing	10,475	13	798	10,355,293	5.22	540,923	0.01	0.15
332323	Ornamental and architectural metal work	28,608	42	673	2,069,492	4.70	97,346	0.03	0.69
332439	Other metal container manufacturing	43,857	56	784	5,260,693	3.58	188,521	0.01	0.42
332510	Hardware manufacturing	78,538	104	756	4,442,699	5.22	232,070	0.02	0.33
332611	Spring (heavy gauge) manufacturing	14,071	19	754	6,621,896	5.22	345,904	0.01	0.22
332612	Spring (light gauge) manufacturing	36,826	44	834	4,500,760	5.22	235,103	0.02	0.35
332618	Other fabricated wire product manufacturing	113,603	148	765	3,440,489	5.22	179,719	0.02	0.43
332710	Machine shops	1,032,483	1,399	738	1,464,380	5.80	84,907	0.05	0.87
332812	Metal coating and allied services	2,492,357	2,301	1,083	2,904,851	4.85	141,018	0.04	0.77
332911	Industrial valve manufacturing	53,520	71	752	5,841,019	6.81	397,593	0.01	0.19
332912	Fluid power valve and hose fitting manufacturing	41,712	55	757	6,486,405	6.81	441,524	0.01	0.17

332913	Plumbing fixture fitting and trim manufacturing	19,037	25	752	9,183,477	6.81	625,111	0.01	0.12
332919	Other metal valve and pipe fitting manufacturing	30,618	40	764	9,432,914	6.81	642,090	0.01	0.12
332991	Ball and roller bearing manufacturing	13,624	18	741	5,892,239	6.81	401,079	0.01	0.18
332996	Fabricated pipe and pipe fitting manufacturing	74,633	99	754	4,377,576	6.81	297,978	0.02	0.25
332997	Industrial pattern manufacturing	20,767	28	736	1,127,301	6.81	76,734	0.07	0.96
332998	Enameled iron and metal sanitary ware manufacturing.	13,779	22	630	3,195,173	6.81	217,493	0.02	0.29
332999	All other miscellaneous fabricated metal product manufacturing.	230,825	311	742	2,904,500	6.81	197,707	0.03	0.38
333319	Other commercial and service industry machinery manufacturing.	123,816	165	750	4,960,861	4.86	241,023	0.02	0.31
333411	Air purification equipment manufacturing	27,021	36	748	4,449,669	4.55	202,591	0.02	0.37
333412	Industrial and commercial fan and blower manufacturing.	27,149	34	791	7,928,953	4.55	361,000	0.01	0.22
333414	Heating equipment (except warm air furnaces) manufacturing.	45,308	61	741	5,667,272	4.55	258,027	0.01	0.29
333511	Industrial mold manufacturing	143,216	193	743	2,121,298	5.29	112,203	0.04	0.66
333512	Machine tool (metal cutting types) manufacturing	44,845	60	746	4,136,962	5.29	218,818	0.02	0.34
333513	Machine tool (metal forming types) manufacturing	30,365	40	758	4,358,035	5.29	230,511	0.02	0.33
333514	Special die and tool, die set, jig, and fixture manufacturing.	203,742	274	743	2,083,166	5.29	110,186	0.04	0.67
333515	Cutting tool and machine tool accessory manufacturing.	104,313	140	746	2,082,357	5.29	110,143	0.04	0.68
333516	Rolling mill machinery and equipment manufacturing	9,604	13	744	8,330,543	5.29	440,630	0.01	0.17
333518	Other metalworking machinery manufacturing	38,359	50	765	5,680,062	5.29	300,438	0.01	0.25
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	25,087	32	777	6,028,137	2.63	158,355	0.01	0.49
333613	Mechanical power transmission equipment manufacturing.	26,182	35	754	9,094,798	2.63	238,915	0.01	0.32
333911	Pump and pumping equipment manufacturing	41,360	54	762	6,220,799	4.58	284,686	0.01	0.27
333912	Air and gas compressor manufacturing	23,948	32	758	6,290,845	4.58	287,891	0.01	0.26
333991	Power-driven handtool manufacturing	9,867	13	732	3,816,319	4.58	174,648	0.02	0.42
333992	Welding and soldering equipment manufacturing	23,144	31	745	5,635,771	4.58	257,913	0.01	0.29
333993	Packaging machinery manufacturing	54,872	74	742	4,240,165	4.58	194,045	0.02	0.38
333994	Industrial process furnace and oven manufacturing	34,418	45	757	4,470,378	4.58	204,580	0.02	0.37
333995	Fluid power cylinder and actuator manufacturing	32,249	43	756	5,830,077	4.58	266,805	0.01	0.28
333996	Fluid power pump and motor manufacturing	15,258	20	772	4,401,836	4.58	201,444	0.02	0.38
333997	Scale and balance (except laboratory) manufacturing	12,129	16	764	4,987,858	4.58	228,262	0.02	0.33
333999	All other miscellaneous general purpose machinery manufacturing.	123,384	166	745	3,262,128	4.58	149,287	0.02	0.50
334518	Watch, clock, and part manufacturing	6,646	9	732	2,878,581	5.94	171,059	0.03	0.43
335211	Electric housewares and household fans	3,326	5	643	6,088,365	4.21	256,514	0.01	0.25
335221	Household cooking appliance manufacturing	6,521	10	649	10,460,359	4.21	440,715	0.01	0.15
335222	Household refrigerator and home freezer manufacturing.	32,118	18	1,784	271,746,735	4.21	11,449,210	0.00	0.02
335224	Household laundry equipment manufacturing	30,521	17	1,795	299,665,426	4.21	12,625,478	0.00	0.01
335228	Other major household appliance manufacturing	1,917	3	671	8,269,046	4.21	348,391	0.01	0.19
336111	Automobile manufacturing	293,357	167	1,757	555,733,594	2.04	11,339,563	0.00	0.02
336112	Light truck and utility vehicle manufacturing	404,778	63	6,425	2,359,286,755	2.04	48,140,479	0.00	0.01
336120	Heavy duty truck manufacturing	125,181	77	1,626	240,029,218	2.04	4,897,718	0.00	0.03
336211	Motor vehicle body manufacturing	187,131	239	784	16,910,028	2.04	345,044	0.00	0.23
336212	Truck trailer manufacturing	54,137	72	748	9,018,164	2.04	184,013	0.01	0.41
336213	Motor home manufacturing	84,073	79	1,064	75,358,742	2.04	1,537,671	0.00	0.07
336311	Carburetor, piston, piston ring, and valve manufacturing.	10,269	14	748	2,242,044	2.04	45,748	0.03	1.64
336312	Gasoline engine and engine parts manufacturing	65,767	94	703	4,245,230	2.04	86,623	0.02	0.81
336322	Other motor vehicle electrical and electronic equipment manufacturing.	71,423	101	706	6,746,386	2.04	137,658	0.01	0.51
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	25,492	36	708	7,742,773	2.04	157,989	0.01	0.45
336340	Motor vehicle brake system manufacturing	32,886	46	710	6,554,128	2.04	133,735	0.01	0.53
336350	Motor vehicle transmission and power train parts manufacturing.	46,869	66	710	6,058,947	2.04	123,631	0.01	0.57
336370	Motor vehicle metal stamping	159,156	201	792	11,477,248	2.04	234,190	0.01	0.34
336399	All other motor vehicle parts manufacturing	169,401	235	721	6,985,145	2.04	142,530	0.01	0.51
336611	Ship building and repair	8,749,619	575	15,217	27,083,446	5.86	1,587,570	0.06	0.96

TABLE VIII–12—SCREENING ANALYSIS FOR SMALL ENTITIES IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected small entities	Annualized cost per affected entity	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
336612	Boat building	2,612,088	814	3,209	5,304,212	5.86	310,921	0.06	1.03
336992	Military armored vehicle, tank, and tank component manufacturing.	27,227	32	845	54,437,815	6.31	3,434,642	0.00	0.02
337215	Showcase, partition, shelving, and locker manufacturing.	176,800	235	751	3,637,716	4.54	165,266	0.02	0.45
339114	Dental equipment and supplies manufacturing	261,393	292	895	2,619,222	10.77	282,066	0.03	0.32
339116	Dental laboratories	1,397,271	7,011	199	532,828	10.77	57,381	0.04	0.35
339911	Jewelry (except costume) manufacturing	1,392,054	1,751	795	2,615,940	5.80	151,608	0.03	0.52
339913	Jewelers' materials and lapidary work manufacturing	257,285	258	997	2,775,717	5.80	160,868	0.04	0.62
339914	Costume jewelry and novelty manufacturing	242,158	588	412	971,681	5.80	56,314	0.04	0.73
339950	Sign manufacturing	264,810	428	618	1,642,826	5.80	95,211	0.04	0.65
423840	Industrial supplies, wholesalers	143,614	226	636	5,001,467	3.44	171,830	0.01	0.37
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	370,174	7,423	50	663,948	7.34	48,739	0.01	0.10
	Total	86,520,059	41,136	2,103					

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–13—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected entities with <20 employees	Annualized costs per affected entities	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$27,770	260	$107	$4,335,678	7.50	$325,227	0.00	0.03
324122	Asphalt shingle and roofing materials	85,253	57	1,496	4,013,780	7.50	301,081	0.04	0.50
325510	Paint and coating manufacturing	18,910	324	58	1,871,296	5.38	100,758	0.00	0.06
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	26,606	19	1,400	327,368	4.41	14,453	0.43	9.69
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	747,902	645	1,160	155,258	4.41	6,855	0.75	16.92
327113	Porcelain electrical supply mfg	79,824	57	1,400	601,316	4.41	26,548	0.23	5.28
327121	Brick and structural clay mfg	76,696	31	2,474	715,098	4.41	31,571	0.35	7.84
327122	Ceramic wall and floor tile mfg	382,871	136	2,815	807,291	4.41	35,641	0.35	7.90
327123	Other structural clay product mfg	67,176	25	2,687	782,505	4.41	34,547	0.34	7.78
327124	Clay refractory manufacturing	29,861	55	543	1,521,469	4.41	67,172	0.04	0.81
327125	Nonclay refractory manufacturing	34,061	40	852	1,506,151	4.41	66,495	0.06	1.28
327211	Flat glass manufacturing	4,450	4	1,075	905,562	3.42	30,978	0.12	3.47
327212	Other pressed and blown glass and glassware manufacturing.	87,895	79	1,107	370,782	3.42	12,684	0.30	8.73
327213	Glass container manufacturing	4,798	4	1,107	2,690,032	3.42	92,024	0.04	1.20
327320	Ready-mixed concrete manufacturing	1,897,131	1,429	1,328	1,922,659	6.64	127,628	0.07	1.04
327331	Concrete block and brick mfg	544,975	339	1,608	1,995,833	6.64	132,485	0.08	1.21
327332	Concrete pipe mfg	116,670	67	1,741	2,375,117	6.64	157,662	0.07	1.10
327390	Other concrete product mfg	1,885,496	1,326	1,422	974,563	6.64	64,692	0.15	2.20
327991	Cut stone and stone product manufacturing	2,753,051	1,471	1,872	946,566	5.49	51,957	0.20	3.60
327992	Ground or treated mineral and earth manufacturing	389,745	78	4,997	1,635,092	5.49	89,751	0.31	5.57
327993	Mineral wool manufacturing	48,575	46	1,061	1,398,274	5.49	76,752	0.08	1.38
327999	All other misc. nonmetallic mineral product mfg	311,859	235	1,327	1,457,181	5.49	79,985	0.09	1.66
331111	Iron and steel mills	9,342	12	777	4,177,841	4.49	187,668	0.02	0.41
331112	Electrometallurgical ferroalloy product manufacturing	0	0	N/A	1,202,610	4.49	54,021	N/A	N/A
331210	Iron and steel pipe and tube manufacturing from purchased steel.	1,706	2	774	2,113,379	4.49	94,933	0.04	0.82
331221	Rolled steel shape manufacturing	1,612	2	774	2,108,498	4.49	94,713	0.04	0.82

331222	Steel wire drawing	2,939	4	774	835,444	4.49	37,528	0.09	2.06
331314	Secondary smelting and alloying of aluminum	1,254	2	774	2,039,338	4.46	91,055	0.04	0.85
331423	Secondary smelting, refining, and alloying of copper	0	0	N/A	2,729,146	4.42	120,492	N/A	N/A
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	2,897	4	774	1,546,332	4.42	68,271	0.05	1.13
331511	Iron foundries	330,543	201	1,644	1,031,210	4.11	42,422	0.16	3.88
331512	Steel investment foundries	47,902	27	1,774	1,831,394	4.11	75,340	0.10	2.35
331513	Steel foundries (except investment)	162,670	102	1,595	1,577,667	4.11	64,902	0.10	2.46
331524	Aluminum foundries (except die-casting)	503,027	235	2,141	874,058	4.11	35,957	0.24	5.95
331525	Copper foundries (except die-casting)	370,110	164	2,257	814,575	4.11	33,510	0.28	6.73
331528	Other nonferrous foundries (except die-casting)	162,043	77	2,104	837,457	4.11	34,451	0.25	6.11
332111	Iron and steel forging	4,089	5	774	1,175,666	4.71	55,316	0.07	1.40
332112	Nonferrous forging	784	1	774	1,431,874	4.71	67,371	0.05	1.15
332115	Crown and closure manufacturing	992	1	774	1,715,882	4.71	80,733	0.05	0.96
332116	Metal stamping	27,154	35	775	1,146,408	4.71	53,939	0.07	1.44
332117	Powder metallurgy part manufacturing	2,072	3	774	1,580,975	4.71	74,386	0.05	1.04
332211	Cutlery and flatware (except precious) manufacturing	2,217	3	774	391,981	5.22	20,476	0.20	3.78
332212	Hand and edge tool manufacturing	19,535	25	774	770,858	5.22	40,267	0.10	1.92
332213	Saw blade and handsaw manufacturing	2,296	3	774	975,698	5.22	50,967	0.08	1.52
332214	Kitchen utensil, pot, and pan manufacturing	0	0	N/A	826,410	5.22	43,169	N/A	N/A
332323	Ornamental and architectural metal work	9,527	14	694	695,970	4.70	32,737	0.10	2.12
332439	Other metal container manufacturing	5,279	7	788	1,027,511	3.58	36,822	0.08	2.14
332510	Hardware manufacturing	11,863	15	777	776,986	5.22	40,587	0.10	1.92
332611	Spring (heavy gauge) manufacturing	1,927	2	786	1,774,584	5.22	92,698	0.04	0.85
332612	Spring (light gauge) manufacturing	4,960	6	774	1,085,302	5.22	56,692	0.07	1.36
332618	Other fabricated wire product manufacturing	19,946	26	774	778,870	5.22	40,685	0.10	1.90
332710	Machine shops	416,115	537	774	649,804	5.80	37,677	0.12	2.06
332812	Metal coating and allied services	613,903	885	694	602,598	4.85	29,254	0.12	2.37
332911	Industrial valve manufacturing	5,886	8	774	1,294,943	6.81	88,146	0.06	0.88
332912	Fluid power valve and hose fitting manufacturing	4,491	6	774	1,350,501	6.81	91,927	0.06	0.84
332913	Plumbing fixture fitting and trim manufacturing	1,505	2	774	811,318	6.81	55,226	0.10	1.40
332919	Other metal valve and pipe fitting manufacturing	2,710	3	781	2,164,960	6.81	147,367	0.04	0.53
332991	Ball and roller bearing manufacturing	1,132	1	774	1,808,246	6.81	123,086	0.04	0.63
332996	Fabricated pipe and pipe fitting manufacturing	12,453	16	774	1,237,265	6.81	84,220	0.06	0.92
332997	Industrial pattern manufacturing	8,917	12	774	503,294	6.81	34,259	0.15	2.26
332998	Enameled iron and metal sanitary ware manufacturing.	3,287	5	690	725,491	6.81	49,384	0.10	1.40
332999	All other miscellaneous fabricated metal product manufacturing.	55,981	72	774	933,734	6.81	63,558	0.08	1.22
333319	Other commercial and service industry machinery manufacturing.	19,776	26	774	1,127,993	4.86	54,803	0.07	1.41
333411	Air purification equipment manufacturing	4,745	6	774	1,152,661	4.55	52,480	0.07	1.47
333412	Industrial and commercial fan and blower manufacturing.	1,675	2	774	1,454,305	4.55	66,214	0.05	1.17
333414	Heating equipment (except warm air furnaces) manufacturing.	6,087	8	777	901,560	4.55	41,047	0.09	1.89
333511	Industrial mold manufacturing	43,738	56	774	716,506	5.29	37,898	0.11	2.04
333512	Machine tool (metal cutting types) manufacturing	8,756	11	776	911,891	5.29	48,233	0.09	1.61
333513	Machine tool (metal forming types) manufacturing	4,666	6	774	1,308,768	5.29	69,225	0.06	1.12
333514	Special die and tool, die set, jig, and fixture manufacturing.	65,867	85	774	816,990	5.29	43,213	0.09	1.79
333515	Cutting tool and machine tool accessory manufacturing.	31,406	41	775	771,162	5.29	40,789	0.10	1.90
333516	Rolling mill machinery and equipment manufacturing	1,361	2	774	2,243,812	5.29	118,683	0.03	0.65
333518	Other metalworking machinery manufacturing	6,766	9	774	965,694	5.29	51,079	0.08	1.51
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	3,318	4	774	1,393,898	2.63	36,617	0.06	2.11
333613	Mechanical power transmission equipment manufacturing.	3,114	4	774	2,113,156	2.63	55,511	0.04	1.39
333911	Pump and pumping equipment manufacturing	7,209	9	774	1,343,868	4.58	61,500	0.06	1.26
333912	Air and gas compressor manufacturing	4,228	5	774	1,644,664	4.58	75,266	0.05	1.03
333991	Power-driven handtool manufacturing	2,212	3	774	2,158,268	4.58	98,770	0.04	0.78
333992	Welding and soldering equipment manufacturing	3,835	5	774	1,331,521	4.58	60,935	0.06	1.27
333993	Packaging machinery manufacturing	9,742	13	774	809,474	4.58	37,044	0.10	2.09
333994	Industrial process furnace and oven manufacturing	5,631	7	774	1,324,790	4.58	60,627	0.06	1.28
333995	Fluid power cylinder and actuator manufacturing	3,955	5	774	916,613	4.58	41,947	0.08	1.84

TABLE VIII–13—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected entities with <20 employees	Annualized costs per affected entities	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
333996	Fluid power pump and motor manufacturing	2,670	3	774	1,417,549	4.58	64,872	0.05	1.19
333997	Scale and balance (except laboratory) manufacturing	1,947	3	774	1,527,651	4.58	69,911	0.05	1.11
333999	All other miscellaneous general purpose machinery manufacturing.	32,637	42	774	871,700	4.58	39,892	0.09	1.94
334518	Watch, clock, and part manufacturing	1,322	2	774	586,350	5.94	34,844	0.13	2.22
335211	Electric housewares and household fans	0	0	N/A	847,408	4.21	35,703	N/A	N/A
335221	Household cooking appliance manufacturing	722	1	698	2,228,319	4.21	93,883	0.03	0.74
335222	Household refrigerator and home freezer manufacturing.	0	0	N/A	4,917,513	4.21	207,184	N/A	N/A
335224	Household laundry equipment manufacturing	0	0	N/A	1,767,776	4.21	74,480	N/A	N/A
335228	Other major household appliance manufacturing	0	0	N/A	1,706,991	4.21	71,919	N/A	N/A
336111	Automobile manufacturing	2,147	3	774	1,507,110	2.04	30,752	0.05	2.52
336112	Light truck and utility vehicle manufacturing	795	1	774	1,089,801	2.04	22,237	0.07	3.48
336120	Heavy duty truck manufacturing	943	1	774	4,371,350	2.04	89,196	0.02	0.87
336211	Motor vehicle body manufacturing	12,371	16	774	1,720,545	2.04	35,107	0.04	2.20
336212	Truck trailer manufacturing	5,147	7	774	2,706,375	2.04	55,223	0.03	1.40
336213	Motor home manufacturing	1,193	2	774	2,184,388	2.04	44,572	0.04	1.74
336311	Carburetor, piston, piston ring, and valve manufacturing.	1,329	2	774	870,496	2.04	17,762	0.09	4.36
336312	Gasoline engine and engine parts manufacturing	11,683	15	774	867,703	2.04	17,705	0.09	4.37
336322	Other motor vehicle electrical and electronic equipment manufacturing.	8,618	11	774	1,383,831	2.04	28,237	0.06	2.74
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	2,876	4	774	1,543,436	2.04	31,493	0.05	2.46
336340	Motor vehicle brake system manufacturing	2,386	3	774	1,378,684	2.04	28,132	0.06	2.75
336350	Motor vehicle transmission and power train parts manufacturing.	6,390	8	774	864,746	2.04	17,645	0.09	4.38
336370	Motor vehicle metal stamping	5,759	7	778	1,519,875	2.04	31,013	0.05	2.51
336399	All other motor vehicle parts manufacturing	16,021	21	774	1,369,097	2.04	27,936	0.06	2.77
336611	Ship building and repair	212,021	65	3,252	770,896	5.86	45,188	0.42	7.20
336612	Boat building	391,950	121	3,247	1,101,324	5.86	64,557	0.29	5.03
336992	Military armored vehicle, tank, and tank component manufacturing.	0	0	N/A	1,145,870	6.31	72,296	N/A	N/A
337215	Showcase, partition, shelving, and locker manufacturing.	28,216	36	774	866,964	4.54	39,387	0.09	1.96
339114	Dental equipment and supplies manufacturing	79,876	87	922	657,192	10.77	70,773	0.14	1.30
339116	Dental laboratories	1,040,112	6,664	156	326,740	10.77	35,187	0.05	0.44
339911	Jewelry (except costume) manufacturing	533,353	1,532	348	673,857	5.80	39,054	0.05	0.89
339913	Jewelers' materials and lapidary work manufacturing	86,465	218	397	919,422	5.80	53,285	0.04	0.74
339914	Costume jewelry and novelty manufacturing	100,556	368	274	454,292	5.80	26,329	0.06	1.04
339950	Sign manufacturing	89,586	140	639	521,518	5.80	30,225	0.12	2.12
423840	Industrial supplies, wholesalers	50,612	95	531	2,432,392	3.44	83,567	0.02	0.64
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	320,986	6,506	49	562,983	7.34	41,328	0.01	0.12
	Total	15,745,425	25,544	616					

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

As a point of clarification, OSHA would like to draw attention to industries with captive foundries. There are three industries with captive foundries whose annualized costs for very small entities approach five percent of annual profits: NAICS 336311 (Carburetor, piston ring, and valve manufacturing); NAICS 336312 (Gasoline engine and engine parts manufacturing); and NAICS 336350 (Motor vehicle transmission and power train parts manufacturing). For very small entities in all three of these industries, the annualized costs as a percentage of annual profits are approximately 4.4 percent. OSHA believes, however, that very small entities in industries with captive foundries are unlikely to actually have captive foundries and that the captive foundries allocated to very small entities in fact belong in larger entities. This would have the result that the costs as percentage of profits for these larger entities would be lower than the 4.4 percent reported above. Instead, OSHA assumed that the affected employees would be distributed among entities of different size according to each entity size class's share of total employment. In other words, if 15 percent of employees in an industry worked in very small entities (those with fewer than 20 employees), then OSHA assumed that 15 percent of affected employees in the industry would work in very small entities. However, in reality, OSHA anticipates that in industries with captive foundries, none of the entities with fewer than 20 employees have captive foundries or, if they do, that the impacts are much smaller than estimated here. OSHA invites comment about whether and to what extent very small entities have captive foundries (in industries with captive foundries).

Regardless of whether the cost estimates have been inflated for very small entities in the three industries with captive foundries listed above, there are two reasons why OSHA is confident that the competitive structure of these industries would not be threatened by adverse competitive conditions for very small entities. First, as shown in Appendix VI–B of the PEA, very small entities in NAICS 336311, NAICS 336312, and NAICS 336350 account for 3 percent, 2 percent, and 3 percent, respectively, of the total number of establishments in the industry. Although it is possible that some of these very small entities could exit the industry in response to the proposed rule, courts interpreting the OSH Act have historically taken the view that losing at most 3 percent of the establishments in an industry would alter the competitive structure of that industry. Second, very small entities in industries with captive foundries, when confronted with higher foundry costs as a result of the proposed rule, have the option of dropping foundry activities, purchasing foundry products and services from businesses directly in the foundry industry, and focusing on the main goods and services produced in the industry. This, after all, is precisely what the rest of the establishments in these industries do.

e. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold level cannot be exceeded for affected small entities or very small entities in any affected industry.

Table VIII–12 and Table VIII–13 show that, in general industry and maritime, the annualized costs of the proposed rule do not exceed one percent of annual revenues for small entities or for very small entities in any industry. These tables also show that the annualized costs of the proposed rule exceed five percent of annual profits for small entities in 10 industries and for very small entities in 13 industries. OSHA is therefore unable to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Section VIII.I of this preamble.

3. Impacts in Construction

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed rule's projected costs of compliance would threaten the economic viability of affected construction industries, OSHA used the same data sources and methodological approach that were used earlier in this chapter for general industry and maritime. OSHA first compared, for each affected construction industry, annualized compliance costs to annual revenues and profits per (average) affected establishment. The results for all affected establishments in all affected construction industries are presented in Table VIII–14, using annualized costs per establishment for the proposed 50 μg/m³ PEL. The annualized cost of the proposed rule for the average establishment in construction, encompassing all construction industries, is estimated at $1,022 in 2009 dollars. It is clear from Table VIII–14 that the estimates of the annualized costs per affected establishment in the 10 construction industries vary widely. These estimates range from $2,598 for NAICS 237300 (Highway, street, and bridge construction) and $2,200 for NAICS 237100 (Utility system construction) to $241 for NAICS 238200 (Building finishing contractors) and $171 for NAICS 237200 (Land subdivision).

Table VIII–14 shows that in no construction industry do the annualized costs of the proposed rule exceed one percent of annual revenues or ten percent of annual profits. NAICS 238100 (Foundation, structure, and building exterior contractors) has both the highest cost impact as a percentage of revenues, of 0.13 percent, and the highest cost impact as a percentage of profits, of 2.97 percent. Based on these results, even if the costs of the proposed rule were 50 percent higher than OSHA has estimated, the highest cost impact as a percentage of revenues in any affected construction industry would be less than 0.2 percent. Furthermore, the costs of the proposed rule would have to be more than 650 percent higher than OSHA has estimated for the cost impact as a percentage of revenues to equal 1 percent in any affected construction industry. For all affected establishments in construction, the estimated annualized cost of the proposed rule is, on average, equal to 0.05 percent of annual revenue and 1.0 percent of annual profit.

Therefore, even though the annualized costs of the proposed rule incurred by the construction industry as a whole are almost four times the combined annualized costs incurred by general industry and maritime, OSHA preliminarily concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the economic viability of any of the construction industries. OSHA further notes that while there would be additional costs (not attributable to the proposed rule) for some employers in construction industries to come into compliance with the *current* silica standard, these costs would not affect the Agency's preliminary determination of the economic feasibility of the proposed rule.

Below, OSHA provides additional information to further support the Agency's conclusion that the proposed rule would not threaten the economic viability of any construction industry.

TABLE VIII–14—SCREENING ANALYSIS FOR ESTABLISHMENTS IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$23,288,881	55,338	$421	$2,002,532	4.87	$97,456	0.02	0.43
236200	Nonresidential Building Construction.	39,664,913	44,702	887	7,457,045	4.87	362,908	0.01	0.24
237100	Utility System Construction.	46,718,162	21,232	2,200	4,912,884	5.36	263,227	0.04	0.84
237200	Land Subdivision	1,110,789	6,511	171	2,084,334	11.04	230,214	0.01	0.07
237300	Highway, Street, and Bridge Construction.	30,807,861	11,860	2,598	8,663,019	5.36	464,156	0.03	0.56
237900	Other Heavy and Civil Engineering Construction.	7,164,210	5,561	1,288	3,719,070	5.36	199,264	0.03	0.65
238100	Foundation, Structure, and Building Exterior Contractors.	215,907,211	117,456	1,838	1,425,510	4.34	61,832	0.13	2.97
238200	Building Equipment Contractors.	4,902,138	20,358	241	1,559,425	4.34	67,640	0.02	0.36
238300	Building Finishing Contractors.	50,259,239	120,012	419	892,888	4.34	38,729	0.05	1.08
238900	Other Specialty Trade Contractors.	68,003,978	74,446	913	1,202,048	4.48	53,826	0.08	1.70
999000	State and local governments [d].	23,338,234	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	511,165,616	477,476	1,022					

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

b. Normal Year-to-Year Variations in Profit Rates

As previously noted, the United States has a dynamic and constantly changing economy in which large year-to-year changes in industry profit rates are commonplace. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers in construction affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000—2006. For the combined affected manufacturing industries in general industry and maritime over the 7-year period, the average change in profit rates was 15.4 percent a year.

What these data indicate is that, even if, theoretically, the annualized costs of the proposed rule for the most significantly affected construction industries were completely absorbed in reduced annual profits, the magnitude of reduced annual profit rates are well within normal year-to-year variations in profit rates in those industries and do not threaten their economic viability. Of course, a permanent loss of profits would present a greater problem than a temporary loss, but it is unlikely that all costs of the proposed rule would be absorbed in lost profits. Given that, as discussed in Chapter VI of the PEA, the overall price elasticity of demand for the outputs of the construction industry is fairly low and that almost all of the costs estimated in Chapter V of the PEA are variable costs, there is a reasonable chance that most firms will see small declines in output rather than that any but the most extremely marginal firms would close.

Considering the costs of the proposed rule relative to the size of construction activity in the United States, OSHA preliminarily concludes that the price and profit impacts of the proposed rule on construction industries would, in practice, be quite limited. Based on ERG (2007a), on an annual basis, the cost of the proposed rule would be equal to approximately 2 percent of the value of affected, silica-generating construction activity, and silica-generating construction activity accounts for approximately 4.8 percent of all construction spending in the U.S. Thus, the annualized cost of the proposed rule would be equal to approximately 0.1 percent of the value of annual construction activity in the U.S. On top of that, construction activity in the U.S. is not subject to any meaningful foreign competition, and any foreign firms performing construction activities in the United States would be subject to OSHA regulations.

c. Impacts by Type of Construction Demand

The demand for construction services originates in three independent sectors: residential building construction, nonresidential building construction, and nonbuilding construction.

Residential Building Construction: Residential housing demand is derived from the household demand for housing services. These services are provided by the stock of single and multi-unit residential housing units. Residential housing construction represents changes to the housing stock and includes construction of new units and modifications, renovations, and repairs to existing units. A number of studies have examined the price sensitivity of the demand for housing services. Depending on the data source and estimation methodologies, these studies have estimated the demand for housing services at price elasticity values ranging from –0.40 to –1.0, with the smaller (in absolute value) less elastic values estimated for short-run periods. In the long run, it is reasonable to expect the demand for the stock of housing to reflect similar levels of price sensitivity. Since housing investments include changes in the existing stock (renovations, depreciation, etc.) as well as new construction, it is likely that the price elasticity of demand for new residential construction will be lower than that for residential construction as a whole.

OSHA judges that many of the silica-generating construction activities affected by the proposed rule are not widely used in single-family construction. This assessment is consistent with the cost estimates that show relatively low impacts for residential building contractors. Multi-family residential construction might have more substantial impacts, but, based on census data, this type of construction represents a relatively small share of net investment in residential buildings.

Nonresidential Building Construction: Nonresidential building construction consists of industrial, commercial, and other nonresidential structures. As such, construction demand is derived from the demand for the output of the industries that use the buildings. For example, the demand for commercial office space is derived from the demand for the output produced by the users of the office space. The price elasticity of demand for this construction category will depend, among other things, on the price elasticity of demand for the final products produced, the importance of the costs of construction in the total cost of the final product, and the elasticity of substitution of other inputs that could substitute for nonresidential building construction. ERG (2007c) found no studies that attempted to quantify these relationships. But given the costs of the proposed rule relative to the size of construction spending in the United States, the resultant price or revenue effects are likely to be so small as to be barely detectable.

Nonbuilding Construction: Nonbuilding construction includes roads, bridges, and other infrastructure projects. Utility construction (power lines, sewers, water mains, etc.) and a variety of other construction types are also included. A large share of this construction (63.8 percent) is publicly financed (ERG, 2007a). For this reason, a large percentage of the decisions regarding the appropriate level of such investments is not made in a private market setting. The relationship between the costs and price of such investments and the level of demand might depend more on political considerations than the factors that determine the demand for privately produced goods and services.

While a number of studies have examined the factors that determine the demand for publicly financed construction projects, these studies have focused on the ability to finance such projects (*e.g.,* tax receipts) and socio-demographic factors (*e.g.,* population growth) to the exclusion of cost or price factors. In the absence of budgetary constraints, OSHA believes, therefore, that the price elasticity of demand for public investment is probably quite low. On the other hand, budget-imposed limits might constrain public construction spending. If the dollar value of public investments were fixed, a price elasticity of demand of 1 (in absolute terms) would be implied. Any percentage increase in construction costs would be offset with an equal percentage reduction in investment (measured in physical units), keeping public construction expenditures constant.

Public utility construction comprises the remainder of nonbuilding construction. This type of construction is subject to the same derived-demand considerations discussed for nonresidential building construction, and for the same reasons, OSHA expects the price and profit impacts to be quite small.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected construction industries in their entirety and found that the proposed standard did not threaten the survival of these construction industries. Now OSHA wishes to demonstrate that the competitive structure of these industries would not be significantly altered.

To address this issue, OSHA examined the annualized costs per affected small and very small entity for each affected construction industry. Table VIII–15 and Table VIII–16 show that in no construction industries do the annualized costs of the proposed rule exceed one percent of annual revenues or ten percent of annual profits either for small entities or for very small entities. Therefore, OSHA preliminarily concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the competitive structure of any of the construction industries.

TABLE VIII–15—SCREENING ANALYSIS FOR SMALL ENTITIES IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected small entities	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$18,527,934	44,212	$419	$1,303,262	4.87	$67,420	0.03	0.62
236200	Nonresidential Building Construction.	24,443,185	42,536	575	4,117,755	4.87	200,396	0.01	0.29
237100	Utility System Construction.	30,733,201	20,069	1,531	3,248,053	5.36	174,027	0.05	0.88
237200	Land Subdivision	546,331	3,036	180	1,215,688	11.04	134,272	0.01	0.13
237300	Highway, Street, and Bridge Construction.	13,756,992	10,350	1,329	3,851,971	5.36	206,385	0.03	0.64
237900	Other Heavy and Civil Engineering Construction.	5,427,484	5,260	1,032	2,585,858	5.36	138,548	0.04	0.74
238100	Foundation, Structure, and Building Exterior Contractors.	152,160,159	115,345	1,319	991,258	4.34	42,996	0.13	3.07

TABLE VIII–15—SCREENING ANALYSIS FOR SMALL ENTITIES IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Affected small entities	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
238200	Building Equipment Contractors.	3,399,252	13,933	244	1,092,405	4.34	47,383	0.02	0.51
238300	Building Finishing Contractors.	36,777,673	87,362	421	737,930	4.34	32,008	0.06	1.32
238900	Other Specialty Trade Contractors.	53,432,213	73,291	729	1,006,640	4.48	45,076	0.07	1.62
999000	State and local governments [d].	2,995,955	13,482	222	N/A	N/A	N/A	N/A	N/A
	Total	342,200,381	428,876	798	....	....	....	....	....

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–16—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected entities with <20 employees	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$13,837,293	32,042	$432	$922,275	4.87	$44,884	0.05	0.96
236200	Nonresidential Building Construction.	10,777,269	35,746	301	1,902,892	4.87	92,607	0.02	0.33
237100	Utility System Construction.	8,578,771	16,113	532	991,776	5.36	53,138	0.05	1.00
237200	Land Subdivision	546,331	3,036	180	1,215,688	11.04	134,272	0.01	0.13
237300	Highway, Street, and Bridge Construction.	4,518,038	8,080	559	1,649,324	5.36	88,369	0.03	0.63
237900	Other Heavy and Civil Engineering Construction.	1,650,007	4,436	372	834,051	5.36	44,688	0.04	0.83
238100	Foundation, Structure, and Building Exterior Contractors.	81,822,550	105,227	778	596,296	4.34	25,864	0.13	3.01
238200	Building Equipment Contractors.	1,839,588	7,283	253	579,724	4.34	25,146	0.04	1.00
238300	Building Finishing Contractors.	21,884,973	50,749	431	429,154	4.34	18,615	0.10	2.32
238900	Other Specialty Trade Contractors.	30,936,078	68,075	454	600,658	4.48	26,897	0.08	1.69
999000	State and local governments [d].	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	176,390,899	330,786	533	....	....	....	....	....

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

e. Differential Impacts on Small Entities and Very Small Entities

Below, OSHA provides some additional information about differential compliance costs for small and very small entities that might influence the magnitude of differential impacts for these smaller businesses.

The distribution of impacts by size of business is affected by the characteristics of the compliance measures. For silica controls in construction, the dust control measures consist primarily of equipment modifications and additions made to individual tools, rather than large, discrete investments, such as might be applied in a manufacturing setting. As a result, compliance advantages for large firms through economies of scale are limited. It is possible that some large construction firms might derive purchasing power by buying dust control measures in bulk. Given the simplicity of many control measures, however, such as the use of wet methods on machines already manufactured to accommodate them, such differential purchasing power appears to be of limited consequence.

The greater capital resources of large firms will give them some advantage in making the relatively large investments for some control measures. For example, cab enclosures on heavy construction equipment or foam-based dust control systems on rock crushers might be particularly expensive for some small entities with an unusual number of heavy equipment pieces. Nevertheless, where differential investment capabilities might exist, small construction firms might also have the capability to achieve compliance with lower-cost measures, such as by modifying work practices. In the case of rock crushing, for example, simple water spray systems can be arranged without large-scale investments in the best commercially available systems.

In the program area, large firms might have a slight advantage in the delivery of training or in arranging for health screenings. Given the likelihood that small firms can, under most circumstances, call upon independent training specialists at competitive prices, and the widespread availability of medical services for health screenings, the advantage for large firms is, again, expected to be fairly modest.

f. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold levels cannot be exceeded for affected small or very small entities in any affected industry.

Table VIII–15 and Table VIII–16 show that in no construction industries do the annualized costs of the proposed rule exceed one percent of annual revenues or five percent of annual profits either for small entities or for very small entities. However, as previously noted in this section, OSHA is unable to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Section VIII.I of this preamble.

4. Employment Impacts on the U.S. Economy

In October 2011, OSHA directed Inforum—a not-for-profit Maryland corporation (based at the University of Maryland)—to run its macroeconomic model to estimate the employment impacts of the costs of the proposed silica rule.[20] The specific model of the U.S. economy that Inforum used—called the LIFT model—is particularly suitable for this work because it combines the industry detail of a pure input-output model (which shows, in matrix form, how the output of each industry serves as inputs in other industries) with macroeconomic modeling of demand, investment, and other macroeconomic parameters.[21] The Inforum model can thus both trace changes in particular industries through their effect on other industries and also examine the effects of these changes on aggregate demand, imports, exports, and investment, and in turn determine net changes to GDP, employment, prices, etc.

In order to estimate the possible macroeconomic impacts of the proposed rule, Inforum had to run its model twice: once to establish a baseline and then again with changes in industry expenditures to reflect the year-by-year costs of the proposed silica rule as estimated by OSHA in its Preliminary Economic Analysis (PEA).[22] The difference in employment, GDP, etc. between the two runs of the model revealed the estimated economic impacts of the proposed rule.[23]

OSHA selected 2014 as the starting year for running the Inforum model under the assumption that that would be the earliest that a final silica rule could take effect. Inforum ran the model through the year 2023 and reported its annual and cumulative results for the ten-year period 2014–2023. The most important Inforum result is that the proposed silica rule cumulatively generates an additional 8,625 job-years over the period 2014–2023, or an additional 862.5 job-years annually, on average, over the period (Inforum, 2011).[24]

For a fuller discussion of the employment and other macroeconomic impacts of the silica rule, see Inforum (2011) and Chapter VI of the PEA for the proposed rule.

G. Benefits and Net Benefits

In this section, OSHA presents a summary of the estimated benefits, net benefits, and incremental benefits of the proposed silica rule. This section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and benefit parameters. A full explanation of the derivation of the estimates presented here is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of its estimation of the benefits and net benefits of the proposed rule.

1. Estimation of the Number of Silica-Related Diseases Avoided

OSHA estimated the benefits associated with the proposed PEL of 50 μg/m^3 and, for economic analysis purposes, with an alternative PEL of 100 μg/m^3 for respirable crystalline silica by applying the dose-response relationship developed in the Agency's quantitative risk assessment (QRA)—summarized in Section VI of this preamble—to exposures at or below the current PELs. OSHA determined exposures at or below the current PELs by first developing an exposure profile (presented in Chapter IV of the PEA) for industries with workers exposed to respirable crystalline silica, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile was previously presented in Section VIII.C of this preamble.

By applying the dose-response relationship to estimates of exposures at or below the current PELs across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given exposures at or below the current PELs (the ''baseline''):

- Fatal cases of lung cancer,
- fatal cases of non-malignant respiratory disease (including silicosis),
- fatal cases of end-stage renal disease, and
- cases of silicosis morbidity.

In addition, it is possible to project the number of these cases that would be avoided under alternative, lower PELs.

[20] Inforum has over 40 years experience designing and using macroeconomic models of the United States (and other countries).

[21] LIFT stands for Long-Term Interindustry Forecasting Tool. This model combines a dynamic input-output core for 97 productive sectors with a full macroeconomic model with more than 800 macroeconomic variables. LIFT employs a ''bottoms-up'' regression approach to macroeconomic modeling (so that aggregate investment, employment, and exports, for example, are the sum of investment and employment by industry and exports by commodity). Unlike some simpler forecasting models, price effects are embedded in the model and the results are time-dependent (that is, they are not static or steady-state, but present year-by-year estimates of impacts consistent with economic conditions at the time).

[22] OSHA worked with Inforum to disaggregate compliance costs into categories that mapped into specific LIFT production sectors. Inforum also established a mapping between OSHA's NAICS-based industries and the LIFT production sectors. OSHA's compliance cost estimates were based on production and employment levels in affected industries in 2006 (although the costs were then inflated to 2009 dollars). Therefore, Inforum benchmarked compliance cost estimates in future years to production and employment conditions in 2006 (that is, compliance costs in a future year were proportionately adjusted to production and employment changes from 2006 to that future year). See Inforum (2011) for a discussion of these and other transformations of OSHA's cost estimates to conform to the specifications of the LIFT model.

[23] Because OSHA's analysis of the hydraulic fracturing industry for the proposed silica rule was not conducted until after the draft PEA had been completed, OSHA's estimates of the compliance costs for this industry were not included in Inforum's analysis of the rule's employment and other macroeconomic impacts on the U.S. economy. It should be noted that, according to the Agency's estimates, compliance costs for the hydraulic fracturing industry represent only about 4 percent of the total compliance costs for all affected industries.

[24] A ''job-year'' is the term of art used to reflect the fact that an additional person is employed for a year, not that a new job has necessarily been permanently created.

As a simplified example, suppose that the risk per worker of a given health endpoint is 2 in 1,000 at 100 μg/m³ and 1 in 1,000 at 50 μg/m³ and that there are 100,000 workers currently exposed at 100 μg/m³. In this example, the proposed PEL would lower exposures to 50 μg/m³, thereby cutting the risk in half and lowering the number of expected cases in the future from 200 to 100.

The estimated benefits for the proposed silica rule represent the additional benefits derived from employers achieving full compliance with the proposed PEL relative to the current PELs. They do not include benefits associated with current compliance that has already been achieved with regard to the new requirements or benefits obtained from future compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

The technological feasibility analysis, described earlier in this section of the preamble, demonstrated the effectiveness of controls in meeting or exceeding the proposed OSHA PEL. For purposes of estimating the benefit of reducing the PEL, OSHA has made some simplifying assumptions. On the one hand, given the lack of background information on respirator use related to existing exposure data, OSHA used existing personal exposure measurement information, unadjusted for potential respirator use.[25] On the other hand, OSHA assumed that compliance with the existing and proposed rule would result in reductions in exposure levels to exactly the existing standard and proposed PEL, respectively. However, in many cases, indivisibilities in the application of respirators, as well as certain types of engineering controls, may cause employers to reduce exposures to some point below the existing standard or the proposed PEL. This is particularly true in the construction sector for employers who opt to follow Table 1, which specifies particular controls.

In order to examine the effect of simply changing the PEL, OSHA compared the number of various kinds of cases that would occur if a worker were exposed for an entire working life to PELs of 50 μg/m³ or 100 μg/m³ to the number of cases that would occur at levels of exposure at or below the current PELs. The number of avoided cases over a hypothetical working life of exposure for the current population at a lower PEL is then equal to the difference between the number of cases at levels of exposure at or below the current PEL for that population minus the number of cases at the lower PEL. This approach represents a steady-state comparison based on what would hypothetically happen to workers who received a specific average level of occupational exposure to silica during an entire working life. (In order to incorporate the element of timing to assess the economic value of the health benefits, OSHA presents a modified approach later in this section.)

Based on OSHA's application of the Steenland et al. (2001) log-linear and the Attfield and Costello (2004) models, Table VIII–17 shows the estimated number of avoided fatal lung cancers for PELs of 50 μg/m³ and 100 μg/m³. At the proposed PEL of 50 μg/m³, an estimated 2,404 to 12,173 lung cancers would be prevented over the lifetime of the current worker population, with a midpoint estimate of 7,289 fatal cancers prevented. This is the equivalent of between 53 and 271 cases avoided annually, with a midpoint estimate of 162 cases avoided annually, given a 45-year working life of exposure.

Following Park (2002), as discussed in summary of the Agency's QRA in Section VI of this preamble, OSHA also estimates that the proposed PEL of 50 μg/m³ would prevent an estimated 16,878 fatalities over a lifetime from non-malignant respiratory diseases arising from silica exposure. This is equivalent to 375 fatal cases prevented annually. Some of these fatalities would be classified as silicosis, but most would be classified as other pneumoconioses and chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema.

As also discussed in the summary of the Agency's QRA in Section VI of this preamble, OSHA finds that workers with large exposures to silica are at elevated risk of end-stage renal disease (ESRD). Based on Steenland, Attfield, and Mannetje (2002), OSHA estimates that the proposed PEL of 50 μg/m³ would prevent 6,774 cases of end-stage renal disease over a working life of exposure, or about 151 cases annually.

Combining the three major fatal health endpoints—for lung cancer, non-malignant respiratory diseases, and end-stage renal disease—OSHA estimates that the proposed PEL would prevent between 26,055 and 35,825 premature fatalities over a lifetime, with a midpoint estimate of 30,940 fatalities prevented. This is the equivalent of between 579 and 796 premature fatalities avoided annually, with a midpoint estimate of 688 premature fatalities avoided annually, given a 45-year working life of exposure.

In addition, the rule would prevent a large number of cases of silicosis morbidity. Based on Rosenman et al. (2003), the Agency estimates that between 2,700 and 5,475 new cases of silicosis, at an ILO X-ray rating of 1/0 or higher, occur annually at the present PELs as a result of silica exposure at establishments within OSHA's jurisdiction. Based on the studies summarized in OSHA's QRA, OSHA expects that the proposed rule will eliminate the large majority of these cases.

The Agency has not included the elimination of the less severe silicosis cases in its estimates of the monetized benefits and net benefits of the proposed rule. Instead, OSHA separately estimated the number of silicosis cases reaching the more severe levels of 2/1 and above. Based on a study by Buchannan et al. (2003) of a cohort of coal miners (as discussed in the Agency's QRA), OSHA estimates that the proposed PEL of 50 μg/m³ would prevent 71,307 cases of moderate-to-severe silicosis (registering 2/1 or more, using the ILO method for assessing severity) over a working life, or about 1,585 cases of moderate-to-severe silicosis prevented annually.

Note that the Agency based its estimates of reductions in the number of silica-related diseases over a working life of constant exposure for workers who are employed in a respirable crystalline silica-exposed occupation for their entire working lives, from ages 20 to 65. While the Agency is legally obligated to examine the effect of exposures from a working lifetime of exposure,[26] in an alternative analysis purely for informational purposes, the Agency examined, in Chapter VII of the PEA, the effect of assuming that workers are exposed for only 25 working years, as opposed to the 45 years assumed in the main analysis. While all workers are assumed to have less cumulative exposure under the 25-years-of-

[25] Based on available data, the Agency estimated the weighted average for the relevant exposure groups to match up with the quantitative risk assessment. For the 50–100 μg/m³ exposure range, the Agency estimated an average exposure of 62.5 μg/m³. For the 100–250 μg/m³ range, the Agency estimated an average exposure of 125 μg/m³.

[26] Section (6)(b)(5) of the OSH Act states: ''The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' Given that it is necessary for OSHA to reach a determination of significant risk over a working life, it is a logical extension to estimate what this translates into in terms of estimated benefits for the affected population over the same period.

exposure assumption, the effective exposed population over time is proportionately increased. Estimated prevented cases of end-stage renal disease and silicosis morbidity are lower in the 25-year model, whereas cases of fatal non-malignant lung disease are higher. In the case of lung cancer, the effect varies by model, with a lower high-end estimate (Attfield & Costello, 2004) and a higher low-end estimate (Steenland et. al., 2001 log-linear model). Overall, however, the 45-year-working-life assumption yields larger estimates of the number of cases of avoided fatalities and illnesses than does the 25-years-of-exposure assumption. For example, the midpoint estimates of the number of avoided fatalities and illnesses under the proposed PEL of 50 μg/m³ would decline from 688 and 1,585, respectively, under the 45-year-working-life assumption to 683 and 642, respectively, under the 25-year-working-life assumption. Note the effect, in this case, of going from a 45-year-working-life assumption to a 25-year-working-life assumption would be a 1 percent reduction in the number of avoided fatalities and a 59 percent reduction in the number of avoided illnesses. The divergence reflects differences in the mathematical structure of the risk assessment models that are the basis for these estimates.[27]

OSHA believes that 25 years of worker exposure to respirable crystalline silica may be a reasonable alternative estimate for informational purposes. However, to accommodate the possibility that average worker exposure to silica over a working life may be shorter, at least in certain industries (see the following paragraph), the Agency also examined the effect of assuming only 13 years of exposure for the average worker. The results were broadly similar to the 25 years of exposure—annual fatalities prevented were higher (788), but illnesses prevented lower (399), with the lower average cumulative exposure being offset to a substantial degree by a larger exposed population. The same effect is seen if one assumes only 6.6 years of cumulative exposure to silica for the average worker: estimated fatalities rise to 832 cases annually, with 385 cases of silicosis morbidity. In short, the aggregate estimated benefits of the rule appear to be relatively insensitive to implicit assumptions of average occupational tenure. Nonetheless, the Agency is confident that the typical affected worker sustains an extended period of exposure to silica.

Even in the construction industry, which has an extremely high rate of job turnover, the mean job tenure with one's current employer is 6.6 years (BLS, 2010a), and the median age of construction workers in the U.S. is 41.6 years (BLS, 2010b). OSHA is unaware of any data on job tenure within an industry, but the Agency would expect job tenure in the construction industry would be at least twice the job tenure with one's current employer. Furthermore, many workers may return to the construction industry after unemployment or work in another industry. Of course, job tenure is longer in the other industries affected by the proposed rule.

The proposed rule also contains specific provisions for diagnosing latent tuberculosis (TB) in the silica-exposed population and thereby reducing the risk of TB being spread to the population at large. The Agency currently lacks good methods for quantifying these benefits. Nor has the Agency attempted to assess benefits directly stemming from enhanced medical surveillance in terms of reducing the severity of symptoms from the illnesses that do result from present or future exposure to silica. However, the Agency welcomes comment on the likely magnitude of these currently non-quantified health benefits arising from the proposed rule and on methods for better measuring these effects.

OSHA's risk estimates are based on application of exposure-response models derived from several individual epidemiological studies as well as the pooled cohort studies of Steenland et al. (2001) and Mannetje et al. (2002). OSHA recognizes that there is uncertainty around any of the point estimates of risk derived from any single study. In its preliminary risk assessment (summarized in Section VI of this preamble), OSHA has made efforts to characterize some of the more important sources of uncertainty to the extent that available data permit. This specifically includes characterizing statistical uncertainty by reporting the confidence intervals around each of the risk estimates; by quantitatively evaluating the impact of uncertainties in underlying exposure data used in the cohort studies; and by exploring the use of alternative exposure-response model forms. OSHA believes that these efforts reflect much, but not necessarily all, of the uncertainties associated with the approaches taken by investigators in their respective risk analyses. However, OSHA believes that characterizing the risks and benefits as a range of estimates derived from the full set of available studies, rather than relying on any single study as the basis for its estimates, better reflects the uncertainties in the estimates and more fairly captures the range of risks likely to exist across a wide range of industries and exposure situations.

Another source of uncertainty involves the degree to which OSHA's risk estimates reflect the risk of disease among workers with widely varying exposure patterns. Some workers are exposed to fairly high concentrations of crystalline silica only intermittently, while others experience more regular and constant exposure. Risk models employed in the quantitative assessment are based on a cumulative exposure metric, which is the product of average daily silica concentration and duration of worker exposure for a specific job. Consequently, these models predict the same risk for a given cumulative exposure regardless of the pattern of exposure, reflecting a worker's long-term average exposure without regard to intermittencies or other variances in exposure, and are therefore generally applicable to all workers who are exposed to silica in the various industries. Section VI of this preamble provides evidence supporting the use of cumulative exposure as the preferred dose metric. Although the Agency believes that the results of its risk assessment are broadly relevant to all occupational exposure situations involving crystalline silica, OSHA acknowledges that differences exist in the relative toxicity of crystalline silica particles present in different work settings due to factors such as the presence of mineral or metal impurities on quartz particle surfaces, whether the particles have been freshly fractured or are aged, and size distribution of particles. However, in its preliminary risk assessment, OSHA preliminarily concludes that the estimates from the studies and analyses relied upon are fairly representative of a wide range of workplaces reflecting differences in silica polymorphism, surface properties, and impurities.

Thus, OSHA has a high degree of confidence in the risk estimates associated with exposure to the current and proposed PELs. OSHA acknowledges there is greater uncertainty in the risk estimates for the proposed action level of 0.025 mg/m³ than exists at the current (0.1 mg/m³)

[27] Technically, this analysis assumes that workers receive 25 years worth of silica exposure, but that they receive it over 45 working years, as is assumed by the risk models in the QRA. It also accounts for the turnover implied by 25, as opposed to 45, years of work. However, it is possible that an alternate analysis, which accounts for the larger number of post-exposure worker-years implied by workers departing their jobs before the end of their working lifetime, might find larger health effects for workers receiving 25 years worth of silica exposure.

and proposed (0.05 mg/m^3) PELs, particularly given some evidence of a threshold for silicosis between the proposed PEL and action level. Given the Agency's findings that controlling exposures below the proposed PEL would not be technologically feasible for employers, OSHA believes that a precise estimate of the risk for exposures below the proposed action level is not necessary to further inform the Agency's regulatory action. OSHA requests comment on remaining sources of uncertainties in its risk and benefits estimates that have not been specifically characterized by OSHA in its analysis.

Table VIII-17

Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over a 45-Year Working Life Due to Proposed PEL of 50 μg/m³ and Alternative PEL of 100 μg/m³

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50			100			50			100		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
High	12,173	9,537	2,636	6,563	6,277	286	271	212	59	146	139	6
Midpoint	7,289	5,852	1,437	3,719	3,573	146	162	130	32	83	79	3
Low	2,404	2,166	238	875	869	6	53	48	5	19	19	0
Silicosis & Other Non-Malignant Respiratory Diseases	16,878	13,944	2,934	8,490	8,403	87	375	310	65	189	187	2
End Stage Renal Disease	6,774	5,722	1,052	2,684	2,655	29	151	127	23	60	59	1
Total Number of Fatal Illnesses Prevented												
High	35,825	29,203	6,622	17,737	17,335	402	796	649	147	394	385	9
Midpoint	30,940	25,517	5,423	14,893	14,631	262	688	567	121	331	325	6
Low	26,055	21,831	4,224	12,049	11,927	122	579	485	94	268	265	3
Total Number of Silicosis Morbidity Cases Prevented*	71,307	48,617	22,689	42,881	41,375	1,506	1,585	1,080	504	953	919	33

*Assessed at 2/1 or higher X-ray, following ILO criteria

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

2. Estimating the Stream of Benefits Over Time

Risk assessments in the occupational environment are generally designed to estimate the risk of an occupationally related illness over the course of an individual worker's lifetime. As previously discussed, the current occupational exposure profile for a particular substance for the current cohort of workers can be matched up against the expected profile after the proposed standard takes effect, creating a ''steady state'' estimate of benefits. However, in order to annualize the benefits for the period of time after the silica rule takes effect, it is necessary to create a timeline of benefits for an entire active workforce over that period.

In order to characterize the magnitude of benefits before the steady state is reached, OSHA created a linear phase-in model to reflect the potential timing of benefits. Specifically, OSHA estimated that, for all non-cancer cases, while the number of cases would gradually decline as a result of the proposed rule, they would not reach the steady-state level until 45 years had passed. The reduction in cases estimated to occur in any given year in the future was estimated to be equal to the steady-state reduction (the number of cases in the baseline minus the number of cases in the new steady state) times the ratio of the number of years since the standard was implemented and a working life of 45 years. Expressed mathematically:

$N_t=(C—S) \times (t/45)$,

where N_t is the number of non-malignant silica-related diseases avoided in year t; C is the current annual number of non-malignant silica-related diseases; S is the steady-state annual number of non-malignant silica-related diseases; and *t* represents the number of years after the proposed standard takes effect, with $t \leq 45$.

In the case of lung cancer, the function representing the decline in the number of cases as a result of the proposed rule is similar, but there would be a 15-year lag before any reduction in cancer cases would be achieved. Expressed mathematically, for lung cancer:

$L_t=(C_m—S_m) \times ((t-15)/45))$,

where $15 \leq t \leq 60$ and L_t is the number of lung cancer cases avoided in year t as a result of the proposed rule; C_m is the current annual number of silica-related lung cancers; and S_m is the steady-state annual number of silica-related lung cancers.

A more complete discussion of the functioning and results of this model is presented in Chapter VII of the PEA.

This model was extended to 60 years for all the health effects previously discussed in order to incorporate the 15-year lag, in the case of lung cancer, and a 45-year working life. As a practical matter, however, there is no overriding reason for stopping the benefits analysis at 60 years. An internal analysis by OSHA indicated that, both in terms of cases prevented, and even with regard to monetized benefits, particularly when lower discount rates are used, the estimated benefits of the standard are noticeably larger on an annualized basis if the analysis extends further into the future. The Agency welcomes comment on the merit of extending the benefits analysis beyond the 60 years analyzed in the PEA.

In order to compare costs to benefits, OSHA assumes that economic conditions remain constant and that annualized costs—and the underlying costs—will repeat for the entire 60-year time horizon used for the benefits analysis (as discussed in Chapter V of the PEA). OSHA welcomes comments on the assumption for both the benefit and cost analysis that economic conditions remain constant for sixty years. OSHA is particularly interested in what assumptions and time horizon should be used instead and why.

3. Monetizing the Benefits

To estimate the monetary value of the reductions in the number of silica-related fatalities, OSHA relied, as OMB recommends, on estimates developed from the willingness of affected individuals to pay to avoid a marginal increase in the risk of fatality. While a willingness-to-pay (WTP) approach clearly has theoretical merit, it should be noted that an *individual's* willingness to pay to reduce the risk of fatality would tend to underestimate the total willingness to pay, which would include the willingness of others—particularly the immediate family—to pay to reduce that individual's risk of fatality.[28]

For estimates using the willingness-to-pay concept, OSHA relied on existing studies of the imputed value of fatalities avoided based on the theory of compensating wage differentials in the labor market. These studies rely on certain critical assumptions for their accuracy, particularly that workers understand the risks to which they are exposed and that workers have legitimate choices between high- and low-risk jobs. These assumptions are far from obviously met in actual labor markets.[29] A number of academic studies, as summarized in Viscusi & Aldy (2003), have shown a correlation between higher job risk and higher wages, suggesting that employees demand monetary compensation in return for a greater risk of injury or fatality. The estimated trade-off between lower wages and marginal reductions in fatal occupational risk—that is, workers' willingness to pay for marginal reductions in such risk—yields an imputed value of an avoided fatality: the willingness-to-pay amount for a reduction in risk divided by the reduction in risk.[30] OSHA has used this approach in many recent proposed and final rules. Although this approach has been found to yield results that are less than statistically robust (*see,* for example, Hintermann, Alberini and Markandya, 2010), OSHA views these estimates as the best available, and will use them for its basic estimates. OSHA welcomes comments on the use of willingness-to-pay measures and estimates based on compensating wage differentials.

Viscusi & Aldy (2003) conducted a meta-analysis of studies in the economics literature that use a willingness-to-pay methodology to estimate the imputed value of life-saving programs and found that each fatality avoided was valued at approximately $7 million in 2000 dollars. This $7 million base number in 2000 dollars yields an estimate of $8.7 million in 2009 dollars for each fatality avoided.[31]

In addition to the benefits that are based on the implicit value of fatalities avoided, workers also place an implicit value on occupational injuries or illnesses avoided, which reflect their

[28] See, for example, Thaler and Rosen (1976), pp. 265–266. In addition, see Sunstein (2004), p. 433. ''This point demonstrates a general and badly neglected problem for WTP as it is currently used: agencies consider people's WTP to eliminate statistical risks, without taking account of the fact that others—especially family members and close friends—would also be willing to pay something to eliminate those risks.''

[29] On the former assumption, see the discussion in Chapter II of the PEA on imperfect information. On the latter, see, for example, the discussion of wage compensation for risk for union versus nonunion workers in Dorman and Hagstrom (1998).

[30] For example, if workers are willing to pay $50 each for a 1/100,000 reduction in the probability of dying on the job, then the imputed value of an avoided fatality would be $50 divided by 1/100,000, or $5,000,000. Another way to consider this result would be to assume that 100,000 workers made this trade-off. On average, one life would be saved at a cost of $5,000,000.

[31] An alternative approach to valuing an avoided fatality is to monetize, for each year that a life is extended, an estimate from the economics literature of the value of that statistical life-year (VSLY). See, for instance, Aldy and Viscusi (2007) for discussion of VSLY theory and FDA (2003), pp. 41488–9, for an application of VSLY in rulemaking. OSHA has not investigated this approach, but welcomes comment on the issue.

willingness to pay to avoid monetary costs (for medical expenses and lost wages) and quality-of-life losses as a result of occupational illness. Silicosis, lung cancer, and renal disease can adversely affect individuals for years or even decades in non-fatal cases, or before ultimately proving fatal. Because measures of the benefits of avoiding these illnesses are rare and difficult to find, OSHA has included a range based on a variety of estimation methods.

Consistent with Buchannan et al. (2003), OSHA estimated the total number of moderate to severe silicosis cases prevented by the proposed rule, as measured by 2/1 or more severe X-rays (based on the ILO rating system). However, while radiological evidence of moderate to severe silicosis is evidence of significant material impairment of health, placing a precise monetary value on this condition is difficult, in part because the severity of symptoms may vary significantly among individuals. For that reason, for this preliminary analysis, the Agency employed a broad range of valuation, which should encompass the range of severity these individuals may encounter. Using the willingness-to-pay approach, discussed in the context of the imputed value of fatalities avoided, OSHA has estimated a range in valuations (updated and reported in 2009 dollars) that runs from approximately $62,000 per case—which reflects estimates developed by Viscusi and Aldy (2003), based on a series of studies primarily describing simple accidents—to upwards of $5.1 million per case—which reflects work developed by Magat, Viscusi & Huber (1996) for non-fatal cancer. The latter number is based on an approach that places a willingness-to-pay value to avoid serious illness that is calibrated relative to the value of an avoided fatality. OSHA (2006) previously used this approach in the Final Economic Analysis (FEA) supporting its hexavalent chromium final rule, and EPA (2003) used this approach in its Stage 2 Disinfection and Disinfection Byproducts Rule concerning regulation of primary drinking water. Based on Magat, Viscusi & Huber (1996), EPA used studies on the willingness-to-pay to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing a case of nonfatal cancer at 58.3 percent of the value of a fatal cancer. OSHA's estimate of $5.1 million for an avoided case of non-fatal cancer is based on this 58.3 percent figure.

The Agency believes this range of estimates is descriptive of the value of preventing morbidity associated with moderate to severe silicosis, as well as the morbidity preceding mortality due to other causes enumerated here—lung cancer, lung diseases other than cancer, and renal disease.[32] OSHA therefore is applying these values to those situations as well.

The Agency is interested in public input on the issue of valuing the cost to society of non-fatal cases of moderate to severe silicosis, as well as the morbidity associated with other related diseases of the lung, and with renal disease.

a. The Monetized Benefits of the Proposed Rule

Table VIII–18 presents the estimated annualized (over 60 years, using a 0 percent discount rate) benefits from each of these components of the valuation, and the range of estimates, based on risk model uncertainty (notably in the case of lung cancer), and the range of uncertainty regarding valuation of morbidity. (Mid-point estimates of the undiscounted benefits for each of the first 60 years are provided in the middle columns of Table VII–A–1 in Appendix VII–A in the PEA. The estimates by year reach a peak of $11.9 billion in the 60th year.)

As shown, the full range of monetized benefits, undiscounted, for the proposed PEL of 50 μg/m³ runs from $3.2 billion annually, in the case of the lowest estimate of lung cancer risk and the lowest valuation for morbidity, up to $10.9 billion annually, for the highest of both. Note that the value of total benefits is more sensitive to the valuation of morbidity (ranging from $3.5 billion to $10.3 billion, given estimates at the midpoint of the lung cancer models) than to the lung cancer model used (ranging from $6.4 to $7.4 billion, given estimates at the midpoint of the morbidity valuation).[33]

This comports with the very wide range of valuation for morbidity. At the low end of the valuation range, the total value of benefits is dominated by mortality ($3.4 billion out of $3.5 billion at the case frequency midpoint), whereas at the high end the majority of the benefits are related to morbidity ($6.9 billion out of $10.3 billion at the case frequency midpoint). Also, the analysis illustrates that most of the morbidity benefits are related to silicosis cases that are not ultimately fatal. At the valuation and case frequency midpoint, $3.4 billion in benefits are related to mortality, $1.0 billion are related to morbidity preceding mortality, and $2.4 billion are related to morbidity not preceding mortality.

[32] There are several benchmarks for valuation of health impairment due to silica exposure, using a variety of techniques, which provide a number of mid-range estimates between OSHA's high and low estimates. For a fuller discussion of these estimates, see Chapter VII of the PEA.

[33] As previously indicated, these valuations include all the various estimated health endpoints. In the case of mortality this includes lung cancer, non-malignant respiratory disease and end-stage renal disease. The Agency highlighted lung cancers in this discussion due to the model uncertainty. In calculating the monetized benefits, the Agency is typically referring to the midpoint of the high and low ends of potential valuation—in this case, the undiscounted midpoint of $3.2 billion and $10.9 billion..

TABLE VIII-18

Estimated Annualized Undiscounted Monetized Benefits of the Silica Proposal for Morbidity and Mortality

PEL	50 μg/m³			100 μg/m³		
		Valuation			Valuation	
	Low	Midpoint	High	Low	Midpoint	High
Cases						
Fatalities - Total						
Low	$3,074,165,270	$3,074,165,270	$3,074,165,270	$1,433,022,347	$1,433,022,347	$1,433,022,347
Midpoint	$3,436,186,835	$3,436,186,835	$3,436,186,835	$1,643,786,936	$1,643,786,936	$1,643,786,936
High	$3,798,208,401	$3,798,208,401	$3,798,208,401	$1,643,786,936	$1,643,786,936	$1,643,786,936
Morbidity Preceding Mortality						
Low	$21,907,844	$912,002,363	$1,802,096,882	$10,212,343	$425,129,963	$840,047,583
Midpoint	$24,487,768	$1,019,402,094	$2,014,316,421	$11,714,344	$487,656,791	$963,599,238
High	$27,067,692	$1,126,801,826	$2,226,535,959	$11,714,344	$487,656,791	$963,599,238
Morbidity Not Preceding Mortality						
Total	$58,844,551	$2,449,641,696	$4,840,438,842	$35,733,901	$1,487,567,728	$2,939,401,554
TOTAL						
Low	$3,154,917,665	$6,435,809,329	$9,716,700,994	$1,478,968,592	$3,345,720,038	$5,212,471,484
Midpoint	$3,519,519,154	$6,905,230,626	$10,290,942,098	$1,691,235,181	$3,619,011,454	$5,546,787,728
High	$3,884,120,643	$7,374,651,923	$10,865,183,202	$1,691,235,181	$3,619,011,454	$5,546,787,728

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

b. A Suggested Adjustment to Monetized Benefits

OSHA's estimates of the monetized benefits of the proposed rule are based on the imputed value of each avoided fatality and each avoided silica-related disease. To this point, these imputed values have been assumed to remain constant over time.

OSHA now would like to suggest that an adjustment be made to monetized benefits to reflect the fact that the imputed value of avoided fatalities and avoided diseases will tend to increase over time. Two related factors suggest such an increase in value over time.

First, economic theory suggests that the value of reducing life-threatening and health-threatening risks will increase as real per capita income increases. With increased income, an individual's health and life become more valuable relative to other goods because, unlike other goods, they are without close substitutes and in relatively fixed or limited supply. Expressed differently, as income increases, consumption will increase but the marginal utility of consumption will decrease. In contrast, added years of life (in good health) is not subject to the same type of diminishing returns—implying that an effective way to increase lifetime utility is by extending one's life and maintaining one's good health (Hall and Jones, 2007).

Second, real per capita income has broadly been increasing throughout U.S. history, including recent periods. For example, for the period 1950 through 2000, real per capita income grew at an average rate of 2.31 percent a year (Hall and Jones, 2007) [34] although real per capita income for the recent 25 year period 1983 through 2008 grew at an average rate of only 1.3 percent a year (U.S. Census Bureau, 2010). More important is the fact that real U.S. per capita income is projected to grow significantly in future years. For example, the Annual Energy Outlook (AEO) projections, prepared by the Energy Information Administration (EIA) in the Department of Energy (DOE), show an average annual growth rate of per capita income in the United States of 2.7 percent for the period 2011–2035.[35] The U.S. Environmental Protection Agency prepared its economic analysis of the Clean Air Act using the AEO projections. Although these estimates may turn out to be somewhat higher or lower than predicted, OSHA believes that it is reasonable to use the same AEO projections employed by DOE and EPA, and correspondingly projects that per capita income in the United States will increase by 2.7 percent a year.

On the basis of the predicted increase in real per capita income in the United States over time and the expected resulting increase in the value of avoided fatalities and diseases, OSHA is considering adjusting its estimates of the benefits of the proposed rule to reflect the anticipated increase in their value over time. This type of adjustment has been recognized by OMB (2003), supported by EPA's Science Advisory Board (EPA, 2000), and applied by EPA.[36] OSHA proposes to accomplish this adjustment by modifying benefits in year i from $[B_i]$ to $[B_i * (1 + \eta)^i]$, where ''η'' is the estimated annual increase in the magnitude of the benefits of the proposed rule.

What remains is to estimate a value for ''η'' with which to increase benefits annually in response to annual increases in real per capita income. Probably the most direct evidence of the value of ''η'' comes from the work of Costa and Kahn (2003, 2004). They estimate repeated labor market compensating wage differentials from cross-sectional hedonic regressions using census and fatality data from the Bureau of Labor Statistics for 1940, 1950, 1960, 1970, and 1980. In addition, with the imputed income elasticity of the value of life on per capita GNP of 1.7 derived from the 1940–1980 data, they then predict the value of an avoided fatality in 1900, 1920, and 2000. Given the change in the value of an avoided fatality over time, it is possible to estimate a value of ''η'' of 3.4 percent a year from 1900–2000; of 4.3 percent a year from 1940–1980; and of 2.5 percent a year from 1980–2000. Other, more indirect evidence comes from estimates in the economics literature on the income elasticity for the value of a statistical life. Viscusi and Aldy (2003) performed a meta-analysis on 50 wage-risk studies and concluded that the point estimates across a variety of model specifications ranged between 0.5 and 0.6. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''η'' of about 1.5 percent a year. More recently, Kniesner, Viscusi, and Ziliak (2010), using panel data quintile regressions, developed an estimate of the overall income elasticity of the value of a statistical life of 1.44. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''η'' of about 3.9 percent a year.

Based on the preceding discussion of these two approaches for estimating the annual increase in the value of the benefits of the proposed rule and the fact that, as previously noted, the projected increase in real per capita income in the United States has flattened in the most recent 25 year period, OSHA suggests a value of ''η'' of approximately 2 percent a year. The Agency invites comment on this estimate and on estimates of the income elasticity of the value of a statistical life.

While the Agency believes that the rising value, over time, of health benefits is a real phenomenon that should be taken into account in estimating the annualized benefits of the proposed rule, OSHA is at this time only offering these adjusted monetized benefits as analytic alternatives for consideration. Table VIII–19, which follows the discussion on discounting monetized benefits, shows estimates of the monetized benefits of the proposed rule (under alternative discount rates) both with and without this suggested increase in monetized benefits over time. The Agency invites comment on this suggested adjustment to monetized benefits.

4. Discounting of Monetized Benefits

As previously noted, the estimated stream of benefits arising from the proposed silica rule is not constant from year to year, both because of the 45-year delay after the rule takes effect until all active workers obtain reduced silica exposure over their entire working lives and because of, in the case of lung cancer, a 15-year latency period between reduced exposure and a reduction in the probability of disease. An appropriate discount rate [37] is needed to reflect the timing of benefits over the 60-year period after the rule takes effect and to allow conversion to an equivalent steady stream of annualized benefits.

a. Alternative Discount Rates for Annualizing Benefits

Following OMB (2003) guidelines, OSHA has estimated the annualized benefits of the proposed rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent proposed and final rules, OSHA has also estimated, for benchmarking purposes, undiscounted benefits—that is, benefits using a zero percent discount rate.

The question remains, what is the ''appropriate'' or ''preferred'' discount rate to use to monetize health benefits? The choice of discount rate is a controversial topic, one that has been the source of scholarly economic debate for several decades. However, in simplest terms, the basic choices involve a social opportunity cost of capital approach or social rate of time preference approach.

[34] The results are similar if the historical period includes a major economic downturn (such as the United States has recently experienced). From 1929 through 2003, a period in U.S. history that includes the Great Depression, real per capita income still grew at an average rate of 2.22 percent a year (Gomme and Rupert, 2004).

[35] The EIA used DOE's National Energy Modeling System (NEMS) to produce the Annual Energy Outlook (AEO) projections (EIA, 2011). Future per capita GDP was calculated by dividing the projected real gross domestic product each year by the projected U.S. population for that year.

[36] See, for example, EPA (2003, 2008).

[37] Here and elsewhere throughout this section, unless otherwise noted, the term ''discount rate'' always refers to the real discount rate—that is, the discount rate net of any inflationary effects.

The social opportunity cost of capital approach reflects the fact that private funds spent to comply with government regulations have an opportunity cost in terms of foregone private investments that could otherwise have been made. The relevant discount rate in this case is the pre-tax rate of return on the foregone investments (Lind, 1982b, pp. 24–32). The rate of time preference approach is intended to measure the tradeoff between current consumption and future consumption, or in the context of the proposed rule, between current benefits and future benefits. The *individual* rate of time preference is influenced by uncertainty about the availability of the benefits at a future date and whether the individual will be alive to enjoy the delayed benefits. By comparison, the *social* rate of time preference takes a broader view over a longer time horizon—ignoring individual mortality and the riskiness of individual investments (which can be accounted for separately) .

The usual method for estimating the social rate of time preference is to calculate the post-tax real rate of return on long-term, risk-free assets, such as U.S. Treasury securities (OMB, 2003). A variety of studies have estimated these rates of return over time and reported them to be in the range of approximately 1–4 percent.

In accordance with OMB Circular A–4 (2003), OSHA presents benefits and net benefits estimates using discount rates of 3 percent (representing the social rate of time preference) and 7 percent (a rate estimated using the social cost of capital approach). The Agency is interested in any evidence, theoretical or applied, that would inform the application of discount rates to the costs and benefits of a regulation.

b. Summary of Annualized Benefits Under Alternative Discount Rates

Table VIII–19 presents OSHA's estimates of the sum of the annualized benefits of the proposed rule, using alternative discount rates at 0, 3, and 7 percent, with a breakout between construction and general industry, and including the possible alternative of increasing monetized benefits in response to annual increases in per capita income over time.

Given that the stream of benefits extends out 60 years, the value of future benefits is sensitive to the choice of discount rate. As previously established in Table VIII–18, the undiscounted benefits range from $3.2 billion to $10.9 billion annually. Using a 7 percent discount rate, the annualized benefits range from $1.6 billion to $5.4 billion. As can be seen, going from undiscounted benefits to a 7 percent discount rate has the effect of cutting the annualized benefits of the proposed rule approximately in half.

The Agency's best estimate of the total annualized benefits of the proposed rule—using a 3 percent discount rate with no adjustment for the increasing value of health benefits over time— is between $2.4 and $8.1 billion, with a mid-point value of $5.3 billion.

As previously mentioned, OSHA has not attempted to estimate the monetary value of less severe silicosis cases, measured at 1/0 to 1/2 on the ILO scale. The Agency believes the economic loss to individuals with less severe cases of silicosis could be substantial, insofar as they may be accompanied by a lifetime of medical surveillance and lung damage, and potentially may require a change in career. However, many of these effects can be difficult to isolate and measure in economic terms, particularly in those cases where there is no obvious effect yet on physiological function or performance. The Agency invites public comment on this issue.

Table VIII-19

Total Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica Due to Proposed PEL of 50 μg/m^3 and Alternative PEL of 100 μg/m^3

($Billions)

PEL		**50**			**100**		
Discount Rate	**Range**	**Total**	**Construction**	**GI & Maritime**	**Total**	**Construction**	**GI & Maritime**
Undiscounted (0%)	Low	$3.2	$2.6	$0.5	$1.5	$1.5	$0.0
	Midpoint	$7.0	$5.4	$1.6	$3.7	$3.6	$0.1
	High	$10.9	$8.2	$2.7	$5.9	$5.7	$0.2
Discounted at 3%, with a suggested increased in monetized benefits over time	Low	$2.9	$2.4	$0.5	$1.4	$1.3	$0.0
	Midpoint	$6.4	$5.0	$1.5	$3.4	$3.3	$0.1
	High	$9.9	$7.5	$2.4	$5.4	$5.2	$0.1
Discounted at 3%	**Low**	**$2.4**	**$2.0**	**$0.4**	**$1.1**	**$1.1**	**$0.0**
	Midpoint	**$5.3**	**$4.1**	**$1.2**	**$2.8**	**$2.7**	**$0.1**
	High	**$8.1**	**$6.1**	**$2.0**	**$4.4**	**$4.3**	**$0.1**
Discounted at 7%, with a suggested increased in monetized benefits over time	Low	$2.0	$1.6	$0.3	$0.9	$0.9	$0.0
	Midpoint	$4.3	$3.3	$1.0	$2.2	$2.2	$0.1
	High	$6.6	$5.0	$1.6	$3.6	$3.5	$0.1
Discounted at 7%	Low	$1.6	$1.3	$0.3	$0.8	$0.8	$0.0
	Midpoint	$3.5	$2.7	$0.8	$1.8	$1.8	$0.0
	High	$5.4	$4.1	$1.3	$2.9	$2.8	$0.1

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

5. Net Benefits of the Proposed Rule

OSHA has estimated, in Table VIII–20, the net benefits of the proposed rule (with a PEL of 50 μg/m³), based on the benefits and costs previously presented. Table VIII–20 also provides estimates of annualized net benefits for an alternative PEL of 100 μg/m³. Both the proposed rule and the alternative rule have the same ancillary provisions and an action level equal to half of the PEL in both cases.

Table VIII–20 is being provided for informational purposes only. As previously noted, the OSH Act requires the Agency to set standards based on eliminating significant risk to the extent feasible. An alternative criterion of maximizing net (monetized) benefits may result in very different regulatory outcomes. Thus, this analysis of net benefits has not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed silica rule.

Table VIII–20 shows net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs and includes a possible adjustment to monetized benefits to reflect increases in real per capita income over time. (An expanded version of Tables VIII–20, with a breakout of net benefits between construction and general industry/maritime, is provided in Table VII–B–1 in Appendix B, of the PEA.) OSHA has relied on a uniform discount rate applied to both costs and benefits. The Agency is interested in any evidence, theoretical or applied, that would support or refute the application of differential discount rates to the costs and benefits of a regulation.

As previously noted, the choice of discount rate for annualizing benefits has a significant effect on annualized benefits. The same is true for net benefits. For example, the net benefits using a 7 percent discount rate for benefits are considerably smaller than the net benefits using a 0 percent discount rate, declining by more than half under all scenarios. (Conversely, as noted in Chapter V of the PEA, the choice of discount rate for annualizing costs has only a very minor effect on annualized costs.)

Based on the results presented in Table VIII–20, OSHA finds:

• While the net benefits of the proposed rule vary considerably—depending on the choice of discount rate used to annualize benefits and on whether the benefits being used are in the high, midpoint, or low range—benefits exceed costs for the proposed 50 μg/m³ PEL in all cases that OSHA considered.

• The Agency's best estimate of the net annualized benefits of the proposed rule—using a uniform discount rate for both benefits and costs of 3 percent—is between $1.8 billion and $7.5 billion, with a midpoint value of $4.6 billion.

• The alternative of a 100 μg/m³ PEL was found to have lower net benefits under all assumptions, relative to the proposed 50 μg/m³ PEL. However, for this alternative PEL, benefits were found to exceed costs in all cases that OSHA considered.

6. Incremental Benefits of the Proposed Rule

Incremental costs and benefits are those that are associated with increasing the stringency of the standard. A comparison of incremental benefits and costs provides an indication of the relative efficiency of the proposed PEL and the alternative PEL. Again, OSHA has conducted these calculations for informational purposes only and has not used this information as the basis for selecting the PEL for the proposed rule.

OSHA provided, in Table VIII–20, estimates of the net benefits of an alternative 100 μg/m³ PEL. The incremental costs, benefits, and net benefits of going from a 100 μg/m³ PEL to a 50 μg/m³ PEL (as well as meeting a 50 μg/m³ PEL and then going to a 25 μg/m³ PEL—which the Agency has determined is not feasible), for alternative discount rates of 3 and 7 percent, are presented in Tables VIII–21 and VIII–22. Table VIII–21 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–22 breaks out costs and benefits by major industry sector. As Table VIII–21 shows, at a discount rate of 3 percent, a PEL of 50 μg/m³, relative to a PEL of 100 μg/m³, imposes additional costs of $339 million per year; additional benefits of $2.5 billion per year, and additional net benefits of $2.16 billion per year. The proposed PEL of 50 μg/m³ also has higher net benefits using either a 3 percent or 7 percent discount rate.

Table VIII–22 continues this incremental analysis but with breakdowns between construction and general industry/maritime. This table shows that construction provides most of the incremental costs, but the incremental benefits are more evenly divided between the two sectors. Nevertheless, both sectors show strong positive net benefits, which are greater for the proposed PEL of 50 μg/m³ than the alternative of 100 μg/m³.

Tables VIII–21 and VIII–22 demonstrate that, across all discount rates, there are net benefits to be achieved by lowering exposures to 100 μg/m³ and then, in turn, lowering them further to 50 μg/m³. However, the majority of the benefits and costs attributable to the proposed rule are from the initial effort to lower exposures to 100 μg/m³. Consistent with the previous analysis, net benefits decline across all increments as the discount rate for annualizing benefits increases.

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These alternatives are discussed in Section VIII.H of this preamble.

TABLE VIII–20—ANNUAL MONETIZED NET BENEFITS RESULTING FROM A REDUCTION IN EXPOSURE TO CRYSTALLINE SILICA DUE TO PROPOSED PEL OF 50 μg/m³ AND ALTERNATIVE PEL OF 100 μg/m³

[$Billions]

PEL		50	100
Discount rate	Range		
Undiscounted (0%)	Low	$2.5	$1.2
	Midpoint	6.4	3.4
	High	10.2	5.6
Discounted at 3%, with a suggested increased in monetized benefits over time.	Low	2.3	1.1
	Midpoint	5.8	3.1
	High	9.3	5.1
3%	Low	1.8	0.8
	Midpoint	4.6	2.5
	High	7.5	4.1

TABLE VIII–20—ANNUAL MONETIZED NET BENEFITS RESULTING FROM A REDUCTION IN EXPOSURE TO CRYSTALLINE SILICA DUE TO PROPOSED PEL OF 50 μg/m³ AND ALTERNATIVE PEL OF 100 μg/m³—Continued

[$Billions]

PEL		50	100
Discount rate	Range		
Discounted at 7%, with a suggested increased in monetized benefits over time.	Low	1.3	0.6
	Midpoint	3.6	1.9
	High	5.9	3.3
7%	Low	1.0	0.5
	Midpoint	2.8	1.5
	High	4.7	2.6

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table VIII-21: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table VIII-22: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

7. Sensitivity Analysis

In this section, OSHA presents the results of two different types of sensitivity analysis to demonstrate how robust the estimates of net benefits are to changes in various cost and benefit parameters. In the first type of sensitivity analysis, OSHA made a series of isolated changes to individual cost and benefit input parameters in order to determine their effects on the Agency's estimates of annualized costs, annualized benefits, and annualized net benefits. In the second type of sensitivity analysis—a so-called ''break-even'' analysis—OSHA also investigated isolated changes to individual cost and benefit input parameters, but with the objective of determining how much they would have to change for annualized costs to equal annualized benefits.

Again, the Agency has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the proposed rule.

Analysis of Isolated Changes to Inputs

The methodology and calculations underlying the estimation of the costs and benefits associated with this rulemaking are generally linear and additive in nature. Thus, the sensitivity of the results and conclusions of the analysis will generally be proportional to isolated variations a particular input parameter. For example, if the estimated time that employees need to travel to (and from) medical screenings were doubled, the corresponding labor costs would double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the economic analysis held up. OSHA first considered changes to input parameters that affected only costs and then changes to input parameters that affected only benefits. Each of the sensitivity tests on cost parameters had only a very minor effect on total costs or net costs. Much larger effects were observed when the benefits parameters were modified; however, in all cases, net benefits remained significantly positive. On the whole, OSHA found that the conclusions of the analysis are reasonably robust, as changes in any of the cost or benefit input parameters still show significant net benefits for the proposed rule. The results of the individual sensitivity tests are summarized in Table VIII–23 and are described in more detail below.

In the first of these sensitivity test where OSHA doubled the estimated portion of employees in regulated areas requiring disposable clothing, from 10 to 20 percent, and estimates of other input parameters remained unchanged, Table VIII–23 shows that the estimated total costs of compliance would increase by $3.6 million annually, or by about 0.54 percent, while net benefits would also decline by $3.6 million, from $4,582 million to $4,528 million annually.

In a second sensitivity test, OSHA decreased the estimated current prevalence of baseline silica training by half, from 50 percent to 25 percent. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $7.9 million annually, or by about 1.19 percent, while net benefits would also decline by $7.9 million annually, from $4,532 million to $4,524 million annually.

Table VIII-23

Sensitivity Tests

Impact Variable	OSHA's Best Estimate	Sensitivity Test	Impact on Annualized Costs	Percentage Impact on Costs		Adjusted Annualized Costs		Adjusted Annualized Net Benefit
Cost								
OSHA's Best Estimate of (a) Annualized Total Cost and (b) Annualized Net Benefits					**(a)**	*$657,892,211*	**(b)**	*$4,531,808,579*
Percentage of employees requiring disposable clothing (in regulated areas)	10%	20%	$3,572,444	0.54%		$661,464,655		$4,528,236,135
Percentage of Employees with Baseline Training	50%	25%	$7,854,808	1.19%		$665,747,020		$4,523,953,770
Travel times for medical exams	60 minutes	120 minutes	$1,422,117	0.22%		$659,314,329		$4,530,386,461
Exposure monitoring--persons per sample area	4	3	$24,807,252	3.77%		$682,699,463		$4,507,001,326
Cost for respirator filters	$332 per year	-40%	-$21,246,533	-3.23%		$636,645,678		$4,553,055,112
Discount rate for costs	7%	3%	$20,562,832	3.13%		$678,455,043		$4,552,371,410
Benefit	**HA's Best Estin**	**Sensitivity Test**	**on Annualized B**	**ntage Impact on Benefits**		**Adjusted Annualized Benefits**		**Adjusted Annualized Net Benefit**
OSHA's Best Estimate of (c) Annualized Total Benefits and (b) Annualized Net Benefits					**(c)**	*$5,189,700,790*	**(b)**	*$4,531,808,579*
Monetized Benefits (High Morbidity Valuation/High Mortality Case Estimate)	Midpoint	High	$2,926,681,791	56%		$8,116,382,581		$7,458,490,370
Monetized Benefits (Low Morbidity Valuation/Low Mortality Case Estimate)	Midpoint	Low	-$2,797,448,568	-54%		$2,392,252,222		$1,734,360,011
Discount rate for benefits (7%)	3%	7%	-$1,723,993,210	-33%		$3,465,707,579		$2,807,815,368
Discount rate for benefits (3%), with Adjustment to Monetized Benefits to Reflect Increases in Real Per Capita Income Over Time	3%	Adjusted 3%	$1,130,801,817	22%		$6,320,502,607		$5,662,610,396

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

In a third sensitivity test, OSHA doubled the estimated travel time for employees to and from medical exams from 60 to 120 minutes. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $1.4 million annually, or by about 0.22 percent, while net benefits would also decline by $1.4 million annually, from $4,532 million to $4,530 million annually.

In a fourth sensitivity test, OSHA reduced its estimate of the number of workers who could be represented by an exposure monitoring sample from four to three. This would have the effect of increasing such costs by one-third. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $24.8 million annually, or by about 3.77 percent, while net benefits would also decline by $24.8 million annually, from $4,532 million to $4,507 million annually.

In a fifth sensitivity test, OSHA increased by 50 percent the size of the productivity penalty arising from the use of engineering controls in construction. As shown in Table VIII–

23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $35.8 million annually, or by about 5.44 percent (and by 7.0 percent in construction), while net benefits would also decline by $35.8 million annually, from $4,532 million to $4,496 million annually.

In a sixth sensitivity test, based on the discussion in Chapter V of this PEA, OSHA reduced the costs of respirator cartridges to reflect possible reductions in costs since the original costs per filter were developed in 2003, and inflated to current dollars. For this purpose, OSHA reduced respirator filter costs by 40 percent to reflect the recent lower-quartile estimates of costs relative to the costs used in OSHA's primary analysis. As shown in Table VIII–23, the total estimated costs of compliance would be reduced by $21.2 million annually, or by about 3.23 percent, while net benefits would also increase by $21.2 million annually, from $4,532 million to $4,553 million annually.

In a seventh sensitivity test, OSHA reduced the average crew size in general industry and maritime subject to a ''unit'' of engineering controls from 4 to 3. This would have the effect of increasing such costs by one-third. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $20.8 million annually, or by about 3.16 percent (and by 14.2 percent in general industry and maritime), while net benefits would also decline by $20.8 million annually, from $4,532 million to $4,511 million annually.

In an eighth sensitivity test, OSHA considered the effect on annualized net benefits of varying the discount rate for costs and the discount rate for benefits separately. In particular, the Agency examined the effect of reducing the discount rate for costs from 7 percent to 3 percent. As indicated in Table VIII–23, this parameter change lowers the estimated annualized cost by $20.6 million, or 3.13 percent. Total annualized net benefits would increase from $4,532 million annually to $4,552 million annually.

The Agency also performed sensitivity tests on several input parameters used to estimate the benefits of the proposed rule. In the first two tests, in an extension of results previously presented in Table VIII–21, the Agency examined the effect on annualized net benefits of employing the high-end estimate of the benefits, as well as the low-end estimate. As discussed previously, the Agency examined the sensitivity of the benefits to both the number of different fatal lung cancer cases prevented, as well as the valuation of individual morbidity cases. Table VIII–23 presents the effect on annualized net benefits of using the extreme values of these ranges, the high mortality count *and* high morbidity valuation case, and the low mortality count *and* low morbidity valuation case. As indicated, using the high estimate of mortality cases prevented and morbidity valuation, the benefits rise by 56% to $8.1 billion, yielding net benefits of $7.5 billion. For the low estimate of both cases and valuation, the benefits decline by 54 percent, to $2.4 billion, yielding net benefits of $1.7 billion.

In the third sensitivity test of benefits, the Agency examined the effect of raising the discount rate for benefits to 7 percent. The fourth sensitivity test of benefits examines the effect of adjusting monetized benefits to reflect increases in real per capita income over time. The results of these two sensitivity tests were previously shown in Table VIII–20 and are repeated in Table VIII–23. Raising the interest rate to 7 percent lowers the estimated benefits by 33 percent, to $3.5 billion, yielding annualized net benefits of $2.8 billion. Adjusting monetized benefits to reflect increases in real per capita income over time raises the benefits by 22 percent, to $6.3 billion, yielding net benefits of $5.7 billion.

''Break-Even'' Analysis

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the proposed rule. However, for these, the Agency performed a ''break-even'' analysis, asking how much the various cost and benefits inputs would have to vary in order for the costs to equal, or break even with, the benefits. The results are shown in Table VIII–24.

Table VIII-24

Break-Even Sensitivity Analysis

	OSHA's Best Estimate of Annualized Cost or Benefit Factor	Factor Value at which Benefits Equal Costs	Required Factor Dollar/Number Change	Percentage Factor Change
Total Costs	$657,892,211	$5,189,700,790	$4,531,808,579	688.8%
Engineering Control Costs	$343,818,700	$4,875,627,279	$4,531,808,579	1318.1%
Benefits Valuation per Case Avoided				
Monetized Benefit per Fatality Avoided*	$8,700,000	$1,102,889	-$7,597,111	-87.3%
Monetized Benefit per Illness Avoided*	$2,575,000	$326,430	-$2,248,570	-87.3%
Cases Avoided				
Deaths Avoided*	688	87	-600	-87.3%
Illnesses Avoided*	1,585	201	-1,384	-87.3%

*Note: The total estimated value of prevented mortality or morbidity alone exceeds the estimated cost of the rule, providing no break-even point. Accordingly, these numbers represent a reduction in the composite valuation of an avoided fatality or illness or in the composite number of cases avoided.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

In one break-even test on cost estimates, OSHA examined how much costs would have to increase in order for costs to equal benefits. As shown in Table VIII–24, this point would be reached if costs increased by $4.5 billion, or 689 percent.

In a second test, looking specifically at the estimated engineering control costs, the Agency found that these costs would need to increase by $4.5 billion, or 1,318 percent, for costs to equal benefits.

In a third sensitivity test, on benefits, OSHA examined how much its estimated monetary valuation of an avoided illness or an avoided fatality would need to be reduced in order for the costs to equal the benefits. Since the total valuation of prevented mortality and morbidity are each estimated to exceed $1.9 billion, while the estimated costs are $0.6 billion, an independent break-even point for each is impossible. In other words, for example, if no value is attached to an avoided illness associated with the rule, but the estimated value of an avoided fatality is held constant, the rule still has substantial net benefits. Only through a reduction in the estimated net value of both components is a break-even point possible.

The Agency, therefore, examined how large an across-the-board reduction in the monetized value of all avoided illnesses and fatalities would be necessary for the benefits to equal the costs. As shown in Table VIII–24, an 87 percent reduction in the monetized value of all avoided illnesses and fatalities would be necessary for costs to equal benefits, reducing the estimated value to $1.1 million per life saved, and an equivalent percentage reduction to about $0.3 million per illness prevented.

In a fourth break-even sensitivity test, OSHA estimated how many fewer silica-related fatalities and illnesses would be required for benefits to equal costs. Paralleling the previous discussion, eliminating either the prevented mortality or morbidity cases alone would be insufficient to lower benefits to the break-even point. The Agency therefore examined them as a group. As shown in Table VIII–24, a reduction of 87 percent, for both simultaneously, is required to reach the break-even point—600 fewer mortality cases prevented annually, and 1,384 fewer morbidity cases prevented annually.

Taking into account both types of sensitivity analysis the Agency performed on its point estimates of the annualized costs and annualized benefits of the proposed rule, the results demonstrate that net benefits would be positive in all plausible cases tested. In particular, this finding would hold even with relatively large variations in individual input parameters. Alternately, one would have to imagine extremely large changes in costs or benefits for the rule to fail to produce net benefits. OSHA concludes that its finding of significant net benefits resulting from the proposed rule is a robust one.

OSHA welcomes input from the public regarding all aspects of this sensitivity analysis, including any data or information regarding the accuracy of the preliminary estimates of compliance costs and benefits and how the estimates of costs and benefits may be affected by varying assumptions and methodological approaches.

H. Regulatory Alternatives

This section discusses various regulatory alternatives to the proposed OSHA silica standard. OSHA believes that this presentation of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to respirable crystalline silica. The second is tied to the Agency's statutory requirement, which underlies the proposed rule, to reduce significant risk to the extent feasible. If, based on evidence presented during notice and comment, OSHA is unable to justify its preliminary findings of significant risk and feasibility as presented in this preamble to the proposed rule, the Agency must then consider regulatory alternatives that do satisfy its statutory obligations.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m³; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

Alternative PELs

OSHA is proposing a new PEL for respirable crystalline silica of 50 μg/m³ for all industry sectors covered by the rule. OSHA's proposal is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. See Section II of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases. As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act (29 U.S.C. 655(b)) requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in this section (Section VIII) of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industry sectors covered by the rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³).

Tables VIII–25 and VIII–26 present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m³ and for the regulatory alternatives of a PEL of 100 μg/m³ and a PEL of 25 μg/m³ (Regulatory Alternatives # 1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m³ to the proposed PEL of 50 μg/m³ and then of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Table VIII–25 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–26 breaks out costs and benefits by major industry sector.

Table VIII-25: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 µg/m³ and 100 µg/m³ Alternative
Millions ($2009)

	25 µg/m³			Incremental Costs/Benefits			50 µg/m³			Incremental Costs/Benefits			100 µg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table VIII-26: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

As Tables VIII–25 and VIII–26 show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its preliminary findings that the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables VIII–25 and VIII–26 also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables VIII–25 and VIII–26, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other the PEL), including requirements for exposure assessment, medical surveillance, silica training, and regulated areas or access control. As shown in Table VIII–25, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in this preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr.Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) help to ensure the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table VIII–27. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Table VIII-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	——	——	——
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	——	——	——
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Under Regulatory Alternative #3, the action level would be raised from 25 μg/ m^3 to 50 μg/m^3 while keeping the PEL at 50 μg/m^3. As a result, exposure monitoring requirements would be triggered only if workers were exposed above the proposed PEL of 50 μg/m³. As shown in Table VIII–27, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table VIII–27, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table VIII–27, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table VIII–27, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed construction standard, employers would be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under this regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

One regulatory alternative (Regulatory Alternative #9) involving the timing of the standard would arise if, contrary to OSHA's preliminary findings, a PEL of 50 $\mu g/m^3$ with an action level of 25 $\mu g/m^3$ were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 $\mu g/m^3$ and an action level of 25 $\mu g/m^3$ to take effect in five years, but at the same time issue an interim PEL of 100 $\mu g/m^3$ and an action level of 50 $\mu g/m^3$ to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 $\mu g/m^3$ with an action level of 50 $\mu g/m^3$ and those estimated for a PEL of 50 $\mu g/m^3$ with an action level of 25 $\mu g/m^3$, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), OSHA is soliciting comments on this issue. Such a particularized, multi-year phase-in would have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. A differential phase-in for smaller firms would also aid very small firms by allowing them to gain from the control experience of larger firms. A phase-in would also be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard, recognizing, as described in Chapter VII of the PEA, that the full benefits of the proposal would take a number of years to fully materialize even in the absence of a phase-in.

As previously discussed in the Introduction to this preamble, OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

I. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires the preparation of an Initial Regulatory Flexibility Analysis (IRFA) for proposed rules where there would be a significant economic impact on a substantial number of small entities. (5 U.S.C. 601–612). Under the provisions of the law, each such analysis shall contain:

1. A description of the impact of the proposed rule on small entities;
2. A description of the reasons why action by the agency is being considered;
3. A succinct statement of the objectives of, and legal basis for, the proposed rule;
4. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
5. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
6. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
7. A description and discussion of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities, such as

(a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(b) The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(c) The use of performance rather than design standards; and

(d) An exemption from coverage of the rule, or any part thereof, for such small entities.

5 U.S.C. 603, 607.

The Regulatory Flexibility Act further states that the required elements of the IRFA may be performed in conjunction with or as part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of the IRFA. 5 U.S.C. 605.

While a full understanding of OSHA's analysis and conclusions with respect to costs and economic impacts on small entities requires a reading of the complete PEA and its supporting materials, this IRFA will summarize the key aspects of OSHA's analysis as they affect small entities.

A Description of the Impact of the Proposed Rule on Small Entities

Section VIII.F of this preamble summarized the impacts of the proposed rule on small entities. Tables VIII–12 and VIII–15 showed costs as a percentage of profits and revenues for small entities in general industry and maritime and in construction, respectively, classified as small by the Small Business Administration, and Tables VIII–13 and VIII–16 showed costs as a percentage of revenues and profits for business entities with fewer than 20 employees in general industry and maritime and in construction, respectively. (The costs in these tables were annualized using a discount rate of 7 percent.)

A Description of the Reasons Why Action by the Agency Is Being Considered

Exposure to crystalline silica has been shown to increase the risk of several serious diseases. Crystalline silica is the only known cause of silicosis, which is a progressive respiratory disease in which respirable crystalline silica particles cause an inflammatory reaction in the lung, leading to lung damage and scarring, and, in some cases, to complications resulting in disability and death. In addition, many well-conducted investigations of exposed workers have shown that exposure increases the risk of mortality from lung cancer, chronic obstructive pulmonary disease (COPD), and renal disease. OSHA's detailed analysis of the scientific literature and silica-related health risks are presented in the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (placed in Docket OSHA–2010–0034).

Based on a review of over 60 epidemiological studies covering more than 30 occupational groups, OSHA preliminarily concludes that crystalline silica is a human carcinogen. Most of these studies documented that exposed workers experience higher lung cancer mortality rates than do unexposed workers or the general population, and that the increase in lung cancer mortality is related to cumulative exposure to crystalline silica. These exposure-related trends strongly implicate crystalline silica as a likely causative agent. This is consistent with the conclusions of other government and public health organizations, including the International Agency for Research on Cancer (IARC), the Agency for Toxic Substance and Disease Registry (ATSDR), the World Health Organization (WHO), the U.S. Environmental Protection Agency (EPA), the National Toxicology Program (NTP), the National Academies of Science (NAS), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH).

OSHA believes that the strongest evidence for carcinogenicity comes from studies in five industry sectors (diatomaceous earth, pottery, granite, industrial sand, and coal mining) as well as a study by Steenland et al. (2001) that analyzed pooled data from 10 occupational cohort studies; each of these studies found a positive relationship between exposure to crystalline silica and lung cancer mortality. Based on a variety of relative risk models fit to these data sets, OSHA estimates that the excess lifetime risk to workers exposed over a working life of 45 years at the current general industry permissible exposure limit (PEL) (approximately 100 μg/m^3 respirable crystalline silica) is between 13 and 60 deaths per 1,000 workers. For exposure over a working life at the current construction and shipyard employment PELs (estimated to range between 250 and 500 μg/m^3), the estimated risk lies between 37 and 653 deaths per 1,000. Reducing these PELs to the proposed PEL of 50 μg/m^3 respirable crystalline silica results in a substantial reduction of these risks, to a range estimated to be between 6 and 26 deaths per 1,000 workers.

OSHA has also quantitatively evaluated the mortality risk from non-malignant respiratory disease, including silicosis and COPD. Risk estimates for silicosis mortality are based on a study by Mannetje et al. (2002), which pooled data from six worker cohort studies to derive a quantitative relationship between exposure and death rate for silicosis. For non-malignant respiratory disease, risk estimates are based on an epidemiologic study of diatomaceous earth workers, which included a quantitative exposure-response analysis (Park et al., 2002). For 45 years of exposure to the current general industry PEL, OSHA's estimates of excess lifetime risk are 11 deaths per 1,000 workers for the pooled analysis and 83 deaths per 1,000 workers based on Park et al.'s (2002) estimates. At the proposed PEL, estimates of silicosis and non-malignant respiratory disease mortality are 7 and 43 deaths per 1,000, respectively. As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis; thus, Mannetje et al.'s selection of deaths may tend to underestimate the true risk of silicosis mortality, while Park et al.'s (2002) analysis would more fairly capture the total respiratory mortality risk from all non-malignant causes, including silicosis and COPD.

OSHA also identified seven studies that quantitatively described relationships between exposure to respirable crystalline silica and silicosis morbidity, as diagnosed from chest radiography (*i.e.,* chest x-rays or computerized tomography). Estimates of silicosis morbidity derived from these cohort studies range from 60 to 773 cases per 1,000 workers for a 45-year exposure to the current general industry PEL, and approach unity for a 45-year exposure to the current construction/shipyard PEL. Estimated risks of silicosis morbidity range from 20 to 170 cases per 1,000 workers for a 45-year exposure to the proposed PEL, reflecting a substantial reduction in the risk associated with exposure to the current PELs.

OSHA's estimates of crystalline silica-related renal disease mortality risk are derived from an analysis by Steenland et al. (2002), in which data from three cohort studies were pooled to derive a quantitative relationship between exposure to silica and the relative risk of end-stage renal disease mortality. The cohorts included workers in the U.S. gold mining, industrial sand, and granite industries. From this study, OSHA estimates that exposure to the current general industry and proposed PELs over a working life would result in a lifetime excess renal disease risk of 39 and 32 deaths per 1,000 workers, respectively. For exposure to the current construction/shipyard PEL, OSHA estimates the excess lifetime risk to range from 52 to 63 deaths per 1,000 workers.

A Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed rule is to reduce the numbers of fatalities and illnesses occurring among employees exposed to respirable crystalline silica in general industry, maritime, and construction sectors. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, exposure monitoring, medical surveillance, and other protective measures to perform their jobs safely. The legal basis for the rule is the responsibility given the U.S. Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act provides that, in promulgating health standards dealing with toxic materials or harmful physical agents, the Secretary ''shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. Sec. 655(b)(5). See Section II of this preamble for a more detailed discussion of the Secretary's legal authority to promulgate standards.

A Description of and Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

OSHA has completed a preliminary analysis of the impacts associated with this proposal, including an analysis of the type and number of small entities to which the proposed rule would apply, as described above. In order to determine the number of small entities potentially affected by this rulemaking, OSHA used the definitions of small entities developed by the Small Business Administration (SBA) for each industry.

OSHA estimates that approximately 470,000 small business or government entities would be affected by the proposed standard. Within these small entities, roughly 1.3 million workers are exposed to crystalline silica and would be protected by the proposed standard. A breakdown, by industry, of the number of affected small entities is provided in Table III–3 in Chapter III of the PEA.

OSHA estimates that approximately 356,000 very small entities would be affected by the proposed standard. Within these very small entities, roughly 580,000 workers are exposed to crystalline silica and would be protected by the proposed standard. A breakdown, by industry, of the number of affected very small entities is provided in Table III–4 in Chapter III of the PEA.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

Tables VIII–28 and VIII–29 show the average costs of the proposed standard by NAICS code and by compliance requirement for, respectively, small entities (classified as small by SBA) and very small entities (fewer than 20 employees). For the average small entity in general industry and maritime, the estimated cost of the proposed rule would be about $2,103 annually, with engineering controls accounting for 67 percent of the costs and exposure monitoring accounting for 23 percent of the costs. For the average small entity in construction, the estimate cost of the proposed rule would be about $798 annually, with engineering controls accounting for 47 percent of the costs, exposure monitoring accounting for 17 percent of the costs, and medical surveillance accounting for 15 percent of the costs.

For the average very small entity in general industry and maritime, the estimate cost of the proposed rule would be about $616 annually, with engineering controls accounting for 55 percent of the costs and exposure monitoring accounting for 33 percent of the costs. For the average very small entity in construction, the estimate cost of the proposed rule would be about $533 annually, with engineering controls accounting for 45 percent of the costs, exposure monitoring accounting for 16 percent of the costs, and medical surveillance accounting for 16 percent of the costs.

Table VIII–30 shows the unit costs which form the basis for these cost estimates for the average small entity and very small entity.

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
324121	Asphalt paving mixture and block manufacturing.	$232	$4	$13	$1	$74	$1	$326
324122	Asphalt shingle and roofing materials	5,721	297	1,887	103	114	111	8,232
325510	Paint and coating manufacturing	0	10	36	3	15	4	69
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	6,310	428	2,065	150	162	160	9,274
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,679	114	663	41	47	42	2,586
327113	Porcelain electrical supply mfg	6,722	458	2,656	162	188	170	10,355
327121	Brick and structural clay mfg	28,574	636	3,018	226	237	236	32,928
327122	Ceramic wall and floor tile mfg	10,982	245	1,160	87	91	91	12,655
327123	Other structural clay product mfg	10,554	235	1,115	83	87	87	12,162
327124	Clay refractory manufacturing	1,325	92	653	33	81	34	2,218
327125	Nonclay refractory manufacturing	1,964	136	802	48	110	51	3,110
327211	Flat glass manufacturing	4,068	160	520	56	50	60	4,913
327212	Other pressed and blown glass and glassware manufacturing.	889	34	110	12	11	13	1,068
327213	Glass container manufacturing	2,004	76	248	27	24	29	2,408
327320	Ready-mixed concrete manufacturing	1,728	460	1,726	163	121	171	4,369
327331	Concrete block and brick mfg	3,236	245	1,257	87	134	91	5,049
327332	Concrete pipe mfg	5,105	386	1,983	137	211	143	7,966
327390	Other concrete product mfg	3,016	228	1,171	81	125	85	4,705
327991	Cut stone and stone product manufacturing.	2,821	207	1,040	74	65	77	4,284
327992	Ground or treated mineral and earth manufacturing.	12,034	174	3,449	62	191	65	15,975
327993	Mineral wool manufacturing	1,365	56	185	20	17	21	1,664
327999	All other misc. nonmetallic mineral product mfg.	2,222	168	863	60	92	62	3,467
331111	Iron and steel mills	604	34	138	12	11	13	812

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
331112	Electrometallurgical ferroalloy product manufacturing.	514	29	118	10	10	11	692
331210	Iron and steel pipe and tube manufacturing from purchased steel.	664	38	154	13	13	14	896
331221	Rolled steel shape manufacturing	583	33	135	12	11	12	787
331222	Steel wire drawing	638	36	148	13	12	14	862
331314	Secondary smelting and alloying of aluminum.	577	33	133	11	11	12	777
331423	Secondary smelting, refining, and alloying of copper.	534	30	125	11	10	11	722
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	548	31	128	11	11	12	741
331511	Iron foundries	9,143	522	2,777	185	200	194	13,021
331512	Steel investment foundries	11,874	675	3,596	240	249	251	16,885
331513	Steel foundries (except investment)	9,223	526	2,802	187	202	196	13,135
331524	Aluminum foundries (except die-casting).	7,367	419	2,231	149	155	156	10,476
331525	Copper foundries (except die-casting)	4,563	260	1,382	92	96	96	6,489
331528	Other nonferrous foundries (except die-casting).	3,895	222	1,179	79	82	82	5,539
332111	Iron and steel forging	531	30	161	11	12	11	756
332112	Nonferrous forging	533	30	162	11	12	11	760
332115	Crown and closure manufacturing	514	29	156	10	11	11	732
332116	Metal stamping	533	30	162	11	12	11	759
332117	Powder metallurgy part manufacturing	535	31	163	11	12	11	762
332211	Cutlery and flatware (except precious) manufacturing.	518	30	157	10	11	11	738
332212	Hand and edge tool manufacturing	542	31	165	11	12	12	772
332213	Saw blade and handsaw manufacturing.	528	30	160	11	12	11	752
332214	Kitchen utensil, pot, and pan manufacturing.	560	32	170	11	12	12	798
332323	Ornamental and architectural metal work.	524	20	102	7	11	8	673
332439	Other metal container manufacturing	550	31	167	11	12	12	784
332510	Hardware manufacturing	531	30	161	11	12	11	756
332611	Spring (heavy gauge) manufacturing	529	30	161	11	12	11	754
332612	Spring (light gauge) manufacturing	585	33	178	12	13	12	834
332618	Other fabricated wire product manufacturing.	537	31	163	11	12	11	765
332710	Machine shops	518	30	157	10	11	11	738
332812	Metal coating and allied services	843	33	165	12	18	12	1,083
332911	Industrial valve manufacturing	528	30	160	11	12	11	752
332912	Fluid power valve and hose fitting manufacturing.	532	30	162	11	12	11	757
332913	Plumbing fixture fitting and trim manufacturing.	528	30	160	11	12	11	752
332919	Other metal valve and pipe fitting manufacturing.	536	31	163	11	12	11	764
332991	Ball and roller bearing manufacturing	545	31	131	11	11	12	741
332996	Fabricated pipe and pipe fitting manufacturing.	529	30	161	11	12	11	754
332997	Industrial pattern manufacturing	517	29	157	10	11	11	736
332998	Enameled iron and metal sanitary ware manufacturing.	484	23	97	8	10	9	630
332999	All other miscellaneous fabricated metal product manufacturing.	521	30	158	11	11	11	742
333319	Other commercial and service industry machinery manufacturing.	526	30	160	11	12	11	750
333411	Air purification equipment manufacturing.	525	30	160	11	11	11	748
333412	Industrial and commercial fan and blower manufacturing.	555	32	169	11	12	12	791
333414	Heating equipment (except warm air furnaces) manufacturing.	520	30	158	11	11	11	741
333511	Industrial mold manufacturing	522	30	159	11	11	11	743
333512	Machine tool (metal cutting types) manufacturing.	524	30	159	11	11	11	746
333513	Machine tool (metal forming types) manufacturing.	532	30	162	11	12	11	758
333514	Special die and tool, die set, jig, and fixture manufacturing.	522	30	158	11	11	11	743
333515	Cutting tool and machine tool accessory manufacturing.	524	30	159	11	11	11	746

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
333516	Rolling mill machinery and equipment manufacturing.	522	30	159	11	11	11	744
333518	Other metalworking machinery manufacturing.	537	31	163	11	12	11	765
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	546	31	166	11	12	12	777
333613	Mechanical power transmission equipment manufacturing.	529	30	161	11	12	11	754
333911	Pump and pumping equipment manufacturing.	535	31	163	11	12	11	762
333912	Air and gas compressor manufacturing	532	30	162	11	12	11	758
333991	Power-driven handtool manufacturing	514	29	156	10	11	11	732
333992	Welding and soldering equipment manufacturing.	523	30	159	11	11	11	745
333993	Packaging machinery manufacturing	521	30	158	11	11	11	742
333994	Industrial process furnace and oven manufacturing.	531	30	161	11	12	11	757
333995	Fluid power cylinder and actuator manufacturing.	531	30	161	11	12	11	756
333996	Fluid power pump and motor manufacturing.	542	31	165	11	12	11	772
333997	Scale and balance (except laboratory) manufacturing.	537	31	163	11	12	11	764
333999	All other miscellaneous general purpose machinery manufacturing.	523	30	159	11	11	11	745
334518	Watch, clock, and part manufacturing	514	29	156	10	11	11	732
335211	Electric housewares and household fans.	523	20	76	7	9	8	643
335221	Household cooking appliance manufacturing.	529	20	77	7	9	8	649
335222	Household refrigerator and home freezer manufacturing.	1,452	56	210	19	26	21	1,784
335224	Household laundry equipment manufacturing.	1,461	56	212	19	26	21	1,795
335228	Other major household appliance manufacturing.	523	20	101	7	11	8	671
336111	Automobile manufacturing	1,309	75	297	25	23	28	1,757
336112	Light truck and utility vehicle manufacturing.	4,789	273	1,085	92	86	102	6,425
336120	Heavy duty truck manufacturing	1,211	69	275	23	22	26	1,626
336211	Motor vehicle body manufacturing	579	33	137	11	11	12	784
336212	Truck trailer manufacturing	525	30	160	11	11	11	748
336213	Motor home manufacturing	792	45	181	15	15	17	1,064
336311	Carburetor, piston, piston ring, and valve manufacturing.	525	30	160	11	11	11	748
336312	Gasoline engine and engine parts manufacturing.	522	30	120	10	10	11	703
336322	Other motor vehicle electrical and electronic equipment manufacturing.	524	30	121	10	10	11	706
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	526	30	120	10	10	11	708
336340	Motor vehicle brake system manufacturing.	527	30	121	10	10	11	710
336350	Motor vehicle transmission and power train parts manufacturing.	528	30	121	10	10	11	710
336370	Motor vehicle metal stamping	556	32	169	11	12	12	792
336399	All other motor vehicle parts manufacturing.	535	30	123	10	10	11	721
336611	Ship building and repair	13,685	0	718	692	47	75	15,217
336612	Boat building	2,831	0	202	149	11	16	3,209
336992	Military armored vehicle, tank, and tank component manufacturing.	624	35	149	12	12	13	845
337215	Showcase, partition, shelving, and locker manufacturing.	527	30	160	11	12	11	751
339114	Dental equipment and supplies manufacturing.	671	39	145	14	11	15	895
339116	Dental laboratories	12	7	130	3	44	3	199
339911	Jewelry (except costume) manufacturing.	120	92	475	33	41	34	795
339913	Jewelers' materials and lapidary work manufacturing.	151	115	596	41	51	43	997
339914	Costume jewelry and novelty manufacturing.	87	44	229	16	19	16	412
339950	Sign manufacturing	465	20	107	7	11	8	618
423840	Industrial supplies, wholesalers	313	29	257	10	15	11	636

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
482110	Rail transportation							
621210	Dental offices	3	2	32	1	11	1	50
	Total—General Industry and Maritime	1,399	93	483	46	46	36	2,103
236100	Residential Building Construction	264	43	34	37	27	15	419
236200	Nonresidential Building Construction	234	104	67	89	66	14	575
237100	Utility System Construction	978	89	172	78	185	30	1,531
237200	Land Subdivision	104	9	25	8	30	3	180
237300	Highway, Street, and Bridge Construction.	692	109	179	95	227	26	1,329
237900	Other Heavy and Civil Engineering Construction.	592	60	134	52	175	18	1,032
238100	Foundation, Structure, and Building Exterior Contractors.	401	359	113	307	91	49	1,319
238200	Building Equipment Contractors	156	18	21	16	27	7	244
238300	Building Finishing Contractors	289	24	23	50	27	9	421
238900	Other Specialty Trade Contractors	460	43	65	52	79	30	729
999000	State and Local Governments [c]	108	16	31	14	43	11	222
	Total—Construction	375	132	72	122	71	26	798

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
324121	Asphalt paving mixture and block manufacturing.	$74	$1	$5	$0	$26	$0	$107
324122	Asphalt shingle and roofing materials	914	48	476	17	23	18	1,496
325510	Paint and coating manufacturing	0	7	33	3	13	3	58
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	851	58	422	21	26	22	1,400
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	705	48	349	17	22	18	1,160
327113	Porcelain electrical supply mfg	851	58	422	21	26	22	1,400
327121	Brick and structural clay mfg	2,096	47	277	17	19	17	2,474
327122	Ceramic wall and floor tile mfg	2,385	53	316	19	22	20	2,815
327123	Other structural clay product mfg	2,277	51	301	18	21	19	2,687
327124	Clay refractory manufacturing	301	21	186	8	20	8	543
327125	Nonclay refractory manufacturing	471	33	291	12	32	12	852
327211	Flat glass manufacturing	842	34	163	12	12	12	1,075
327212	Other pressed and blown glass and glassware manufacturing.	873	34	164	12	12	12	1,107
327213	Glass container manufacturing	873	34	164	12	12	12	1,107
327320	Ready-mixed concrete manufacturing	475	127	595	46	37	47	1,328
327331	Concrete block and brick mfg	966	74	470	27	44	27	1,608
327332	Concrete pipe mfg	1,046	80	509	29	48	29	1,741
327390	Other concrete product mfg	854	65	416	23	39	24	1,422
327991	Cut stone and stone product manufacturing.	1,158	86	535	31	30	32	1,872
327992	Ground or treated mineral and earth manufacturing.	3,564	52	1,280	19	63	19	4,997
327993	Mineral wool manufacturing	823	34	166	12	12	13	1,061
327999	All other misc. nonmetallic mineral product mfg.	797	61	388	22	37	22	1,327
331111	Iron and steel mills	517	30	197	11	13	11	777
331112	Electrometallurgical ferroalloy product manufacturing.	0	0	0	0	0	0	0
331210	Iron and steel pipe and tube manufacturing from purchased steel.	514	30	196	11	12	11	774
331221	Rolled steel shape manufacturing	514	30	196	11	12	11	774
331222	Steel wire drawing	514	30	196	11	12	11	774
331314	Secondary smelting and alloying of aluminum.	514	30	196	11	12	11	774
331423	Secondary smelting, refining, and alloying of copper.	0	0	0	0	0	0	0
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	514	30	196	11	12	11	774
331511	Iron foundries	1,093	63	416	23	26	23	1,644
331512	Steel investment foundries	1,181	68	448	24	28	25	1,774
331513	Steel foundries (except investment)	1,060	61	404	22	26	22	1,595

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
331524	Aluminum foundries (except die-casting).	1,425	82	541	29	33	30	2,141
331525	Copper foundries (except die-casting)	1,503	86	570	31	35	32	2,257
331528	Other nonferrous foundries (except die-casting).	1,401	80	532	29	33	30	2,104
332111	Iron and steel forging	514	30	196	11	12	11	774
332112	Nonferrous forging	514	30	196	11	12	11	774
332115	Crown and closure manufacturing	514	30	196	11	12	11	774
332116	Metal stamping	515	30	196	11	12	11	775
332117	Powder metallurgy part manufacturing	514	30	196	11	12	11	774
332211	Cutlery and flatware (except precious) manufacturing.	514	30	196	11	12	11	774
332212	Hand and edge tool manufacturing	514	30	196	11	12	11	774
332213	Saw blade and handsaw manufacturing.	514	30	196	11	12	11	774
332214	Kitchen utensil, pot, and pan manufacturing.	0	0	0	0	0	0	0
332323	Ornamental and architectural metal work.	520	20	127	7	12	8	694
332439	Other metal container manufacturing	524	30	199	11	13	11	788
332510	Hardware manufacturing	517	30	197	11	13	11	777
332611	Spring (heavy gauge) manufacturing	523	30	199	11	13	11	786
332612	Spring (light gauge) manufacturing	514	30	196	11	12	11	774
332618	Other fabricated wire product manufacturing.	514	30	196	11	12	11	774
332710	Machine shops	515	30	196	11	12	11	774
332812	Metal coating and allied services	519	20	127	7	12	8	694
332911	Industrial valve manufacturing	514	30	196	11	12	11	774
332912	Fluid power valve and hose fitting manufacturing.	514	30	196	11	12	11	774
332913	Plumbing fixture fitting and trim manufacturing.	514	30	196	11	12	11	774
332919	Other metal valve and pipe fitting manufacturing.	519	30	198	11	13	11	781
332991	Ball and roller bearing manufacturing	514	30	196	11	12	11	774
332996	Fabricated pipe and pipe fitting manufacturing.	514	30	196	11	12	11	774
332997	Industrial pattern manufacturing	514	30	196	11	12	11	774
332998	Enameled iron and metal sanitary ware manufacturing.	484	23	153	8	12	9	690
332999	All other miscellaneous fabricated metal product manufacturing.	514	30	196	11	12	11	774
333319	Other commercial and service industry machinery manufacturing.	514	30	196	11	12	11	774
333411	Air purification equipment manufacturing.	514	30	196	11	12	11	774
333412	Industrial and commercial fan and blower manufacturing.	514	30	196	11	12	11	774
333414	Heating equipment (except warm air furnaces) manufacturing.	517	30	197	11	13	11	777
333511	Industrial mold manufacturing	515	30	196	11	12	11	774
333512	Machine tool (metal cutting types) manufacturing.	516	30	196	11	13	11	776
333513	Machine tool (metal forming types) manufacturing.	514	30	196	11	12	11	774
333514	Special die and tool, die set, jig, and fixture manufacturing.	515	30	196	11	12	11	774
333515	Cutting tool and machine tool accessory manufacturing.	515	30	196	11	12	11	775
333516	Rolling mill machinery and equipment manufacturing.	514	30	196	11	12	11	774
333518	Other metalworking machinery manufacturing.	514	30	196	11	12	11	774
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	514	30	196	11	12	11	774
333613	Mechanical power transmission equipment manufacturing.	514	30	196	11	12	11	774
333911	Pump and pumping equipment manufacturing.	514	30	196	11	12	11	774
333912	Air and gas compressor manufacturing	514	30	196	11	12	11	774
333991	Power-driven handtool manufacturing	514	30	196	11	12	11	774
333992	Welding and soldering equipment manufacturing.	514	30	196	11	12	11	774
333993	Packaging machinery manufacturing	514	30	196	11	12	11	774
333994	Industrial process furnace and oven manufacturing.	514	30	196	11	12	11	774

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
333995	Fluid power cylinder and actuator manufacturing.	514	30	196	11	12	11	774
333996	Fluid power pump and motor manufacturing.	514	30	196	11	12	11	774
333997	Scale and balance (except laboratory) manufacturing.	514	30	196	11	12	11	774
333999	All other miscellaneous general purpose machinery manufacturing.	514	30	196	11	12	11	774
334518	Watch, clock, and part manufacturing	514	30	196	11	12	11	774
335211	Electric housewares and household fans.	0	0	0	0	0	0	0
335221	Household cooking appliance manufacturing.	523	20	127	7	12	8	698
335222	Household refrigerator and home freezer manufacturing.	0	0	0	0	0	0	0
335224	Household laundry equipment manufacturing.	0	0	0	0	0	0	0
335228	Other major household appliance manufacturing.	0	0	0	0	0	0	0
336111	Automobile manufacturing	514	30	196	11	12	11	774
336112	Light truck and utility vehicle manufacturing.	514	30	196	11	12	11	774
336120	Heavy duty truck manufacturing	514	30	196	11	12	11	774
336211	Motor vehicle body manufacturing	514	30	196	11	12	11	774
336212	Truck trailer manufacturing	514	30	196	11	12	11	774
336213	Motor home manufacturing	514	30	196	11	12	11	774
336311	Carburetor, piston, piston ring, and valve manufacturing.	514	30	196	11	12	11	774
336312	Gasoline engine and engine parts manufacturing.	514	30	196	11	12	11	774
336322	Other motor vehicle electrical and electronic equipment manufacturing.	514	30	196	11	12	11	774
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	514	30	196	11	12	11	774
336340	Motor vehicle brake system manufacturing.	514	30	196	11	12	11	774
336350	Motor vehicle transmission and power train parts manufacturing.	514	30	196	11	12	11	774
336370	Motor vehicle metal stamping	517	30	197	11	13	11	778
336399	All other motor vehicle parts manufacturing.	514	30	196	11	12	11	774
336611	Ship building and repair	2,820	0	253	151	13	16	3,252
336612	Boat building	2,816	0	252	151	12	15	3,247
336992	Military armored vehicle, tank, and tank component manufacturing.	0	0	0	0	0	0	0
337215	Showcase, partition, shelving, and locker manufacturing.	514	30	196	11	12	11	774
339114	Dental equipment and supplies manufacturing.	663	39	180	14	12	14	922
339116	Dental laboratories	8	5	107	2	32	2	156
339911	Jewelry (except costume) manufacturing.	45	35	225	13	17	13	348
339913	Jewelers' materials and lapidary work manufacturing.	52	40	256	14	19	15	397
339914	Costume jewelry and novelty manufacturing.	50	26	166	9	12	10	274
339950	Sign manufacturing	459	20	132	7	12	7	639
423840	Industrial supplies, wholesalers	262	24	215	9	13	9	531
482110	Rail transportation							
621210	Dental offices	3	2	32	1	11	1	49
	Total—General Industry and Maritime	337	29	205	12	23	11	616
236100	Residential Building Construction	264	43	42	38	30	15	432
236200	Nonresidential Building Construction	117	52	42	46	37	7	301
237100	Utility System Construction	326	30	71	27	69	10	532
237200	Land Subdivision	104	9	25	8	30	3	180
237300	Highway, Street, and Bridge Construction.	275	44	89	39	102	10	559
237900	Other Heavy and Civil Engineering Construction.	202	20	57	18	67	6	372
238100	Foundation, Structure, and Building Exterior Contractors.	228	204	80	180	58	28	778
238200	Building Equipment Contractors	156	18	26	16	30	7	253
238300	Building Finishing Contractors	289	24	28	51	30	9	431
238900	Other Specialty Trade Contractors	276	26	49	32	53	18	454
999000	State and Local Governments [c]	N/A	N/A	N/A	N/A	N/A	N/A	N/A

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
	Total—Construction	242	87	56	83	49	17	533

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Saw enclosure	8′ x 8′ x 8′ wood/plastic.	N/A	$487.70	$48.77	$118.95	Fabrication costs estimated by ERG, assuming in-plant work. Five-year life.
Cab enclosures	Enclosed cabs	N/A	15,164.82	5,307.69	3,698.56	ERG estimate based on vendor interviews.
LEV for hand held grinders.	Shrouds + vacuum	N/A	1,671.63	585.07	407.70	Vacuum plus shroud adapter (*http://www.proventilation.com/products/productDetail.asp?id=15*); 35% for maintenance and operating costs.
Upgraded abrasive blast cabinet.	Improved maintenance and purchases for some.	N/A	4,666.10	1,000.00	664.35	Assumes add. maintenance (of up to $2,000) or new cabinets ($8,000) (Norton, 2003).
Improved spray booth for pottery.	Maintenance time & materials.	N/A	116.65	114.68	231.33	Annual: $100 materials plus 4 hours maintenance time.
Improved LEV for ceramics spray booth.	Increased air flow; per cfm.	N/A	3.21	0.88	3.21	25% of installed CFM price.
Exhaust for saw, cut stone industry.	Based on saw LEV (*e.g.,* pg. 10–158, 159, 160, ACGIH, 2001).	450	5,774.30	1,577.35	822.13	ERG based on typical saw cfm requirements.
LEV for hand chipping in cut stone.	Granite cutting and finishing; (pg. 10–94, ACGIH, 2001).	600	7,699.06	2,103.14	1,096.17	ERG estimate of cfm requirements.
Exhaust trimming machine.	Based on abrasive cut-off saw; (pg. 10–134) (ACGIH, 2001).	500	6,415.89	1,752.61	913.48	Opening of 2 sq ft assumed, with 250 cfm/sq.ft.
Bag opening	Bag opening station; (pg. 10–19, ACGIH, 2001).	1,513	19,414.48	5,303.41	2,764.18	3.5′ x 1.5′ opening; with ventilated bag crusher (200 cfm).
Conveyor ventilation	Conveyor belt ventilation; (pg. 10–70, ACGIH, 2001).	700	8,982.24	2,453.66	1,278.87	Per take-off point, 2′ wide belt.
Bucket elevator ventilation.	Bucket elevator ventilation (pg. 10–68; ACGIH, 2001).	1,600	20,530.84	5,608.36	2,923.13	2′ x 3′ x 30′ casing; 4 take-offs @250 cfm; 100 cfm per sq ft of cross section.
Bin and hopper ventilation.	Bin and hopper ventilation (pg. 10–69; ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	350 cfm per ft2; 3' belt width.
Screen ventilation	Ventilated screen (pg. 10–173, ACGIH, 2001).	1,200	15,398.13	4,206.27	2,192.35	4′ x 6′ screen; 50 cfm per ft^2.
Batch operator workstation.	Bin & hopper ventilation for unvented mixers (pg. 10–69, ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	ERG estimate of cfm requirements.
LEV for hand grinding operator (pottery).	Hand grinding bench (pg. 10–135, ACGIH, 2001).	3,750	48,119.16	13,144.60	6,851.09	ERG estimate of cfm requirements.

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
LEV, mixer and muller hood.	Mixer & muller hood (pg. 10–87, ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	ERG estimate of cfm requirements.
LEV for bag filling stations.	Bag filling station (pg. 10–15, ACGIH, 2001).	1,500	19,247.66	5,257.84	2,740.43	Includes costs for air shower.
Installed manual spray mister.	Manual controls, system covers 100 ft of conveyor.	N/A	10,207.09	1,020.71	1,453.26	National Environmental Services Company (Kestner, 2003).
Install cleaning hoses, reslope floor, drainage.	Plumbing for hose installations, floor resloping and troughs.	N/A	36,412.40	3,258.87	5,184.31	ERG estimate. Includes cost of water and labor time.
Shakeout conveyor enclosure.	Ventilated shakeout conveyor enclosure.	10,000	128,317.75	35,052.26	18,269.56	ERG estimate.
Shakeout side-draft ventilation.	Shakeout double side-draft table (pg. 10–23, ACGIH, 2001).	28,800	369,555.11	100,950.52	52,616.33	ERG estimate of cfm requirements.
Shakeout enclosing hood.	Ventilated enclosing hood (pg. 10–23, ACGIH, 2001); 4′ x 4′ openings.	7,040	90,335.69	24,676.79	12,861.77	ERG estimate of opening size required.
Small knockout table ..	Portable grinding table pg. 10–136), ACGIH, 2001), 3′ x 3′ opening.	1,350	17,322.90	4,732.06	2,466.39	ERG estimate of opening size required.
Large knockout table ..	Hand grinding table pg. 10–135), ACGIH, 2001), 4′ x 6′ surface.	4,800	61,592.52	16,825.09	8,769.39	ERG estimate of bench surface area.
Ventilated abrasive cutoff saw.	Ventilated cut-off saw (pg. 10–134, ACGIH, 2001, 2′ x 3′ opening.	1,500	19,247.66	5,257.84	2,740.43	ERG estimate of opening size required.
Hand grinding bench (foundry).	Bench with LEV (pg. 10–135, ACGIH, 2001); 3′ x 5′.	3,750	48,119.16	13,144.60	6,851.09	ERG estimate of cfm requirements; 250 cfm/sq. ft.
Forming operator bench (pottery).	Bench with LEV (pg. 10–149, ACGIH, 2001), 3′ x 4′.	1,400	17,964.48	4,907.32	2,557.74	ERG estimate of cfm requirements; 125 cfm per linear foot.
Hand grinding bench (pottery).	Bench with LEV (pg. 10–135, ACGIH, 2001); 3′ x 4′.	2,400	30,796.26	8,412.54	4,384.69	ERG estimate of cfm requirements; 200 cfm/sq. ft.
Hand tool hardware	Retrofit suction attachment.	200	464.21	701.05	66.09	ERG estimate of cfm requirements.
Clean air island	Clean air supplied directly to worker.	2,500	32,079.44	8,763.07	4,567.39	ERG estimate of cfm requirements; 125 cfm/sq. ft. for 20 square feet.
Water fed chipping equipment drum cleaning.	Shop-built water feed equipment.	N/A	116.65	0.00	116.65	ERG estimate. $100 in annual costs.
Ventilation for drum cleaning.	Ventilation blower and ducting.	N/A	792.74	198.18	193.34	Electric blower (1,277 cfm) and 25 ft. of duct. Northern Safety Co. (p. 193).
Control room	10′ x 10′ ventilated control room with HEPA filter.	200	19,556.79	701.05	2,784.45	ERG estimate based on RSMeans (2003), ACGIH (2001).
Control room improvement.	Repair and improve control room enclosure.	N/A	2,240.00	N/A	318.93	ERG estimate. Assumes repairs are 20% of new control room cost.
Improved bag valves ..	Bags with extended polyethylene valve, incremental cost per bag.	N/A	0.01	N/A	N/A	Cecala et. al., (1986).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Dust suppressants	Kleen Products 50 lb poly bag green sweeping compound.	N/A	N/A	634.54	0.00	0.28/lb, 2 lbs/day; 5 minutes/day (*www.fastenal.com*).
HEPA vacuum for housekeeping.	NILFISK VT60 wet/dry hepa vac, 15 gal.	N/A	3,494.85	511.20	852.36	Nilfisk, HEPA vacuum (*http://www.sylvane.com/nilfisk.html*).
HEPA vacuum for housekeeping.	NILFISK, large capacity.	N/A	7,699.06	988.90	1,877.73	Nilfisk, HEPA vacuum (McCarthy, 2003).
Yard dust suppression	100 ft, 1'' contractor hose and nozzle.	N/A	204.14	0.00	112.91	Contactor hose and nozzle; 2 year life; (*www.pwmall.com*).
Wet methods to clean concrete mixing equip..	10 mins per day per operator.	N/A	0.00	916.82	0.00	10 mins per day per mixer operator.
HEPA vacuum substitute for compressed air.	Incremental time to remove dust by vacuum.	N/A	N/A	494.54	0.00	5 min per day per affected worker.
Spray system for wet concrete finishing.	Shop-built sprayer system.	N/A	204.67	20.47	113.20	Assumes $100 in materials and 4 hours to fabricate. Also 10% for maintenance.
Substitute alt., non-silica, blasting media.	Alternative media estimated to cost 22 percent more.	N/A	0.00	33,646.00	0.00	Based on 212,000 square feet of coverage per year per crew.
Abrasive blasting cost per square foot (dry blasting).	125 blasting days per year.	N/A	N/A	2.00	N/A	ERG estimate based on RSMeans (2009).
Half-mask, non-powered, air-purifying respirator.	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	570.13	N/A	
Full-face nonpowered air-purifying respirator.	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	637.94	N/A	
Half-face respirator (construction).	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	468.74	N/A	
Industrial Hygiene Fees/personal breathing zone.	Consulting IH technician—rate per sample. Assumes IH rate of $500 per day and samples per day of 2, 6, and 8 for small, medium, and large establishments, respectively.	N/A	N/A	500	N/A	
Exposure assessment lab fees and shipping cost.	....	N/A	N/A	133.38	N/A	Lab fees (EMSL Laboratory, 2000) and OSHA estimates. Inflated to 2009 values.
Physical examination by knowledgeable Health Care Practitioner.	Evaluation and office consultation including detailed examination.	N/A	N/A	100.00	N/A	ERG, 2013.
Chest X-ray	Tri-annual radiologic examination, chest; stereo, frontal. Costs include consultation and written report.	N/A	N/A	79.61	N/A	

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Pulmonary function test.	Tri-annual spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurements(s), and/or maximal voluntary ventilation.	N/A	N/A	54.69	N/A	
Examination by a pulmonary specialist [c].	Office consultation and evaluation by a pulmonary specialist.	N/A	N/A	190.28	N/A	
Training instructor cost per hour.	....	N/A	N/A	34.09	N/A	Based on supervisor wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Training materials for class per attendee.	Estimated cost of $2 per worker for the training/reading materials.	N/A	N/A	2.00	N/A	
Value of worker time spent in class.	....	N/A	N/A	17.94	N/A	Based on worker wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Cost—disposable particulate respirator (N95).	1.00 per respirator per day, typical cost for N95 disposable respirator.	N/A	N/A	1.00	N/A	Lab Safety Supply, 2010.
Disposable clothing	Per suit, daily clothing costs for 10% of workers.	N/A	N/A	5.50	N/A	Lab Safety Supply, 2010.
Hazard tape	Per regulated area for annual set-up (300 ft).	N/A	N/A	5.80	N/A	Lab Safety Supply, 2010.
Warning signs (6 per regulated area).	25.30 per sign	N/A	N/A	151.80	N/A	Lab Safety Supply, 2010.
Wet kit, with water tank.	....	N/A	226.73	[d] 0.18	125.40	Contractors Direct (2009); Berland House of Tools (2009); mytoolstore (2009).
Dust shrouds: grinder	....	N/A	97.33	[d] 0.14	97.33	Contractors Direct (2009); Berland House of Tools (2009); Dust-Buddy (2009); Martin (2008).
Water tank, portable (unspecified capacity).	....	N/A	N/A	[e] 15.50	N/A	RSMeans—based on monthly rental cost.
Water tank, small capacity (hand pressurized).	....	N/A	73.87	[d] 0.11	79.04	Contractors Direct (2009); mytoolstore (2009).
Hose (water), 20′, 2″ diameter.	....	N/A	N/A	[e] 1.65	N/A	RSMeans—based on monthly cost.
Custom water spray nozzle and attachments.	....	N/A	363	[d] 0.54	388.68	New Jersey Laborers' Health and Safety Fund (2007).
Hose (water), 200′, 2″ diameter.	....	N/A	N/A	[e] 16.45	N/A	RSMeans—based on monthly rental cost.
Vacuum, 10–15 gal with HEPA.	....	N/A	725	[d] 0.56	400.99	ICS (2009); Dust Collection (2009); EDCO (2009); CS Unitec (2009).
Vacuum, large capacity with HEPA.	....	N/A	2,108	[d] 1.63	1,165.92	ICS (2009); EDCO (2009); Aramsco (2009).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Dust extraction kit (rotary hammers).	....	N/A	215	[d] 0.30	214.81	Grainger (2009); mytoolstore (2009); Toolmart (2009).
Dust control/quarry drill.	....	N/A	N/A	[e] 17.33	N/A	RSMeans Heavy Construction Cost Data (2008).
Dustless drywall sander.	....	N/A	133	[d] 0.19	133.33	Home Depot (2009); LSS (2009); Dustless Tech (2009).
Cab enclosure/w ventilation and air conditioning.	....	N/A	13,000	[d] 2.59	1,850.91	Estimates from equipment suppliers and retrofitters.
Foam dust suppression system.	....	N/A	14,550	[e] 162.07	2,071.59	Midyette (2003).
Water tank, engine driven discharge, 5000 gal..	....	N/A	N/A	[d] 121.50	N/A	RSMeans (2008)—based on monthly rental cost.
Tunnel dust suppression system supplement.	....	N/A	7,928	[e] 2.71	1,933.47	Raring (2003).
Training instructor cost per hour (Construction).	....	N/A	N/A	43.12	N/A	Based on supervisor wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Value of worker time spent in class (Construction).	....	N/A	N/A	22.22	N/A	Based on worker wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Warning signs (3 per regulated area) (Construction).	25.30 per sign	N/A	N/A	75.90	N/A	Lab Safety Supply, 2010.
Per-worker costs for written access control plan or regulated area setup implementation (Construction).	Weighted average annual cost per worker; Applies to workers with exposures above the PEL.			175.56		

[a] For local exhaust ventilation (LEV), maintenance, and conveyor covers, OSHA applied the following estimates:
LEV: capital cost = $12.83 per cfm; operating cost = $3.51 per cfm; annualized capital cost = $1.83 per cfm; based on current energy prices and the estimates of consultants to ERG (2013).
Maintenance: estimated as 10% of capital cost.
Conveyor Covers: estimated as $17.10 per linear foot for 100 ft. (Landola, 2003); capital cost = $19.95 per linear ft., including all hardware; annualized capital cost = $2.84 per linear ft.
[b] Adjusted from 2003 price levels using an inflation factor of 1.166, calculated as the ratio of average annual GDP Implicit Price Deflator for 2009 and 2003.
[c] Mean expense per office-based physician visit to a pulmonary specialist for diagnosis and treatment, based on data from the 2004 Medical Expenditure Panel Survey. Inflated to 2009 dollars using the consumer price inflator for medical services.
Costs for physical exams and tests, chest X-ray, and pulmonary tests are direct medical costs used in bundling services under Medicare (Intellimed International, 2003). Costs are inflated by 30% to eliminate the effect of Medicare discounts that are unlikely to apply to occupational medicine environments.
[d] Daily maintenance and operating cost.
[e] Daily equipment costs derived from RS Means (2008) monthly rental rates, which include maintenance and operating costs.
Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule.

OSHA has not identified any other Federal rules which may duplicate, overlap, or conflict with the proposal, and requests comments from the public regarding this issue.

1. Alternatives to the Proposed Rule which Accomplish the Stated Objectives of Applicable Statutes and which Minimize any Significant Economic Impact of the Proposed Rule on Small Entities

This section first discusses several provisions in the proposed standard that OSHA has adopted or modified based on comments from small entity representatives (SERs) during the SBREFA Panel process or on recommendations made by the SBREFA Panel as potentially alleviating impacts on small entities. Then, the Agency presents various regulatory alternatives to the proposed OSHA silica standard.

a. Elements of Proposed Rule To Reduce Impacts on Small Entities

The SBREFA Panel was concerned that changing work conditions in the construction industry would make it difficult to apply some of the provisions that OSHA suggested at the time of the Panel. OSHA has preliminarily decided to change its approach in this sector. OSHA is proposing two separate standards, one for general industry and maritime and one for construction. As described earlier in this preamble, in construction, OSHA has provided a table—labeled Table 1, Exposure Control Methods for Selected Construction Operations—that for special operations enables the employer to implement engineering controls, work practices, and respiratory protection without the need for exposure assessment. Table 1 in the proposed construction standard presents engineering and work practice controls and respiratory protection options for special operations. Where employees perform the special operations listed in the table and the employer has fully implemented the engineering controls, work practices, and respiratory protection specified in the table, the employer is not required to assess the exposure of employees performing such operations.

As an alternative to the regulated area provision, OSHA is proposing that employers be permitted the option of establishing written access control plans that must contain provisions for a competent person; procedures for notifying employees of the presence of exposure to respirable crystalline silica and demarcating such areas from the rest of the workplace; in multi-employer workplaces, the methods for informing other employers of the presence and location of areas where silica exposures may exceed the PEL; provisions for limiting access to areas where silica exposures are likely; and procedures for providing respiratory protection to employees entering areas with controlled access. Further discussion on this alternative is found in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control.*

OSHA believes that, although the estimated per-worker cost for written access control plans averages somewhat higher than the per-worker cost for regulated areas ($199.29 per worker for the control plans vs. $167.65 per worker for the regulated area), access control plans may be significantly less costly and more protective than regulated areas in certain work situations.

Some SERs were already applying many of the protective controls and practices that would be required by the ancillary provisions of the standard. However, many SERs objected to the provisions regarding housekeeping, protective clothing, and hygiene facilities. For this proposed rule, OSHA removed the requirement for hygiene facilities, which has resulted in the elimination of compliance costs for change rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. OSHA also restricted the provision for protective clothing (or, alternatively, any other means to remove excessive silica dust from work clothing) to situations where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica.

b. Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion of the various regulatory alternatives to the proposed OSHA silica standard presented in the Introduction and in Section VIII.H of this preamble.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m^3; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

Alternative PELs

OSHA is proposing a new PEL for respirable crystalline silica of 50 μg/m^3 for all industry sectors covered by the rule. OSHA's proposal is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. See Section II of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases. As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act (29 U.S.C. 655(b)) requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in this section (Section VIII) of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m^3 is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m^3 is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m^3 or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m^3 to 100 μg/m^3 for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m^3 to 50 μg/m^3 (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m^3 to 25 μg/m^3 for all industry sectors covered by the rule, while the action level would remain at 25 μg/m^3 (because of difficulties in accurately measuring exposure levels below 25 μg/m^3).

Tables VIII–31A and VIII–31B present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m^3 and for the regulatory alternatives of a PEL of 100 μg/m^3 and a PEL of 25 μg/m^3 (Regulatory Alternatives # 1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m^3 to the proposed PEL of 50 μg/m^3 and then of going from the proposed PEL of 50 μg/m^3 to a PEL of 25 μg/m^3. Table VIII–31A breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–31B breaks out costs and benefits by major industry sector.

Table VIII-31A: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Table VIII-31B: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

As Tables VIII–31A and VIII–31B show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its preliminary findings that the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables VIII–31A and VIII–31B also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables VIII–31A and VIII–31B, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other the PEL), including requirements for exposure assessment, medical surveillance, silica training, and regulated areas or access control. As shown in Table VIII–31A, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in the preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr.Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) Help to ensure the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table VIII–32. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Table VIII-32: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	——	——	——
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	——	——	——
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Under Regulatory Alternative #3, the action level would be raised from 25 μg/m^3 to 50 μg/m^3 while keeping the PEL at 50 μg/m^3. As a result, exposure monitoring requirements would be triggered only if workers were exposed above the proposed PEL of 50 μg/m³. As shown in Table VIII–32, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table VIII–32, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table VIII–32, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table VIII–32, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed construction standard, employers would be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under this regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

One regulatory alternative (Regulatory Alternative #9) involving the timing of the standard would arise if, contrary to OSHA's preliminary findings, a PEL of 50 μg/m³ with an action level of 25 μg/m³ were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 μg/m³ and an action level of 25 μg/m³ to take effect in five years, but at the same time issue an interim PEL of 100 μg/m³ and an action level of 50 μg/m³ to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 μg/m³ with an action level of 50 μg/m³ and those estimated for a PEL of 50 μg/m³ with an action level of 25 μg/m³, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), OSHA is soliciting comments on this issue. Such a particularized, multi-year phase-in would have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. A differential phase-in for smaller firms would also aid very small firms by allowing them to gain from the control experience of larger firms. A phase-in would also be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard.

As previous discussed in the Introduction and in Section VIII.H of this preamble, OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

SBREFA Panel

Table VIII–33 lists all of the SBREFA Panel recommendations and OSHA's responses to these recommendations.

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA give consideration to the alternative of improved enforcement of and expanded outreach for the existing rule rather than a new rule. In addition, the Panel recommended that OSHA carefully study the effects of existing compliance and outreach efforts, such as the Special Emphasis Program on silica, with a view to better delineating the effects of such efforts. This examination should include (1) a year-by-year analysis of the extent of noncompliance discovered in OSHA compliance inspections, and (2) the kinds of efforts OSHA made to improve enforcement and outreach.	As discussed in Chapter II of the PEA, Need for Regulation (and summarized in Section VIII.B of this Preamble), OSHA has reviewed existing enforcement and outreach programs, as well as other legal and administrative remedies, and believes that a standard would be the most effective means to protect workers from exposure to silica. A review of OSHA's compliance assistance efforts and an analysis of compliance with the current PELs for respirable crystalline silica are discussed in Section III of the preamble, Events Leading to the Proposed Standard.

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(General Industry) The Panel recommended that OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs, and that the Agency compare OSHA's revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA has reviewed its cost estimates in response to the comments received from the SERs and evaluated the alternative estimates and methodologies suggested by the SERs. In some cases (such as for exposure monitoring and training) OSHA has revised its cost estimates in response to SER comments. However, OSHA has not made all cost changes suggested by the SERs, but has retained (or simply updated) those cost estimates that OSHA determined reflect sound methodology and reliable data. OSHA requests comments on the Agency's estimated costs and on the assumptions applied in the cost analysis, and has included this topic in Section I. Issues (*See* Compliance Costs) and in Chapter V of the PEA.
The Panel recommended that, as time permits, OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs and that the Agency compare the OSHA revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA has extensively reviewed its costs estimates, changed many of them in response to SER comments, and solicits comments on these revised cost estimates. A few examples of OSHA's cost changes are given in the responses to specific issues below (*e.g.,* exposure monitoring, medical exams, training and familiarization). OSHA requests comments on the Agency's estimated costs and on the assumptions applied in the cost analysis, and has included this topic in Section I. Issues (*See* Compliance Costs) and in Chapter V of the PEA.
The Panel recommended that prior to publishing a proposed standard, OSHA should carefully consider the ability of each potentially affected industry to meet any proposed PEL for silica, and that OSHA should recognize, and incorporate in its cost estimates, specific issues or hindrances that different industries may have in implementing effective controls.	The PEA reflects OSHA's judgment on technological feasibility and includes responses to specific issues raised by the Panel and SERs. OSHA solicits comment on the accuracy and reasonableness of these judgments and has included this topic in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL and Compliance Costs).
The Panel recommended that OSHA carefully review the basis for its estimated exposure monitoring costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	Table 1 in the proposed standard is designed to relieve establishments in construction from requirements for exposure assessment when certain controls are established. OSHA developed cost estimates in the PEA for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. OSHA estimated higher exposure monitoring costs for small entities because an industrial hygienist could not take as many samples a day in a small establishment as in a large one. OSHA believes that its unit cost estimates for exposure monitoring are realistic but will raise that as an issue. See Chapter V of the PEA for details of OSHA's unit costs for exposure monitoring in general industry and maritime.
The Panel recommended that OSHA carefully review the basis for its estimated health screening compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA's cost estimates for health screening are a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. OSHA estimated higher medical surveillance costs (than was estimated in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA)) for small entities because smaller establishments would be more likely to send the workers off-site for medical testing. In addition, OSHA significantly increased the total costs of exposure sampling and x-rays in medical surveillance by assuming no existing compliance with the those provisions in the proposed rule (as compared to an average of 32.6 percent and 34.8 percent existing compliance, respectively, in the PIRFA).
(Construction) The Panel recommended that OSHA carefully review the basis for its estimated hygiene compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA removed the specific hygiene provisions in the proposed rule, which has resulted in the elimination of compliance costs for changing rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. However, OSHA has retained requirements and cost estimates for disposable clothing (in regulated areas) where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica.
The Panel recommended that OSHA carefully review the issue of dry sweeping in the analysis, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	Dry sweeping remains a prohibited activity in the proposed standard and OSHA has estimated the costs for the use of wet methods to control dust (*see* Table VIII–30, above). OSHA requests comment on the use of wet methods as a substitute for dry sweeping and has included this topic in Section I. Issues (*See* Compliance Costs and Provisions of the Standards—Methods of compliance).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA carefully review the basis for its training costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	One participant in the silica SBREFA process objected to ERG's analytical assumption (used in OSHA's Preliminary Initial Regulatory Flexibility Analysis) that training is needed only for those workers exposed above the action level and suggested that training might be necessary for all at-risk workers. For the proposed rule, the scope of this requirement was revised so that the provision now would apply to workers with any potential occupational exposure to respirable crystalline silica; OSHA has estimated training costs in the PEA accordingly. OSHA estimated higher training costs for small entities because of smaller-sized training classes and significantly increased training costs by assuming only half compliance for half of the affected establishments (compared to an average of 56 percent existing compliance for all establishments in the PIRFA).
(Construction) SERs raised cost issues similar to those in general industry, but were particularly concerned about the impact in construction, given the high turnover rates in the industry. The Panel recommended that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	The cost estimates in the PEA reflect OSHA's best judgment and take the much higher labor turnover rates in construction into account when calculating costs. For the proposed rule, OSHA used the most recent BLS turnover rate of 64 percent for construction (versus a turnover rate of 27.2 percent for general industry). OSHA believes that the estimates in the PEA capture the effect of high turnover rates in construction and solicits comments on this issue in Section I. Issues (*See* Compliance Costs).
(Construction) The Panel recommended that OSHA (1) carefully review the basis for its estimated labor costs, and issues related to the use of FTEs in the analysis, (2) consider the concerns raised by the SERs, and (3) ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA used the exposure profiles to estimate the number of full-time-equivalent (FTE) workers in construction who are exposed above the PEL. This would be the exposure profile if all exposed workers worked full-time only at the specified silica-generating tasks. In OSHA's analysis, the actual number of workers exposed above the PEL is represented by two to five times the number of FTE workers, depending on the activity. The estimate of the total number of at-risk workers takes into account the fact that most workers, regardless of construction occupation, spend some time working on jobs where no silica contamination is present. For the control cost analysis, however, it matters only how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. The control costs (as opposed to the program costs) are independent of the number of at-risk workers associated with these worker-days. OSHA emphasizes that the use of FTEs does not "discount" its estimates of aggregate control costs.
(Construction) Some SERs requested that OSHA apply a 30-day exclusion for implementing engineering and work practice controls, as was reflected in the draft standard for general industry and maritime. The Panel recommended that OSHA consider this change and request comment on the appropriateness of exempting operations that are conducted fewer than 30 days per year from the hierarchy requirement.	A 30-day exemption from the requirement to implement engineering and work practice controls was not included in the proposed standard for construction, and has been removed from the proposed standard for general industry. OSHA requests comment on a 30-day exemption, and has included this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(Construction) The Panel recommended that OSHA consider and seek comment on the need to prohibit employee rotation as a means of complying with the PEL and the likelihood that employees would be exposed to other serious hazards if the Agency were to retain this provision.	The proposed prohibition on rotation is explained in the Summary and Explanation for paragraph (f) *Methods of Compliance.* OSHA solicits comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL, and has included this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(Construction) Some SERs questioned the scientific and legal basis for the draft prohibitions on the use of compressed air, brushing, and dry sweeping of silica-containing debris. Others raised feasibility concerns such as in instances where water or electric power was unavailable or where use of wet methods could damage construction materials. The Panel recommended that OSHA carefully consider the need for and feasibility of these prohibitions given these concerns, and that OSHA *see*k comment on the appropriateness of such prohibitions.	As discussed in the Summary and Explanation of paragraph (f) *Methods of Compliance,* the prohibition against the use of compressed air, brushing, and dry sweeping applies to situations where such activities could contribute to employee exposure that exceeds the PEL. OSHA solicits comment on this issue, and has included this topic in Section I. Issues (See Provisions of the Standards—Methods of compliance).
(Construction) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* the proposed standard includes a provision for implementation of "access control plans" in lieu of establishing regulated areas. Clarification for establishing either a regulated area or an access control plan is provided in the Summary and Explanation.
(Construction) The Panel recommended that OSHA clarify how the regulated area requirements would apply to multi-employer worksites in the draft standard or preamble, and solicit comments on site control issues.	The Summary and Explanation for paragraph (e) *Regulated Areas and Access Control* clarifies this requirement. OSHA requests comment on this topic, and has included this topic in Section I. Issues (*See* Compliance Costs and Provisions of the Standards—Methods of compliance).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(Construction) Many SERs were concerned with the extent to which they felt the draft proposed standard would require the use of respirators in construction activities. The Panel recommended that OSHA carefully consider its respiratory protection requirements, the respiratory protection requirements in Table 1, and the PEL in light of this concern.	OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. However, as described in the Summary and Explanation of paragraphs (f) *Methods of Compliance* and (g) *Respiratory Protection* and in the Technological Feasibility chapter of the PEA, use of respiratory protection will be required for some operations. OSHA solicits comment on this issue in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL).
(Construction) The Panel recommended that OSHA carefully address the issues of reliability of exposure measurement for silica and laboratory requirements. The Panel also recommended that OSHA seek approaches to a construction standard that can mitigate the need for extensive exposure monitoring to the extent possible.	OSHA discusses the reliability of measuring respirable crystalline silica in the Technological Feasibility chapter of the PEA. An exemption for monitoring is also provided where the employer uses Table 1. As discussed in the Summary and Explanation for paragraph (d) *Exposure Assessment,* the proposed standard also allows a performance option for exposure assessment that is expected to reduce the amount of monitoring needed. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).
(Construction) As in general industry, many SERs were concerned about all of these provisions because, they contended, silica is not recognized as either a take-home or dermal hazard. Further, many said that these provisions would be unusually expensive in the context of construction work. Other SERs pointed out that protective clothing could lead to heat stress problems in some circumstances. The Panel recommended that OSHA carefully re-examine the need for these provisions in the construction industry and solicit comment on this issue.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* OSHA has proposed a limited requirement for use of protective clothing or other means to remove silica dust from contaminated clothing. This requirement would apply only in regulated areas where there is the potential for work clothing to become grossly contaminated with silica dust. No requirement for hygiene facilities is included in the proposed standard. OSHA solicits comment regarding appropriate requirements for use of protective clothing and hygiene facilities in Section I. Issues (*See* Provisions of the Standards—Regulated areas and access control).
(Construction) The Panel recommended that OSHA explicitly examine the issue of availability of specialists called for by these provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	The provisions requiring B-readers and pulmonary specialists are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance,* and the numbers of available specialists are reported. OSHA solicits comment on this issue in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(Construction) The Panel recommended that OSHA carefully consider the need for pre-placement physicals in construction, the possibility of delayed initial screening (so only employees who had been on the job a certain number of days would be required to have initial screening), and solicit comment on this issue.	As described in the Summary and Explanation for paragraph (n) *Medical Surveillance,* an initial examination is required within 30 days after initial assignment to a job with exposure above the action level for more than 30 days per year. OSHA solicits comment on this proposed requirement in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(Construction) Like the general industry SERs, construction SERs raised the issue that they would prefer a warning label with wording similar to that used in asbestos and lead. The Panel recommended that OSHA consider this suggestion and solicit comment on it.	The proposed standard does not specify wording for labels. OSHA solicits comment on this issue in Section I. Issues (*See* Provisions of the Standards—Hazard communication).
(Construction) Some SERs questioned whether hazard communication requirements made sense on a construction site where there are tons of silica-containing dirt, bricks, and concrete. The Panel recommended OSHA consider how to address this issue in the context of hazard communication.	The proposed standard requires hazard communication for employees who are potentially exposed to respirable crystalline silica. Many of the proposed requirements are already required by OSHA's Hazard Communication Standard. The Agency requests comment on the proposed requirements in Section I. Issues (*See* Provisions of the Standards—Hazard communication).
(Construction) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	OSHA has reviewed the recordkeeping requirements as required by the Paperwork Reduction Act. Detailed analysis of the recordkeeping requirements can be found in OSHA's information collection request submitted to OMB. The recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) *Recordkeeping.* OSHA solicits comment on these requirements in Section I. Issues (*See* Provisions of the Standards—Recordkeeping).
The Panel recommended that OSHA, to the extent permitted by the availability of economic data, update economic data to better reflect recent changes in the economic status of the affected industries consistent with its statutory mandate.	OSHA has prepared the PEA using the most current economic data available.
SERs in construction, and some in general industry, felt the estimate of affected small entities and employees did not give adequate consideration to workers who would be subject to exposure at a site but were not directly employed by firms engaged in silica-associated work, such as employees of other subcontractors at a construction site, visitors to a plant, etc. The Panel recommended that OSHA carefully examine this issue, considering both the possible costs associated with such workers, and ways of clarifying what workers are covered by the standard	The scope of the proposed standard is discussed in the Summary and Explanation for paragraph (a) *Scope and Application.*

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA clarify in any rulemaking action how its action is or is not related to designating silica-containing materials as hazardous wastes.	The relationship between the proposed rule and EPA requirements is discussed in Section XVI, Environmental Impacts.
Some SERs also noted the issue that the use of wet methods in some areas may violate EPA rules with respect to suspended solids in run-off unless provision is made for recycling or settling the suspended solids out of the water. The Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment on this issue.	Silica wastes are not classified as hazardous. Therefore OSHA believes that the incremental disposal costs resulting from dust collected in vacuums and other sources are likely to be quite small. An analysis of wet methods for dust controls suggests that in most cases the amount of slurry discharged are not sufficient to cause a run off to storm drains. OSHA solicits comments on this topic in Section I. Issues (*See* Environmental Impacts).
The Panel recommended that OSHA (1) carefully consider and solicit comment on the alternative of improved outreach and support for the existing standard; (2) examine what has and has not been accomplished by existing outreach and enforcement efforts; and (3) examine and fully discuss the need for a new standard and if such a standard can accomplish more than improved outreach and enforcement.	A review of OSHA's outreach efforts is provided in Section III, Events Leading to the Proposed Standards. OSHA solicits comment on this topic in Section I. Issues (*See* Alternatives/Ways to Simplify a New Standard).
The Panel recommended, if there is to be a standard for construction, that OSHA: (1) seek ways to greatly simplify the standard and restrict the number of persons in respirators; (2) consider the alternative of a standard oriented to engineering controls and work practices in construction; and (3) analyze and solicit comment on ways to simplify the standard.	OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. However, as described in the Summary and Explanation of paragraphs (f) *Methods of Compliance* and (g) *Respiratory Protection* and in the Technological Feasibility chapter of the PEA, use of respiratory protection will be required for some operations. OSHA solicits comment on this topic in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL). OSHA also solicits comment on ways to simplify the standard in Section I. Issues (*See* Alternatives/Ways to Simplify a New Standard).
The Panel recommended that, if there is to be a standard, OSHA consider and solicit comment on maintaining the existing PEL. The Panel also recommends that OSHA examine each of the ancillary provisions on a provision-by-provision basis in light of the comments of the SERs on the costs and lack of need for some of these provisions.	As discussed in the Summary and Explanation for paragraph (c) *Permissible Exposure Limit (PEL),* OSHA has made a preliminary determination that the proposed PEL is necessary to meet the legal requirements to reduce significant risk to the extent feasible. Because the proposed PEL is a fixed value, OSHA also believes it is easier to understand when compared to the current PEL. OSHA solicits comment on the proposed PEL in Section I. Issues (*See* Provisions of the Standards—PEL and action level).
(General Industry) The Panel recommended that OSHA carefully examine the technological and economic feasibility of the draft proposed standard in light of these SER comments.	The PEA reflects OSHA's judgment on the technological and economic feasibility of the proposed standard and includes responses to specific issues raised by the Panel. OSHA solicits comment on the accuracy and reasonableness of these judgments in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL).
(General Industry) Some SERs were concerned that the prohibition on dry sweeping was not feasible or cost effective in their industries. The Panel recommended that OSHA consider this issue and solicit comment on the costs and necessity of such a prohibition.	OSHA has proposed to limit the prohibition on dry sweeping to situations where this activity could contribute to exposure that exceeds the PEL. The Agency solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(General Industry) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	Proposed regulated area provisions are explained in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control.* The proposed standard also includes a provision for implementation of "access control plans" in lieu of establishing regulated areas. Clarification for establishing an access control plan is provided in the Summary and Explanation.
(General Industry) The Panel recommended that OSHA carefully examine the issues associated with reliability of monitoring and laboratory standards in light of the SER comments, and solicit comment on these issues.	OSHA has made a preliminary determination in the proposed rule that only certain sampling and analytical methods can be used to measure airborne crystalline silica at the proposed PEL. Issues related to sampling and analytical methods are discussed in the Technological Feasibility section of the PEA. OSHA solicits comment on the Agency's preliminary determination in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).
(General Industry) Some SERs preferred the more performance-oriented Option 2 provision included in the draft exposure assessment requirements, stating that fixed-frequency exposure monitoring can be unnecessary and wasteful. However, other SERs expressed concern over whether such a performance-oriented approach would be consistently interpreted by enforcement officers. The Panel recommended that OSHA continue to consider Option 2 but, should OSHA decide to include it in a proposed rule, clarify what would constitute compliance with the provision. Some SERs were also concerned about the wording of the exposure assessment provision.	The proposed standard provides two options for periodic exposure assessment; (1) a fixed schedule option, and (2) a performance option. The performance option provides employers flexibility in the methods used to determine employee exposures, but requires employers to accurately characterize employee exposures. The proposed approach is explained in the Summary and Explanation for paragraph (d) *Exposure Assessment.* OSHA solicits comments on the proposed exposure assessment provision in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(General Industry) Some SERs were also concerned about the wording of the exposure assessment provision of the draft proposed standard. These SERs felt that the wording could be taken to mean that an employer needed to perform initial assessments annually.	
The Panel recommended that OSHA clarify this issue.	The requirement for initial exposure assessment is clarified in the Summary and Explanation of paragraph (d) *Exposure Assessment.* The term ''initial'' indicates that this is the first action required to assess exposure and is required only once.
(General Industry) While some SERs currently provide both protective clothing and hygiene facilities, others provide neither. Those SERs that do not currently provide either felt that these provisions were both highly expensive and unnecessary. Some SERs stated that these provisions were pointless because silica is not a take-home hazard or a dermal hazard. Others suggested that such provisions only be required when the PEL is exceeded. The Panel recommended that OSHA carefully consider the need for these provisions, and solicit comment on the need for these provisions, and how they might be limited.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* OSHA has proposed a limited requirement for use of protective clothing or other means to remove silica dust from contaminated clothing. This requirement would apply only in regulated areas where there is the potential for work clothing to become grossly contaminated with silica dust. No requirement for hygiene facilities is included in the proposed standard. OSHA solicits comment regarding appropriate requirements for use of protective clothing and hygiene facilities in Section I. Issues (*See* Provisions of the Standards—Regulated areas and access control).
(General Industry) The SER comments included several suggestions regarding the nature and wording of the health screening requirements. (*See, e.g.,* OSHA, 2003, pp. 25–28.). The Panel recommended that OSHA consider revising the standard in light of these comments, as appropriate.	OSHA has considered these comments and revised the proposed standard where appropriate. The revisions are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance.*
(General Industry) The Panel recommended that OSHA explicitly examine and report on the availability of specialists called for by these provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	The provisions requiring B-readers and pulmonary specialists are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance,* and the numbers of available specialists are reported. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(General Industry) Though the provision for hazard communication simply repeats such provisions already in existence, some SERs urged OSHA to use this opportunity to change the requirement so that warning labels would only be required of substances that were more than 1% (rather than the current 0.1%) by weight of silica. The Panel recommended that OSHA consider this suggestion and solicit comment on it.	OSHA has preliminarily determined to rely on the provisions of the Hazard Communication Standard (HCS) in the proposed rule. The HCS requires labels for mixtures that contain more than 0.1% of a carcinogen. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(General Industry) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	The recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) *Recordkeeping.* OSHA solicits comment on these requirements in Section I. Issues (*See* Provisions of the Standards—Recordkeeping).
(Construction) The Panel recommended that OSHA continue to evaluate the appropriateness of and consider modifications to scope Option 2 that can more readily serve to limit the scope of the standard.	OSHA has made the preliminary determination that scope Option 1 is most appropriate. OSHA solicits comment on this subject in Section I. Issues (*See* Provisions of the Standards—Scope).
(Construction) Many SERs found the requirements for a competent person hard to understand. Many SERs took the competent person requirement as requiring a person with a high level of skills, such as the ability to conduct monitoring. Other SERs said this requirement would require training a high percentage of their employees as competent persons because they typically had many very small crews at many sites. In general, the SERs thought this requirement as written would be difficult to comply with and costly. The Panel recommended that OSHA seek ways to clarify OSHA's intent with respect to this requirement and more clearly delineate the responsibilities of competent persons.	The standard requires a competent person only in limited circumstances when an employer selects the option to implement an ''access control plan'' in lieu of establishing a regulated area. Further clarification is provided in the Summary and Explanation of paragraph (e) *Regulated Areas and Access Control.*
(Construction) Many SERs did not understand that Table 1 was offered as an alternative to exposure assessment and demonstration that the PEL is being met. Some SERs, however, understood the approach and felt that it had merit. These SERs raised several issues concerning the use of Table 1, including:. • The Table should be expanded to include all construction activities covered by the standard, or the scope of the standard should be reduced to only those activities covered by Table 1; • The control measures endorsed in Table 1 need to be better established, as necessary; and • Table 1 should require less use of, and possibly no use of, respirators.	

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA carefully consider these suggestions, expand Table 1, and make other modifications, as appropriate	The rationale for the operations and control measures to be included in Table 1 is provided in the Summary and Explanation for paragraph (f) *Methods of Compliance.* Table 1 includes some operations for which it is anticipated that even with the implementation of control measures, exposure levels will routinely exceed the proposed PEL, and thus reliance on the use of respiratory protection is appropriate. Table 1 has been modified to limit requirements for respirator use where operations are performed for less than 4 hours per day. OSHA solicits comment on the proposed requirements in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
The Panel recommends that OSHA thoroughly review the economic impacts of compliance with a proposed silica standard and develop more detailed feasibility analyses where appropriate..	OSHA significantly expanded its economic impact and economic feasibility analyses in Chapter VI of the PEA. As part of the impact analysis, OSHA added data on normal year-to-year variations in prices and profit rates in affected industries to provide a context for evaluating potential price and profit impacts of the proposed rule. A section was also added to estimate the potential international trade impacts of the proposed rule. OSHA solicits comments in Chapter VI of the PEA on the issues of the economic impacts and the economic feasibility of the proposed rule.
(Construction) The panel recommends that OSHA re-examine its cost estimates for respirators to make sure that the full cost of putting employees in respirators is considered.	OSHA re-examined and updated its cost estimates for each type of respirator. Unit respirator costs included the cost of the respirator itself and the annualized cost of respirator use, to include accessories (*e.g.,* filters), training, fit testing, and cleaning. All costs were updated to 2009 dollars. In addition, OSHA added a cost for employers to establish a respirator program. OSHA solicits comments on this issue in Chapter V of the PEA.
(Construction) Some SERs indicated that the unit costs were underestimated for monitoring, similar to the general industry issues raised previously. In addition, special issues for construction were raised (*i.e.,* unpredictability of exposures), suggesting the rule would be costly, if not impossible to comply with. The Panel recommends that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	To reflect the fact that an industrial hygienist could not typically take as many samples a day in a small establishment as in a large one, OSHA developed cost estimates for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates therefore now reflect the fact that smaller entities will tend to experience larger unit costs for exposure monitoring. To reflect possible problems of unpredictability of exposure in construction, Table 1 in the proposed standard has been designed to allow establishments in construction the option, for certain operations, to implement engineering controls, work practices, and respiratory protection without the need for exposure assessment. OSHA has carefully reviewed the basis for its exposure monitoring cost estimates and considered the concerns raised by the SERs. OSHA solicits comments on this issue in Chapter V of the PEA.
(General Industry) The Panel recommends that OSHA use the best scientific evidence and methods available to determine the significance of risks and magnitude of benefits for occupational exposure to silica. The Panel further recommends that OSHA evaluate existing state silicosis surveillance data to determine whether there are industry-specific differences in silicosis risks, and whether or how the draft standard should be revised to reflect such differences.	OSHA has conducted a comprehensive review of the scientific evidence from toxicological and epidemiological studies on adverse health effects associated with occupational exposure to respirable crystalline silica. This review is summarized in Section V of this preamble, Health Effects Summary, and estimates of the risks of developing silica-related diseases are summarized in Section VI, Summary of the Preliminary Quantitative Risk Assessment. The significance of these risks is examined in Section VII, Significance of Risk. The benefits associated with the proposed rule are summarized in Section VIII.G, Benefits and Net Benefits. Although OSHA's preliminary analysis indicates that a variety of factors may affect the toxicologic potency of crystalline silica found in different work environments, OSHA has not identified information that would allow the Agency to calculate how these influences may affect disease risk to workers in any particular workplace setting.
The SERs, however, also had many specific issues concerning what OSHA should do if it chooses to go forward with a proposed rule. In order to reflect these specific issues, the Panel has made many recommendations concerning issues to be considered if the Agency goes forward with a rule. The Panel also recommends that OSHA take great care in reviewing and considering all comments made by the SERs.	OSHA has carefully considered the Panel recommendations, and the Agency's responses are listed in this table. In addition, specific issues raised in comments by individual SERs are addressed throughout the preamble.

IX. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

The proposed general industry/maritime and construction standards (''the standards'') for respirable crystalline silica contain collection of information (paperwork) requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA–95), 44 U.S.C. 3501 *et seq,* and OMB's regulations at 5 CFR part 1320. PRA–95 defines ''collection of information'' to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format'' (44 U.S.C. 3502(3)(A)). Under PRA–95, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it, and the agency displays a currently valid OMB control number.

B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) for the collection of information requirements identified in this NPRM to OMB for review in accordance with 44 U.S.C. 3507(d). The Agency solicits comments on the proposed new collection of information requirements and the estimated burden hours associated with these requirements, including comments on the following items:

- Whether the proposed collection of information requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

C. Proposed Revisions to Information Collection Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about this ICR.

1. *Title:* Respirable Crystalline Silica Standards for General Industry/Maritime (§ 1910.1053) and Construction (§ 1926.1053)

2. *Description of the ICR:* The proposed respirable crystalline silica standards contain collection of information requirements which are essential components of the occupational safety and health standards that will assist both employers and their employees in identifying exposures to crystalline silica, the medical effects of such exposures, and means to reduce or eliminate respirable crystalline silica overexposures.

3. *Summary of the Collections of Information:*

1910.1053(d) and 1926.1053(d)—Exposure Assessment

Under paragraph (d)(6) of the proposed rule, employers covered by the general industry/maritime standard must notify each affected employee within 15 working days of completing an exposure assessment. In construction, employers must notify each affected employee not more than 5 working days after completing the exposure assessment. In these standards, the following provisions require exposure assessment monitoring: § 1910.1053(d)(1) and § 1926.1053(d)(1), General; § 1910.1053(d)(2) and § 1926.1053(d)(2), Initial Exposure Assessment; § 1910.1053(d)(3) and § 1926.1053(d)(3), Periodic Exposure Assessments; § 1910.1053 (d)(4) and § 1926.1053(d)(4), Additional Exposure Assessments; and § 1926.1053(d)(8)(ii), Specific Operations.

Under § 1910.1053(d)(6)(i) and § 1926.1053(d)(6)(i), employers must either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, paragraph (d)(6)(ii) of § 1910.1053 and § 1926.1053 require that whenever the employer exceeds the permissible exposure limit (PEL), the written notification must contain a description of the corrective action(s) the employer is taking to reduce employee exposures to or below the PEL.

1910.1053(e)(3) and 1926.1053(e)(3)—Written Access Control Plan

The standard provides employers with the option to develop and implement a written access control plan in lieu of establishing regulated areas under paragraph (e)(3). Paragraph (e)(3)(ii) sets out the requirements for a written access control plan. The plan must contain provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL. It must describe how the employer will notify employees of the presence and location of areas where exposures are, or can reasonably be expected to be, in excess of the PEL, and how the employer will demarcate these areas from the rest of the workplace. For multi-employer workplaces, the plan must identify the methods the employers will use to inform other employers of the presence, and the location, of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures the employers need to take to protect employees. The written plan must contain provisions for restricting access to these areas to minimize the number of employees exposed, and the level of employee exposure. The plan also must describe procedures for providing each employee entering areas where respirable crystalline silica exposures may exceed the PEL, with an appropriate respirator in accordance with paragraph (g) of the proposed rule; the employer also must provide this information to the employee's designated representative. Additionally, where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the plan must include provisions for the employer to provide either appropriate protective clothing or other means to remove excessive silica dust from contaminated clothing, as well as provisions for the removal or cleaning of such clothing.

The employer must review and evaluate the effectiveness of the written access control plan at least annually, and update it as necessary. The written access control plan must be available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary, and the Director.

1910.1053(f)—Methods of Compliance

Where the employer conducts abrasive blasting operations, paragraph (f)(2) in the general industry/maritime standard requires the employer to comply with the requirements of 29 CFR part 1915, subpart I (Personal Protective Equipment), as applicable. Subpart I contains several information collection requirements. Under subpart I, when conducting hazard assessments, the employer must: (1) Select the type of personal protective equipment (PPE) that will protect the affected employee from the hazards identified in the occupational hazard assessment; (2) communicate selection decisions to affected employees; (3) select PPE that properly fits each affected employee; and (4) verify that the required occupational hazard assessment has been performed. Additionally, subpart I requires employers to provide training and verification of training for each employee required to wear PPE.

1910.1053(g) and 1926.1053(g)—Respiratory Protection

Paragraph (g) in the standards requires the employer to institute a respiratory protection program in accordance with 29 CFR 1910.134. The Respiratory Protection Standard's information collection requirements provide that employers must: develop a written respirator program; obtain and maintain employee medical evaluation records; provide the physician or other licensed health care professional (PLHCP) with information about the employee's respirator and the conditions under which the employee will use the respirator; administer fit tests for employees who will use negative- or positive-pressure, tight-fitting facepieces; and establish and retain written information regarding medical evaluations, fit testing, and the respirator program.

1910.1053(h) and 1926.1053(h)—Medical Surveillance

Paragraph (h)(2) in the standards requires employers to make available to covered employees an initial medical examination within 30 days after initial assignment unless the employee received a medical examination provided in accordance with the standard within the past three years. Proposed paragraphs (h)(2)(i)–(vi) specify that the baseline medical examination provided by the PLHCP must consist of the following information:

1. A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease; history of tuberculosis; and smoking status and history;
2. A physical examination with special emphasis on the respiratory system;
3. A chest X-ray interpreted and classified according to the International Labour Organization International Classification of Radiographs of Pneumoconioses by a National Institute for Occupational Safety and Health (NIOSH)-certified ''B'' reader, or an equivalent diagnostic study;
4. A pulmonary function test administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;
5. Testing for latent tuberculosis infection; and
6. Any other tests deemed appropriate by the PLHCP.

Paragraph (h)(3) in the standards requires periodic medical examinations administered by a PLHCP, every three years or more frequently if recommended by the PLHCP, for covered employees, including medical and work history, physical examination emphasizing the respiratory system, chest X-rays or equivalent diagnostic study, pulmonary function tests, and other tests deemed to be appropriate by the PLHCP.

Paragraph (h)(4) in the standards requires the employer to provide the examining PLHCP with a copy of the standard. In addition, for each employee receiving a medical examination, the employer must provide the PLHCP with the following information: a description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica; the employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica; a description of any PPE used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

Paragraph (h)(5) in the standards requires the employer to obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The employer must provide the employee with a copy the PLHCPs' written medical opinion within two weeks of receipt. This written opinion must contain the following information:

1. A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;
2. Any recommended limitations upon the employee's exposure to respirable crystalline silica or on the use of PPE such as respirators;
3. A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) if the ''B'' reader classifies the chest X-ray as 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and
4. A statement that the PLHCP explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

If the PLHCP's written medical opinion indicates that a pulmonary specialist should examine an employee, paragraph (h)(6) in the standards requires the employer to make available for the employee a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion. The employer must provide the examining pulmonary specialist with information specified by paragraph (h)(4). The employer must obtain a written opinion from the pulmonary specialist within 30 days of the examination. The written opinion must be comparable to the written opinion obtained from the original PLHCP. The pulmonary specialist also must state in the written opinion that the specialist explained these findings to the employee. The employer also must provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

1910.1053(i) and 1926.1053(i)—Communication of Respirable Crystalline Silica Hazards to Employees

Paragraph (i)(1) of the standards requires compliance with the Hazard Communication Standard (29 CFR 1910.1200), and lists cancer, lung effects, immune system effects, and kidney effects as hazards that the employer must address in its hazard communication program. Additionally, employers must ensure that each employee has access to labels on containers of crystalline silica and safety data sheets. Under paragraph (i)(2)(ii), the employer must make a copy of this section readily available without cost to each affected employee.

1910.1053(j) and 1926.1053(j)—Recordkeeping

Paragraph (j)(1)(i) of the standards requires that employers maintain an accurate record of all employee exposure measurement results as prescribed in paragraph (d) of these standards. The record must include the following information: the date of measurement for each sample taken; the operation monitored; sampling and analytical methods used; number, duration, and results of samples taken; identity of the laboratory that performed the analysis; type of PPE, such as respirators, worn by the employees monitored; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were monitored. The employer must maintain, and make available, employee exposure records in accordance with 29 CFR 1910.1020.

Paragraph (j)(2)(i) requires the employer to maintain an accurate record of all objective data relied on to comply with the proposed requirements of this section. The record must include the following information: the crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; and a description of the process, operation, or activity, and how the data support the assessment; and other data relevant to the process, operation, activity, material, or employee exposures. The employer must maintain, and make available, the objective data records in accordance with 29 CFR 1910.1020.

Paragraph (j)(3)(i) requires the employer to establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h). The record must include the following information: the employee's name and social security number; a copy of the PLHCP's and pulmonary specialist's written opinions; and a copy of the information provided to the PLHCP and pulmonary specialist as required by paragraph (h)(4) of the proposed rule. The employer must maintain, and make available, the medical surveillance records in accordance with 29 CFR 1910.1020.

4. *Number of respondents:* Employers in general industry, maritime, or construction that have employees working in jobs affected by respirable crystalline silica exposure (543,041 businesses).

5. *Frequency of responses:* Frequency of response varies depending on the specific collection of information.

6. *Number of responses:* 4,242,296.

7. *Average time per response:* Varies from 5 minutes (.08 hour) for the employer to provide a copy of the written physician's opinion to the employee, to 8 hours to establish a new respiratory protection program in large establishments.

8. *Estimated total burden hours:* 2,585,164.

9. *Estimated costs (capital-operation and maintenance):* $273,504,281.

D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN–1218–AB70), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.* The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA–2010–0034), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES.** Comments submitted in response to this notice are public records; therefore, OSHA cautions commenters about submitting personal information such as Social Security numbers and date of birth.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete Information Collection Request (ICR) (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this notice titled **ADDRESSES**. You also may obtain an electronic copy of the complete ICR by visiting the Web page at *http://www.reginfo.gov/public/do/PRAMain,* scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

OSHA notes that a federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless the collection of information displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.

X. Federalism

The Agency reviewed the proposed crystalline silica rule according to the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, Aug. 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order allows Federal agencies to preempt State law only with the expressed consent of Congress; in such cases, Federal agencies must limit preemption of State law to the extent possible.

Under Section 18 of the Occupational Safety and Health Act (the ''Act''' or ''OSH Act,'' 29 U.S.C. 667), Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State-Plan States.'' (29 U.S.C. 667). Occupational safety and health standards developed by State-Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State-Plan States are free to develop and enforce their own requirements for occupational safety and health standards.

While OSHA drafted the proposed rule to protect employees in every State, Section 18(c)(2) of the OSHA Act permits State-Plan States to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in the proposed rule if it is promulgated.

In summary, the proposed rule complies with Executive Order 13132. In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards; in these States, this rule limits State policy options in the same manner as every standard promulgated by the Agency. In States with OSHA-approved State plans, this rulemaking does not significantly limit State policy options.

XI. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 27 State and U.S. territories with their own OSHA-approved occupational safety and health plans (''State-Plan States'') must revise their standards to reflect the new standard or amendment. The State standard must be at least as effective as the Federal standard or amendment, and must be promulgated within six months of the publication date of the final Federal rule. 29 CFR 1953.5(a).

The State may demonstrate that a standard change is not necessary because, for example, the State standard is already the same as or at least as effective as the Federal standard change. In order to avoid delays in worker protection, the effective date of the State standard and any of its delayed provisions must be the date of State promulgation or the Federal effective date, whichever is later. The Assistant Secretary may permit a longer time period if the State makes a timely demonstration that good cause exists for extending the time limitation. 29 CFR 1953.5(a).

Of the 27 States and territories with OSHA-approved State plans, 22 cover public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. The five states and territories whose OSHA-approved State plans cover only public-sector employees are: Connecticut, Illinois, New Jersey, New York, and the Virgin Islands.

This proposed crystalline silica rule applies to general industry, construction and maritime, and would impose additional or more stringent requirements. If adopted as proposed, all State Plan States would be required to revise their general industry and construction standards appropriately within six months of Federal promulgation. In addition, State plans that cover private sector maritime employment issues and/or have public employees working in the maritime industry covered by this standard would be required to adopt comparable provisions to their maritime employment standards within six months of publication of the final rule.

XII. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532, an agency must prepare a written ''qualitative and quantitative assessment'' of any regulation creating a mandate that ''may result in the expenditure by the State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more'' in any one year before issuing a notice of proposed rulemaking. OSHA's proposal does not place a mandate on State or local governments, for purposes of the UMRA, because OSHA cannot enforce its regulations or standards on State or local governments. (*See* 29 U.S.C. 652(5).) Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. The OSH Act also does not cover tribal governments in the performance of traditional governmental functions, though it does when tribal governments engage in commercial activity. However, the proposal would not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, although OSHA may include compliance costs for affected governmental entities in its analysis of the expected impacts associated with a proposal, the proposal does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Preliminary Economic Analysis (*see* Section VIII above), OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. The Preliminary Economic Analysis constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits required under Section 202(a) of the UMRA (2 U.S.C. 1532).

XIII. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.,* through air, food, water, soil, product use).

The proposed respirable crystalline silica rule is economically significant under Executive Order 12866 (*see* Section VIII of this preamble). However, after reviewing the proposed respirable crystalline silica rule, OSHA has determined that the rule would not impose environmental health or safety risks to children as set forth in Executive Order 13045. The proposed rule would require employers to limit employee exposure to respirable crystalline silica and take other precautions to protect employees from adverse health effects associated with exposure to respirable crystalline silica. OSHA is not aware of any studies showing that exposure to respirable crystalline silica disproportionately affects children or that employees under 18 years of age who may be exposed to respirable crystalline silica are disproportionately affected by such exposure. Based on this preliminary determination, OSHA believes that the proposed respirable crystalline silica rule does not constitute a covered regulatory action as defined by Executive Order 13045. However, if such conditions exist, children who are exposed to respirable crystalline silica in the workplace would be better protected from exposure to respirable crystalline silica under the proposed rule than they are currently.

XIV. Environmental Impacts

OSHA has reviewed the silica proposal according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). Based on that review, OSHA does not expect that the proposed rule, in and of itself, would create additional environmental issues. However, as noted in the SBREFA report (OSHA, 2003, p. 77), some Small Entity Representatives (SERs) raised the possibility that the use of wet methods to limit occupational (and environmental) exposures in some areas may violate EPA rules with respect to suspended solids in runoff unless provision is made for recycling or settling the suspended solids out of the water. The SBREFA Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment on this issue.

Some large construction projects may already require a permit to address storm water runoff, independent of any OSHA requirements to limit worker exposure to silica. These environmental requirements come from or reference the Clean Water Act of 1987. As applied to construction activities, EPA requirements generally pertain to projects of one acre or more and impose the use of Best Management Practices (BMPs) to minimize the pollution, via water runoff, of storm water collection systems and surface waters. In some cases, these requirements are administered by States.

Otherwise, the use of wet methods to control silica dust as mandated by an OSHA silica standard is not directly addressed by EPA requirements. Local governments, however, might require compliance with EPA BMPs when granting construction permits. As an example, the California Department of Transportation's Construction Site Best Management Practice (BMP) Field Manual and Troubleshooting Guide includes the following guidance for paving and grinding operations: ''Do not allow wastes, such as AC [asphalt concrete] pieces, PCC [Portland concrete cement] grinding residue/slurry, sand/gravel, exposed aggregate concrete residue, or dig-out materials into storm drains or receiving waters. Sweep, vacuum, and collect such wastes and recycle or dispose of properly'' (State of California, Department of Transportation, 2003). Contractors following these BMPs would need to take steps to prevent water used for dust control from running into storm drains, drainage ditches, or surface waters. Slurries left on paved areas would need to be swept or vacuumed to prevent subsequent runoff during storms.

It should be noted that the objective of these BMPs is a reduction in the amount of pollutants washed into storm drain systems or surface waters, rather than reductions in discharges per se. The environmental concern is that the use of wet methods to control silica dust would, besides creating silica slurry, facilitate discharges of other pollutants.

The silica controls costed by OSHA in Chapter VI of the Preliminary Economic Analysis show six tasks where wet methods are suggested: stationary masonry saws, hand-held masonry saws, walk-behind and other large concrete saws, concrete grinding with walk-behind equipment, asphalt milling, and pavement breaking and other demolition with jackhammers. A detailed review of the control measures for these equipment types suggests that only the use of wet methods with pavement breakers has the potential to directly result in runoff discharges to storm drains or surface waters. Even then, the water required would most often not create a runoff potential. The control costs for each of these jobs contains a productivity impact factor, part of which is intended to account for extra cleanup time associated with use of wet methods to control dust, including sweeping or vacuuming of silica slurry. However, such efforts may be less laborious than having to clean up free silica dust and may result in a net decrease in silica (and any other contaminants related to its production) running off into the water supply. OSHA's estimate of the potential environmental impact of each of these six equipment types is summarized below:

• Stationary masonry saws: Most stationary saws come equipped with a water basin that typically holds several gallons of water and a pump for recycling water for wet cutting. The water is recirculated and, thus, not continually discharged. When emptied, the amount of water is not sufficient to produce a runoff.

• Hand-held masonry saws: Large quantities of water typically are not required. Water is supplied from a small capacity water tank. Any slurry residue after cutting could be dealt with by sweeping or vacuuming.

• Walk-behind and other large concrete saws: Larger concrete saws are equipped with a tank to supply water to the blade while cutting. These saws leave a slurry residue, but do not require so much water as to create a runoff.

• Walk-behind concrete grinders and millers: Some tools are equipped with a water-feed system. In these, a water line from a tank, a garden hose, or other water supply leads to the grinding head and delivers water to spray or flood the cutting tool and/or the work surface. When an automatic water feed is not available, a helper can apply water directly to the cutting surface. While such wet methods might generate enough water to create a runoff, these grinding and milling activities are typically done during the finishing stages of structure construction (*e.g.,* parking garages) and often inside the structure. Thus, direct discharges to storm drains or surface waters are unlikely.

• Asphalt milling for pavement resurfacing: A typical asphalt milling machine has a built-in reservoir from which water is applied to the cutting drum. The amount of water used, however, is insufficient to produce a runoff.

• Impact drillers/pavement breakers: Water for dust suppression can be applied manually, or using a semi-automated water-feed device. In the simplest method for suppressing dust, a dedicated helper directs a constant spray of mist at the impact point while another worker operates the jackhammer. The helper can use a hose with a garden-style spray nozzle to maintain a steady and carefully directed mist at the impact point where material is broken and crushed. Jackhammers retrofitted with a focused water mist aimed at the tip of the blade offer a dramatic decrease in silica exposure. Although water-fed jackhammers are not commercially available, it is neither expensive nor difficult to retrofit equipment. Studies suggest that a water flow rate of ⅛ to ¼ gallon per minute is best for silica dust control. At this rate, about 7.5 to 15 gallons of water per hour would be applied to (*i.e.,* sprayed on) the work area. It is unclear whether this quantity of water applied to a moveable work area at a constant rate would produce a runoff. If the work were in sufficient proximity to a storm drain or surface water, the contractor might need to use a simple barrier to prevent the water from entering the drain, or filter it. Because the volume of water is relatively small, the costs for such barriers are likely insubstantial. However, because this type of runoff could happen occasionally, OSHA has added costs for barriers in costing silica controls for this task.

As a result of this review, OSHA has made a determination that the silica proposal would have little potential impact on air, water, or soil quality; plant or animal life; the use of land; or aspects of the external environment. As described above in this section, effective abatement measures are available where the potential for environmental impacts exist. Therefore, OSHA preliminarily concludes that the proposed standard would have no significant environmental impacts. However, while the Agency does not believe that the proposed rule would create significant costs, or otherwise pose a significant challenge, for employers to comply with existing environmental rules, OSHA welcomes comment on this or any other environmentally related issues, or potential conflicts with other agency rules.

XV. Public Participation

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal and by providing oral testimony and documentary evidence at the informal public hearings that the Agency will convene after the comment period ends. The Agency invites interested persons having knowledge of, or experience with, occupational exposure to silica and the issues raised by the proposed rule to participate in this process, and welcomes any pertinent data and information that will provide it with the best available evidence on which to develop the final regulatory requirements.

The Agency has scheduled time during the informal rulemaking hearing in Washington, DC, for participants to testify on the Health Effects Literature Review and Preliminary Quantitative Risk Assessment in the presence of peer reviewers. Peer reviewers will subsequently be able to submit amended final comments to the record. As described in OSHA's peer review agenda, peer reviewers have reviewed OSHA's draft Health Effects Literature Review and Preliminary Quantitative Risk Assessment and have submitted written reports that the Agency has considered prior to publication of the proposed rule. The open comment period and informal hearing will provide the public an opportunity to submit information to the record that it believes will benefit the peer review, and to testify in the presence of the reviewers. This section describes the procedures the public must use to submit their comments to the docket in a timely manner, and to schedule an opportunity to deliver oral testimony and provide documentary evidence at informal public hearings on the proposal. Comments, notices of intention to appear, hearing testimony and documentary evidence will be available for inspection and copying at the OSHA Docket Office. You also should read the sections above titled **DATES** and **ADDRESSES** for additional information on submitting comments, documents, the presence of peer reviewers at the hearings, and requests to the Agency for consideration in this rulemaking.

Written Comments. OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised in Section I of this preamble. When submitting comments, persons must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES**. The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the record and will be available for public inspection and copying at the OSHA Docket Office as well as online at *www.regulations.gov* (Docket Number OSHA–2010–0034).

Informal Public Hearings. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity to provide oral testimony concerning the issues raised in this proposal at informal public hearings. The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of the hearing is an administrative law judge (ALJ) and questioning of witnesses is allowed on crucial issues, the proceeding is largely informal and essentially legislative in purpose. Therefore, the hearing provides interested persons with an opportunity to make oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. The hearing is not an adjudicative proceeding subject to the technical rules of evidence. Instead, it is an informal administrative proceeding convened for the purpose of gathering and clarifying information. The regulations that govern the hearings and the prehearing guidelines issued for the hearing will ensure that participants are treated fairly and provided due process. This approach will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will be resolved in favor of developing a clear, accurate, and complete record. Conduct of the hearing will conform to 29 CFR 1911.15. In addition, the Assistant Secretary may, on reasonable notice, issue additional or alternative procedures to expedite the proceedings, to provide greater procedural protections to interested persons or to further any other good cause consistent with applicable law (29 CFR 1911.4).

Although the ALJ presiding over the hearing makes no decision or recommendation on the merits of the proposal, the ALJ has the responsibility and authority necessary to ensure the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested persons receive a full and fair hearing, the ALJ has the power to regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine presentations to matters pertinent to the issues the proposed rule raises; use appropriate means to regulate the conduct of persons present at the hearing; question witnesses and permit others to do so; limit the time for such questioning; and leave the record open for a reasonable time after the hearing for the submission of additional data, evidence, comments and arguments (29 CFR 1911.16).

At the close of the hearing the ALJ will establish a post-hearing comment period for interested persons who filed a timely notice of intention to appear at the hearing. During the first part of the post-hearing period, those persons may submit additional data and information to OSHA. During the second part they may submit final briefs, arguments, and summations.

Notice of Intention to Appear to Provide Testimony at the Informal Public Hearing. Interested persons who intend to provide oral testimony at the informal public hearing must file a notice of intention to appear by using the procedures specified above in the sections titled **DATES** and **ADDRESSES**. This notice must provide the following information:

Name, address, email address, and telephone number of each individual who will give oral testimony;

Name of the establishment or organization each individual represents, if any;

Occupational title and position of each individual testifying;

Approximate amount of time required for each individual's testimony;

If the individual requests to present testimony related to the Health Effects Literature Review and Preliminary Quantitative Risk Assessment, the notice should specify if the submitter requests this testimony be provided in the presence of peer reviewers;

A brief statement of the position each individual will take with respect to the issues raised by the proposed rule; and

A brief summary of documentary evidence each individual intends to present.

Participants who need projectors and other special equipment for their testimony must contact Frank Meilinger at OSHA's Office of Communications, telephone (202) 693–1999, no later than one week before the hearing begins.

OSHA emphasizes that the hearings are open to the public; however, only individuals who file a notice of intention to appear may question witnesses and participate fully at the hearing. If time permits, and at the discretion of the ALJ, an individual who did not file a notice of intention to appear may be allowed to testify at the hearing, but for no more than 10 minutes.

Hearing testimony and documentary evidence. Individuals who request more than 10 minutes to present their oral testimony at the hearing or who will submit documentary evidence at the hearing must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence no later than December 11, 2013.

The Agency will review each submission and determine if the information it contains warrants the amount of time the individual requested for the presentation. If OSHA believes the requested time is excessive, the Agency will allocate an appropriate amount of time for the presentation. The Agency also may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements, and may request that the participant return for questioning at a later time. Before the hearing, OSHA will notify participants of the time the Agency will allow for their presentation and, if less than requested, the reasons for its decision. In addition, before the hearing OSHA will provide the pre-hearing guidelines and hearing schedule to each participant.

Certification of the hearing record and Agency final determination. Following the close of the hearing and the post-hearing comment periods, the ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The record will consist of all of the written comments, oral testimony and documentary evidence received during the proceeding. The ALJ, however, will not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review all the evidence received into the record and will issue the final rule based on the record as a whole.

XVI. Summary and Explanation of the Standards

(a) Scope and application

OSHA is proposing to issue one standard addressing respirable crystalline silica exposure in general industry and maritime and a separate standard addressing exposure in the construction industry. The scope provisions are contained in paragraph (a) of the proposed standards. The proposed standard for the construction industry is similar to the proposed standard for general industry and maritime, and the standards are intended to provide equivalent protection for all workers while accounting for the different work activities, anticipated exposures, and other conditions in these sectors. The limited differences between the proposed construction and general industry/maritime standards exist because OSHA believes, based on the record developed to date, that certain activities in construction are different enough to warrant modified requirements.

The proposed standards do not cover the agricultural sector, due to limited data on exposures and control measures in this sector. OSHA's authority is also restricted in this area; since 1976, an annual rider in the Agency's Congressional appropriations bill has limited OSHA's use of funds with respect to farming operations that employ fewer than ten workers. Consolidated Appropriations Act, 1976, Public Law 94–439, 90 Stat. 1420, 1421 (1976) (and subsequent appropriations acts). However, some evidence indicates that certain agricultural operations may result in exposures to respirable silica in excess of the proposed PEL. A literature review conducted by Swanepoel *et al.* (2010) identified studies that examined respirable quartz exposure and associated diseases in agricultural settings. Three of the exposure studies measured respirable quartz in the personal breathing zone of workers (Popendorf *et al.* 1982; Archer *et al.* 2002; Lee *et al.* 2004). Popendorf *et al.* (1982) investigated exposures among citrus, peach, and grape harvesters; Archer *et al.* (2002) reported on farmworkers in eastern North Carolina; and Lee *et al.* (2004) examined citrus and grape harvesters in California. Each of these studies identified instances where exposures exceeded the proposed PEL. In particular, Archer *et al.* (2002) reported respirable quartz concentrations as high as 3910 μg/m^3 among farmworkers during sweet potato transplanting. Area samples reported in two other studies support the belief that agricultural operations can generate high levels of respirable quartz. Gustafsson *et al.* (1978) reported average respirable quartz concentrations of 2000 μg/m^3 in open tractor cabs, while Lawson *et al.* (1995) reported respirable quartz concentrations ranging from 20–90 μg/m^3 during rice farming operations. Little evidence was reported in the literature regarding diseases associated with respirable crystalline silica exposure in agricultural workers (Swanepoel *et al.,* 2010). OSHA is interested in additional evidence relating to exposures to respirable crystalline silica that occur in agriculture and to associated control measures, as well as information related to the development of respirable crystalline silica-related diseases among workers in the agricultural sector, and is requesting such information in the ''Issues'' section (Section I) of this preamble.

In paragraph (b) (definition of ''respirable crystalline silica''), OSHA proposes to cover quartz, cristobalite, and tridymite under the standard. The Agency believes the evidence supports this approach. OSHA currently has different permissible exposure limits (PELs) for different forms of crystalline silica. The current general industry PELs for cristobalite and tridymite are one half of the general industry PEL for quartz. This difference was based on the fact that early animal studies appeared to suggest that cristobalite and tridymite were more toxic to the lung than quartz. However, as discussed in OSHA's Review of Health Effects Literature and summarized in Section V of this preamble, reviews of more recent studies have led OSHA to preliminarily conclude that cristobalite and tridymite are comparable to quartz in their toxicities. Also, a difference in toxicity between cristobalite and quartz has not been observed in epidemiologic studies. Exposure to tridymite has not been the subject of epidemiologic study.

OSHA's preliminary conclusion that quartz, cristobalite, and tridymite should be addressed under a single standard and subject to the same PEL is consistent with the recommendation of the National Institute for Occupational Safety and Health (NIOSH), which has a single Recommended Exposure Limit (REL) covering all forms of respirable crystalline silica. In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has issued a single Threshold Limit Value (TLV) for quartz and cristobalite.

In 2003, OSHA presented respirable crystalline silica draft standards for both general industry and construction to the Small Business Regulatory Enforcement Fairness Act (SBREFA) review panel. The general industry scope has remained unchanged, while the SBREFA construction draft standard included two alternative scope provisions. The first option, which is included in the proposal, stated that the rule applied to all construction operations covered by 29 CFR part 1926. The second option was more restrictive, indicating the rule would apply only to abrasive blasting and other specified operations (cutting, sanding, drilling, crushing, grinding, milling, sawing, scabbling, scrapping, mixing, jack hammering, excavating, or disturbing materials that contain crystalline silica). The SBREFA panel recommended that OSHA continue to evaluate and consider modifications to the second option that could serve to limit the scope of the standard.

OSHA is proposing to cover all occupational exposures to respirable crystalline silica in construction work, as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926, because the Agency wants to ensure that all activities are covered by the standard if they involve exposures that present a significant risk to workers. The second scope option in the SBREFA draft included activities that are typically associated with higher worker exposures to crystalline silica, but would not cover all operations that present a significant risk.

Collectively, the proposed standards apply to occupational exposure in which respirable crystalline silica is present in an occupationally related context. Exposure of employees to the ambient environment, which may contain small concentrations of respirable crystalline silica unrelated to occupational activities, is not subject to the proposed standards.

(b) Definitions

''Action level'' is defined as an airborne concentration of respirable crystalline silica of 25 micrograms per cubic meter of air (25 μg/m³) calculated as an eight-hour time-weighted average (TWA). The action level triggers requirements for periodic exposure monitoring. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day fall below the PEL but are above the action level, there is a reasonable chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. Previous standards have recognized a statistical basis for using an action level of one-half the PEL (*e.g.,* acrylonitrile, 29 CFR 1910.1045; ethylene oxide, 29 CFR 1910.1047). In brief, OSHA previously determined (based in part on research conducted by Leidel *et al.*) that where exposure measurements are above one-half the PEL, the employer cannot be reasonably confident that the employee is not exposed above the PEL on days when no measurements are taken (Leidel, *et al.,* 1975). Therefore, requiring periodic exposure measurements when the action level is exceeded provides employers with additional assurance that employees are being protected from exposures above the PEL.

As exposures are lowered, the risk of adverse health effects among workers decreases. In addition, there is an economic benefit to employers who reduce exposure levels below the action level: They can avoid the costs associated with periodic exposure monitoring requirements. Some employers will be able to reduce exposures below the action level in all work areas, and other employers in some work areas.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. At least one court has held that OSHA has a duty to impose additional requirements on employers to eliminate remaining significant risk when those requirements will afford benefits to workers and are feasible. *Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1269 (D.C. Cir 1988). OSHA's preliminary conclusion is that the action level will result in a very real and necessary further reduction in risk beyond that provided by the PEL alone. OSHA's decision to propose an action level of one-half of the PEL is based, in part, on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

''Competent person'' means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them. The competent person concept has been broadly used in OSHA construction standards, particularly in safety standards. In OSHA shipyard standards, a defined role for the competent person focuses on confined space hazards, hot work, and explosive environments. Competent person requirements also apply to powder actuated tools. It is not the intent of this proposal to modify the existing competent person requirements in shipyard standards.

As explained below in section (e) (Regulated areas and access control), employers have the option to develop a written access control plan in lieu of establishing regulated areas to minimize exposures to employees not directly involved in operations that generate respirable crystalline silica in excess of the PEL. The access control plan would require that a competent person identify areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL.

The proposed standard does not specify particular training requirements for competent persons. Rather, the requirement for a competent person is performance-based; the competent person must be capable of effectively performing the duties assigned under the standard. Therefore, the competent person must have the knowledge and experience necessary to identify in advance tasks or operations during which exposures are reasonably expected to exceed the PEL, so that affected employees can be notified of the presence and location of areas where such exposures may occur, and the employer can take steps to limit access to these areas and provide appropriate respiratory protection.

OSHA included more extensive competent person requirements in both the draft general industry/maritime and construction standards presented for review to the Small Business Regulatory Enforcement Fairness Act (SBREFA) review panel. The SBREFA draft standards included requirements for a competent person at each worksite to ensure compliance with the provisions of the standard. Specifically, the SBREFA draft standards required that the competent person: Evaluate workplace exposures and the effectiveness of controls, and implement corrective measures to ensure that employees are not exposed in excess of the PEL; establish regulated areas wherever the airborne concentration of respirable crystalline silica exceeds or can reasonably be expected to exceed the PEL, taking into consideration factors that could affect exposures such as wind direction, changes in work processes, and proximity to other workplace operations; and check the regulated area daily to ensure the boundary is maintained. The SBREFA draft standards also required the employer to ensure that the competent person inspect abrasive blasting activities as necessary to ensure that controls are being properly used and remain effective; participate in the evaluation of alternative blast media; and communicate with other employers to inform them of the boundaries of regulated areas established around abrasive blasting operations.

Many small entity representatives (SERs) from the construction industry who reviewed the SBREFA draft standard found the requirements for a competent person hard to understand (OSHA, 2003). Many believed that the competent person required a high skill level, while others thought that a large proportion of their employees would need to be trained. SERs thought that the requirements would be difficult to comply with and costly. These concerns may have been due to the specific regulatory language used in the SBREFA draft, rather than the general concept of competent person requirements. OSHA's Advisory Committee on Construction Safety and Health recommended that the Agency retain the requirement and responsibilities for a competent person in the proposed rule (ACCSH, 2009). The Building and Construction Trades Department, AFL–CIO has also consistently recommended including competent person requirements in a proposed silica standard.

OSHA has proposed limited competent person requirements because the Agency has preliminarily concluded that the provisions of the proposed standard will generally be effective without the involvement of an individual specifically designated as a competent person. For example, the proposed standard requires that the employer use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL. OSHA believes that this provision adequately communicates this requirement to employers, and that an additional requirement for a ''competent person'' to evaluate the effectiveness of these controls and implement corrective measures in this standard is not necessary. However, the Agency is aware that competent person requirements have been included in other health and safety standards, and that some parties believe such requirements would be useful in the silica standard. OSHA is interested in information and comment on the appropriate role of a competent person in the respirable crystalline silica standard, and has included this topic in the ''Issues'' section (Section I) of this preamble.

''Employee exposure'' means exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator. This definition is included to clarify the requirement that employee exposure be measured as if no respiratory protection were being worn. It is consistent with OSHA's previous use of the term in other standards.

''Objective data'' means information, such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product, material, process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Objective data is further discussed below in section (d) (Exposure Assessment).

''Physician or other licensed health care professional (PLHCP)'' means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section. This definition is included because the proposed standard requires that all medical examinations and procedures be performed by or under the supervision of a PLHCP.

Any PLHCP may perform the medical examinations and procedures required under the standard when they are licensed, registered, or certified by state law to do so. The Agency recognizes that this means that the personnel qualified to provide the required medical examinations and procedures may vary from state to state, depending on state licensing or certification laws. This provision of the proposed rule grants the employer the flexibility to retain the services of a variety of qualified licensed health care professionals, provided that these individuals are licensed to perform, or be delegated the responsibility to perform, the specified service. OSHA believes that this flexibility will reduce cost and compliance burdens for employers and increase convenience for employees. The approach taken in this proposed standard is consistent with the approach OSHA has taken in other recent standards, such as chromium (VI) (29 CFR 1910.1026), bloodborne pathogens (29 CFR 1910.1030), and respiratory protection (29 CFR 1910.134).

''Regulated area'' means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL. This definition is consistent with the use of the term in other standards, including those for chromium (VI) (29 CFR 1910.1026), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

''Respirable crystalline silica'' means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

The Agency's proposed definition for respirable crystalline silica seeks to harmonize the Agency's practice with current aerosol science and the ISO definition of respirable particulate mass. Thus, the proposed definition would encompass the polymorphs of silica covered under current OSHA standards and would be consistent with the international consensus that the ISO definition of respirable particulate mass represents. The American Conference of Governmental Industrial Hygienists (ACGIH) and the European Committee for Standardization (CEN) have adopted the ISO definition of respirable particulate mass. The National Institute for Occupational Safety and Health (NIOSH) has also adopted the ISO definition of respirable particulate mass in its Manual of Sampling and Analytical Methods. Adoption of this definition by OSHA would allow for workplace sampling for respirable crystalline silica exposures to be conducted using any particulate sampling device that conforms to the ISO definition (*i.e.,* that collects dust according to the particle collection efficiency curve specified in the ISO standard). OSHA's current respirable crystalline silica PELs are measured according to a particle collection efficiency curve formerly specified by ACGIH, which is now obsolete. The relationship between the ISO definition of respirable particulate mass and the ACGIH criteria is discussed in greater detail in the Technological Feasibility chapter of the Preliminary Economic Analysis, and is summarized in section VIII of this preamble.

The definitions for ''Assistant Secretary,'' ''Director,'' ''High-efficiency particulate air [HEPA] filter,'' and ''This section'' are consistent with OSHA's previous use of these terms in other health standards.

(c) Permissible Exposure Limit (PEL)

In paragraph (c), OSHA proposes to set an 8-hour time-weighted average (TWA) exposure limit of 50 micrograms of respirable crystalline silica per cubic meter of air (50 $\mu g/m^3$). This limit means that over the course of any 8-hour work shift, the average exposure to respirable crystalline silica cannot exceed 50 $\mu g/m^3$. The proposed PEL is the same for both general industry/maritime [38] and construction.

OSHA currently expresses the general industry PEL for respirable crystalline silica in the form of quartz in two ways. The first, which is based on gravimetric measurement, is derived from the formula (PEL = (10 mg/m³)/(% quartz + 2) as respirable dust). This is approximately equivalent to 100 μg/m³ of respirable crystalline silica. The current general industry PELs for the polymorphs cristobalite and tridymite are one-half of the value calculated from this formula, or approximately 50 μg/m³ of respirable crystalline silica. The proposed PEL is thus approximately equivalent to the current general industry PELs for cristobalite and tridymite. In cases where exposures to quartz, cristobalite, and/or tridymite occur at the same time, the PEL is calculated following the procedure specified in 29 CFR 1910.1000(d)(2) for exposures to mixtures of substances having an additive effect on the body or target organ system.

The second way OSHA expresses the general industry PEL for respirable crystalline silica in the form of quartz is based on a now-obsolete particle count sampling method, and is presented in terms of millions of particles per cubic foot (mppcf). This PEL is based on the formula (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust). The current general industry PELs for cristobalite and tridymite are one-half of the value calculated from this formula. These two parallel PELs in general industry were originally believed to be equivalent values (Ayer, 1995). However, as discussed below, the values are now considered to differ substantially.

The current PEL for crystalline silica in the form of quartz in construction and shipyards (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust) is expressed only in terms of mppcf. This is the same formula as the parallel PEL for respirable crystalline silica in the form of quartz in general industry that is expressed in mppcf. The Mineral Dusts tables that contain the silica PELs for construction and shipyards do not clearly express PELs for cristobalite and tridymite. 29 CFR 1926.55; 29 CFR 1915.1000. This lack of textual clarity likely results from a transcription error during the codification of these rules. OSHA's current proposal provides the same PEL for quartz, cristobalite, and tridymite, in general industry, construction, and shipyards.

The current PELs in general industry, construction, and shipyards are 8-hour TWA exposure limits. Both formulas express the PEL in terms of a permissible level of exposure to respirable dust, rather than a permissible level of exposure to respirable crystalline silica. The higher the percentage of crystalline silica in the sample, the lower the level of respirable dust allowed.

The current PELs for construction and shipyards (and the parallel PEL presented for general industry) are based on a particle count method long rendered obsolete by gravimetric respirable mass sampling, which yields results reported in milligrams or micrograms per cubic meter of air (mg/m³or μg/m³). Gravimetric sampling methods are the only methods currently available to OSHA compliance personnel. Since the current construction and shipyard PELs are expressed only in terms of mppcf, the results of the gravimetric sampling must be converted to an equivalent mppcf value.

In order to determine a formula for converting from mg/m³ to mppcf, OSHA requested assistance from the National Institute for Occupational Safety and Health (NIOSH). Based on its review of published studies comparing the particle count and gravimetric methods, NIOSH recommended a conversion factor of 0.1 mg/m³ respirable dust to 1 mppcf. OSHA has determined that this conversion factor should be applied to silica sampling results used to characterize exposures in construction and shipyard operations. Appendix E to CPL 03–00–007, OSHA's National Emphasis Program for Crystalline Silica, illustrates how the conversion factor is applied to enforce the current PEL for crystalline silica in the construction and shipyard industries. Applying the conversion factor to a sample consisting of pure (*i.e.,* 100%) crystalline silica indicates that the current PEL for construction and shipyards is approximately equivalent to 250 μg/m³ of respirable crystalline silica.

OSHA's current PELs for respirable crystalline silica are expressed as respirable dust, or respirable particulate mass. The proposed PEL is expressed as respirable crystalline silica, or the amount of crystalline silica that is present as respirable particulate mass. Respirable particulate mass refers to airborne particulate matter that is capable of entering the gas-exchange region of the lung, where crystalline silica particles cause pathological damage. Only very small particles (particles of about 10 μg/m or less) are able to penetrate into the gas-exchange region of the lung. As particle size decreases, the relative proportion of particles that is expected to reach the gas-exchange region of the lung increases.

Under the proposed definition of respirable crystalline silica in paragraph (b), respirable crystalline silica means airborne particles that contain quartz, cristobalite, and tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for particle-size-selective samplers specified in International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling. This definition of respirable particulate mass is intended to correspond with airborne particulate matter that is capable of entering the gas-exchange region of the lung. It provides a formula for determining the respirable fraction based on the aerodynamic diameter of the particles, and represents an international consensus that has been adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) and the European Committee for Standardization (CEN). The ISO definition is also used by the National Institute for Occupational Safety and Health (NIOSH) in its Manual of Sampling and Analytical Methods. The ISO definition of respirable particulate mass is discussed in greater detail in the Technological Feasibility chapter of the Preliminary Economic Analysis.

OSHA currently has a PEL for exposure to total quartz dust (PEL = (30 mg/m³)/(% quartz + 2) as total dust) in general industry. As with the PEL for respirable dust, the PELs for cristobalite and tridymite are one-half of the value calculated from this formula. The Agency does not have a PEL for exposure to total quartz dust for construction or shipyards. OSHA proposes to delete the PELs for exposure to total crystalline silica dust, because the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment clearly relates development

[38] OSHA regulates silica exposure in three maritime-related activities: Shipyards (29 CFR 1915.1000, Table Z), Marine Terminals (29 CFR 1917.1(a)(2)(xiii)), and Longshoring (29 CFR 1918.1(b)(9)). Marine Terminals and Longshoring incorporate by reference the toxic and hazardous substance requirements in subpart Z of the general industry standard, which includes both a particle-counting formula and a mass formula for the silica PEL (29 CFR 1910.1000, Table Z–3). Shipyards has its own subpart Z, which uses the particle-counting formula for the silica PEL. Thus, under the current scheme, Marine Terminals and Longshoring use two alternative PEL formulas, while Shipyards uses a single PEL formula. The proposal eliminates this discrepancy by adopting a single PEL (50 μg/m³) for all three maritime sectors, in addition to construction and general industry.

In this section, the Agency distinguishes between the *proposed maritime PEL* (50 μg/m³ for all three maritime sectors) and the *current shipyard PEL* (the particle-counting formula required for shipyards and construction).

of crystalline silica-related disease to respirable, rather than total, dust exposure. This view is consistent with ACGIH, which no longer has a TLV for total crystalline silica dust. NIOSH does not have a Recommended Exposure Level for total crystalline silica exposure, and neither the National Toxicology Program nor the International Agency for Research on Cancer has linked exposure to total crystalline silica dust exposure to cancer, as they have with respirable crystalline silica exposure.

OSHA proposes a new PEL of 50 μg/m³ because the Agency has preliminarily determined that occupational exposure to respirable crystalline silica at the current PEL results in a significant risk of material health impairment among exposed workers, and that compliance with the proposed standard will substantially reduce that risk. OSHA's Preliminary Quantitative Risk Assessment, summarized in Section VI of this preamble, indicates that a 45-year exposure to respirable crystalline silica at the current general industry PEL would lead to between 13 and 60 excess deaths from lung cancer, 9 deaths from silicosis, 83 deaths from all forms of non-malignant respiratory disease (including silicosis), and 39 deaths from renal disease per 1000 workers. Exposures at the current construction and shipyard PEL would result in even higher levels of risk. As discussed in Section VII of this preamble, these results clearly represent a risk of material impairment of health that is significant within the context of the ''*Benzene''* decision. *Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607 (1980). OSHA believes that lowering the PEL to 50 μg/m³ would reduce the lifetime excess risk of death per 1000 workers to between 6 and 26 deaths from lung cancer, 7 deaths from silicosis, 43 deaths from all forms of non-malignant respiratory disease (including silicosis), and 32 deaths from renal disease.

OSHA considers the level of risk remaining at the proposed PEL to be significant. However, the proposed PEL is set at the lowest level that the Agency believes to be technologically feasible. As discussed in the Technological Feasibility chapter of the Preliminary Economic Analysis and summarized in section VIII of this preamble, OSHA's analysis indicates that exposures at the proposed PEL can be measured with a reasonable degree of precision and accuracy. In addition, the analysis presented in the Technological Feasibility chapter of the Preliminary Economic Analysis makes clear that many industries and operations could not achieve an alternative PEL of 25 μg/m³ with engineering and work practice controls alone. As guided by the 1988 ''*Asbestos''* decision (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (DC Cir. 1988)), OSHA is proposing additional requirements to further reduce the remaining risk. OSHA anticipates that the ancillary provisions in the proposed standard, including requirements for regulated areas and medical surveillance, will further reduce the risk beyond the reduction that would be achieved by the proposed PEL alone. OSHA also believes that a new PEL, expressed as a gravimetric measurement of respirable crystalline silica, will improve compliance because the PEL is simple and relatively easy to understand. In comparison, the existing PELs require application of a formula to account for the crystalline silica content of the dust sampled and, in the case of the construction and shipyard PELs, a conversion of mppcf to mg/m³ as well.

OSHA believes that it is appropriate to establish a single PEL that applies to respirable quartz, cristobalite, and tridymite. As explained in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (see sections V and VI of this preamble for summaries), research indicates that certain physical factors may affect the toxicologic potency of crystalline silica. These factors include particle surface characteristics, the age of fractured surfaces of the crystal particle, the presence of impurities on particle surfaces, and coating of the particle. These factors may vary among different workplace settings, suggesting that the risk to workers exposed to a given level of respirable crystalline silica may not be equivalent in different work environments. The Agency's Quantitative Risk Assessment, summarized in section VI of this preamble, relies on studies involving a range of work environments; from study to study, workers' exposures to respirable crystalline silica varied in terms of particle age, surface impurities, and particle coatings. While the risk estimates that OSHA derived using data from different work environments are somewhat dissimilar, and these differences may be due in part to variations in particle toxicity, all of OSHA's risk estimates indicate significant risk above the proposed PEL of 50 μg/m³. Thus, while the available evidence is not sufficient to establish precise quantitative differences in risk based on these physical factors, the Agency's findings of significant risk are representative of a wide range of workplaces reflecting differences in the form of silica present, surface properties, and impurities. OSHA is therefore proposing a single PEL for respirable quartz, cristobalite, and tridymite.

OSHA currently has separate entries in 29 CFR 1910.1000 Table Z–1 for cristobalite, quartz, tripoli (as quartz), and tridymite. The proposal would present a single entry for crystalline silica, as respirable dust, with a cross reference to the new standard. As discussed above, the proposed PEL applies to quartz, cristobalite, and tridymite. Tripoli, which is extremely fine-grained crystalline silica, is covered under the proposed PEL as quartz. Comparable revisions would be made to 29 CFR 1915.1000 Table Z and 29 CFR 1926.55 Appendix A.

(d) Exposure Assessment

Paragraph (d) of the proposed standard sets forth requirements for assessing employee exposures to respirable crystalline silica. The requirements are issued pursuant to section 6(b)(7) of the OSH Act, which mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.'' 29 U.S.C. 655(b)(7).

As a general matter, monitoring of employee exposure to toxic substances is a well-recognized and accepted risk management tool. The purposes of requiring an assessment of employee exposures to respirable crystalline silica include: determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure; collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed in excess of the permissible exposure level and to ensure employees have access to accurate information about their exposure levels, as required by section 8(c)(3) of the Act. 29 U.S.C. 657(c)(3). In addition, the availability of exposure data enables PLHCPs performing medical examinations to be informed of the extent of occupational exposures.

Paragraph (d)(1) contains proposed general requirements for exposure assessment. The general requirements for assessing exposure to respirable crystalline silica in the proposed standard are similar to the requirements contained in previous OSHA substance-specific health standards. Except as provided for in the construction standard under paragraph (d)(8), paragraph (d)(1)(i) requires each employer to assess the exposure of any employees who are exposed, or may reasonably be expected to be exposed, to respirable crystalline silica at or above the action level. Under paragraph (d)(1)(ii), monitoring to determine employee exposures must represent the employee's time-weighted average exposure to airborne respirable crystalline silica over an 8-hour workday. Samples must be taken within the employee's breathing zone (*i.e.,* ''personal breathing zone samples'' or ''personal samples''), and must represent the employee's exposure without regard to the use of respiratory protection.

Employers must accurately characterize the exposure of each employee to respirable crystalline silica. In some cases, this will entail monitoring all exposed employees. In other cases, as set out in proposed paragraph (d)(1)(iii), monitoring of ''representative'' employees is sufficient. Representative exposure sampling is permitted when a number of employees perform essentially the same job on the same shift and under the same conditions. For employees engaged in similar work, it may be sufficient to monitor a fraction of these employees in order to obtain data that are ''representative'' of the remaining employees. Under the proposed standard, a representative sample must include employee(s) reasonably expected to have the highest exposures. For example, this may involve monitoring the exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Representative exposure monitoring must include at least one full-shift sample taken for each job function in each job classification, in each work area, for each shift. These samples must consist of either a single sample characteristic of the entire shift or consecutive samples taken over the length of the shift. In many cases, full-shift samples on two or more days may be necessary to adequately characterize exposure and obtain results that are representative of employees with the highest exposure for each job classification. Where employees are not performing the same job under the same conditions, representative sampling will not adequately characterize actual exposures, and individual monitoring is necessary.

Paragraph (d)(2)(i) of the proposed standard requires employers to conduct an initial exposure assessment by performing initial monitoring of any employees who are exposed, or may reasonably be expected to be exposed, to respirable crystalline silica at or above the action level. Further obligations under the standard are based on the results of this initial assessment. These may include obligations for periodic monitoring, establishment of regulated areas, implementation of control measures, and provision of medical surveillance.

The proposed standard, paragraph (d)(2)(ii), provides two exceptions to the requirement to conduct initial exposure monitoring. First, under paragraph (d)(2)(ii)(A), employers may rely on existing monitoring data to satisfy the requirement for an initial exposure assessment if employee exposures have been monitored within 12 months prior to the effective date of the standard under conditions that closely resemble those currently prevailing, and if that monitoring was conducted using one of the sampling and analytical methods specified in paragraph (d)(5)(i). This provision is intended to make it clear that employers who have recently performed appropriate employee monitoring will not be required to conduct additional monitoring to satisfy the requirement for ''initial'' monitoring. OSHA anticipates that this provision will reduce the compliance burden on employers who have already assessed exposure levels, since ''initial'' monitoring would not be required. The Agency believes the use of data obtained no more than 12 months prior to the effective date is appropriate, since samples taken more than 12 months before the effective date may not adequately represent current workplace conditions. The 12 month limit is consistent with the methylene chloride standard, 29 CFR 1910.1052.

Second, to meet the requirement for an initial exposure assessment, the employer may, under paragraph (d)(2)(ii)(B), use objective data that demonstrate that respirable crystalline silica will not be released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling. Objective data must demonstrate that the work operation or the product may not reasonably be foreseen to release respirable crystalline silica in concentrations at or above the action level under any expected conditions of use. OSHA has allowed employers to use objective data in lieu of initial monitoring in other standards, such as formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001). Any existing air monitoring data or objective data used in lieu of conducting initial monitoring must be maintained in accordance with the recordkeeping requirements in paragraph (j) of this standard.

Paragraph (d)(3) of the proposed standard requires the employer to assess employee exposure to respirable crystalline silica on a periodic basis for employees exposed at or above the action level. If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If the initial monitoring indicates employee exposure are at or above the action level, then the employer has the choice of following either a fixed schedule option or a performance option for periodic exposure assessments.

The fixed schedule option in paragraph (d)(3)(i) specifies the frequency of monitoring based on the results of the initial and subsequent monitoring. If the initial monitoring indicates employee exposures to be at or above the action level but at or below the PEL, the employer must perform periodic monitoring at least every six months. If the initial or subsequent monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring at least every three months. If periodic monitoring results indicate that employee exposures have fallen below the action level, and those results are confirmed by a second measurement taken consecutively at least seven days afterwards, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring unless, under paragraph (d)(4), changes in the workplace result in new or additional exposures.

OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring provides the employer with assurance that employees are not experiencing exposures that are higher than expected and require the use of additional control measures. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to respirable crystalline silica.

Because of the fluctuation in exposures, OSHA believes that when initial monitoring results equal or exceed the action level, but are at or below the PEL, employers should continue to monitor employees to ensure that exposures remain at or below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an accurate profile of employee exposures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA believes that the proposed frequencies of six months for subsequent periodic monitoring for exposures at or above the action level but at or below the PEL, and three months for exposures above the PEL, provide intervals that are both practical for employers and protective for employees. This belief is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048).

OSHA recognizes that monitoring can be a time-consuming, expensive endeavor and therefore offers employers the incentive of discontinuing monitoring for employees whose sampling results indicate exposures are below the action level. Periodic monitoring for a specific worker or representative group of workers can be discontinued when at least two consecutive measurements taken at least seven days apart are below the action level, because this indicates a low probability that under the prevailing conditions exposure levels exceed the PEL. Therefore the final rule provides an incentive for employers to control their employees' exposures to respirable crystalline silica to below the action level to minimize their exposure monitoring obligations while maximizing the protection of employees' health.

The performance option described in paragraph (d)(3)(ii) of the proposed standard provides employers flexibility to assess 8-hour TWA exposures on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica. OSHA recognizes that exposure monitoring may present challenges in certain instances, particularly when operations are of short duration or performed under varying environmental conditions. The performance option is intended to allow employers flexibility in performing periodic exposure assessments. Where the employer elects this option, the employer must conduct the exposure assessment prior to the time the work operation commences, and must demonstrate that employee exposures have been accurately characterized.

Previous OSHA substance-specific health standards have usually allowed employers to use objective data to characterize employee exposures, but have generally limited its use to demonstrating that exposures would be below the action level (*e.g.,* cadmium, 29 CFR 1910.1027(d)(2)(iii)). In this instance, OSHA proposes to allow reliance on the use of objective data for periodic exposure assessments, even where exposures may exceed the action level or PEL. However, the burden is on the employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to respirable crystalline silica. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that worker exposures in a given operation exceed the PEL, but do not exceed 10 times the PEL under any expected conditions, the employer may choose to rely on that data to determine his or her compliance obligations (*e.g.,* implementation of feasible engineering and work practice controls, respiratory protection, medical surveillance). OSHA's intent is to allow employers flexibility in methods used to assess employee exposures to respirable crystalline silica, but to ensure that the methods used are accurate in characterizing employee exposures. Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (j)(2) of the proposed standard.

Under paragraph (d)(4), the employer is required to reevaluate employee exposures whenever there has been a change in the production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures to respirable crystalline silica at or above the action level. For example, if an employer has conducted monitoring during an operation while using local exhaust ventilation, and the flow rate of the ventilation system is decreased, then additional monitoring would be necessary to assess employee exposures under the modified conditions. In addition, there may be other situations which can result in new or additional exposures to respirable crystalline silica which are unique to an employee's work situation. For instance, a worker may move from an open, outdoor location to an enclosed or confined space. Even though the task performed and materials used may remain constant, the changed environment could reasonably be expected to result in higher exposures to respirable crystalline silica. In order to cover those special situations, OSHA requires the employer to conduct an additional exposure assessment whenever a change may result in new or additional exposures at or above the action level. This reevaluation is necessary to ensure that the exposure assessment accurately represents existing exposure conditions. The exposure information gained from such assessments will enable the employer to take appropriate action to protect exposed employees, such as instituting additional engineering controls or providing appropriate respiratory protection. On the other hand, additional monitoring is not required simply because a change has been made, if the change is not reasonably expected to result in new or additional exposures to respirable crystalline silica at or above the action level.

Paragraph (d)(5) of the proposed standard contains specifications for the methods to be used for sampling and analysis of respirable crystalline silica samples. OSHA has typically included specifications for the accuracy of exposure monitoring methods in substance specific standards, but not the specific analytical methods to be used or the qualifications of the laboratory that analyzes the samples. The proposed standard includes details regarding the specific sampling and analytical methods to be used, as well as the qualifications of the laboratories at which the samples are analyzed. As discussed in greater detail in the Technological Feasibility section of the Preliminary Economic Analysis, the Agency has preliminarily determined that these provisions are needed to ensure that monitoring can be relied upon to accurately measure employee exposures.

Under proposed paragraph (d)(5)(i), all samples taken to satisfy the monitoring requirements of this section must be evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7. OSHA has determined based on inter-laboratory comparisons that laboratory analysis by either X-ray diffraction (XRD) or infrared (IR) spectroscopy is required to ensure the accuracy of the monitoring results in environments subject to the Agency's jurisdiction. The specified analytical methods are the XRD or IR methods for analysis of respirable crystalline silica that have been established by OSHA, NIOSH, or MSHA.

To ensure the accuracy of air sampling data relied on by employers to achieve compliance with standard, the standard requires that air samples are to be analyzed only at accredited laboratories that meet six requirements listed in paragraphs (d)(5)(ii)(A–F). The requirements were developed based on procedures implemented at laboratories that have achieved acceptable levels of accuracy and precision during a study of inter-laboratory variability. An employer who engages an independent laboratory to analyze respirable crystalline silica samples could rely on an assurance from that laboratory that the specified requirements were met. For example, the laboratory could include a statement that it complied with the requirements of the standard along with the sampling results provided to the employer.

Paragraph (d)(5)(ii)(A) requires employers to ensure that samples taken to monitor employee exposures are analyzed by a laboratory that is accredited to ANS/ISO/IEC Standard 17025 ''General requirements for the competence of testing and calibration laboratories'' (EN ISO/IEC 17025:2005) by an accrediting organization that can demonstrate compliance with the requirements of ISO/IEC 17011 ''Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies'' (EN ISO/IEC 17011:2004). ANS/ISO/IEC 17025 is a consensus standard that was developed by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and approved by the American Society for Testing and Materials (ASTM). This standard establishes criteria by which laboratories can demonstrate proficiency in conducting laboratory analysis through the implementation of quality control measures. To demonstrate competence, laboratories must implement a quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (SAE) when reporting samples. ISO/IEC 17011 establishes criteria for organizations that accredit laboratories under ISO/IEC 17025. For example, the AIHA accredits laboratories for proficiency in the analysis of crystalline silica using criteria based on the ISO 17025 and other criteria appropriate for the scope of the accreditation.

Paragraphs (d)(5)(ii)(B)–(F) contain additional requirements for laboratories that have been demonstrated to improve accuracy and reliability through inter-laboratory comparisons. The laboratory must participate in a round robin testing program with at least two other independent laboratories at least every six months. An example of a testing program that satisfies this requirement, as it is currently implemented, is the program established by AIHA Proficiency Analytical Testing Programs, LLC. The laboratory must use the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification. The laboratory must have an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error. The laboratory must characterize the sample material by identifying polymorphs of respirable crystalline silica present, identifying the presence of any interfering compounds that might affect the analysis, and making the corrections necessary in order to obtain accurate sample analysis. The laboratory must analyze quantitatively for respirable crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, and corrects for analytical interferences. The laboratory must perform routine calibration checks with standards that bracket the sample concentrations using five or more calibration standard levels to prepare calibration curves, and use instruments optimized to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL.

Under paragraph (d)(6) of the proposed rule, employers covered by the general industry standard must notify each affected employee within 15 working days of completing an exposure assessment. Notification is required whenever an exposure assessment has been conducted regardless of whether or not employee exposure exceeds the action level or PEL. In construction, employers must notify each affected employee not more than five working days after the exposure assessment has been completed. A shorter time period for notification is provided in construction in recognition of the often short duration of operations and employment in particular locations in this sector. The time allowed for notification is consistent with the harmonized notification times established for certain health standards applicable to general industry and construction in Phase II of OSHA's Standards Improvement Project. 70 FR 1112; January 5, 2005. Where the employer follows the scheduled monitoring option provided for in paragraph (d)(3)(i), the 15 (or five) day period for notification commences when monitoring results are received by the employer. For employers following the performance-oriented option under paragraph (d)(3)(ii), the period commences when the employer makes a determination of the exposure levels and the need for corresponding control measures (*i.e.,* prior to the time the work operation commences, and whenever exposures are re-evaluated).

The notification requirements in this provision apply to all employees for which an exposure assessment has been conducted, either individually or as part of a representative monitoring strategy. It includes employees who were subject to personal monitoring, as well as employees whose exposure was assessed based on other employees who were sampled, and employees whose exposures have been assessed on the basis of objective data. The employer shall either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, paragraph (d)(6)(ii) requires that whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce employee exposures to or below the PEL. The requirement to inform employees of the corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the OSH Act. 29 U.S.C. 657(c)(3).

Notifying employees of their exposures provides them with knowledge that can permit and encourage them to be more proactive in working to control their own exposures through better and safer work practices and more active participation in safety programs. As OSHA noted with respect to its Hazard Communication Standard: ''Workers provided the necessary hazard information will more fully participate in, and support, the protective measures instituted in their workplaces.'' 59 FR 6126, 6127; Feb. 9, 1994. Exposures to respirable crystalline silica below the PEL may still be hazardous, and making employees aware of such exposures may encourage them to take whatever steps they can, as individuals, to reduce their exposures as much as possible.

Paragraph (d)(7) requires the employer to provide affected employees or their designated representatives an opportunity to observe any air monitoring of employee exposure to respirable crystalline silica, whether the employer uses the fixed schedule option or the performance option. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, and assure that the observer uses such clothing or equipment.

The requirement for employers to provide employees or their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the OSH Act mandates that regulations developed under section 6 of the Act provide employees or their representatives with the opportunity to observe monitoring or measurements. 29 U.S.C. 657(c)(3). Also, section 6(b)(7) of the OSH Act states that, where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. 29 U.S.C. 655(b)(7). The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

Table 1 in paragraph (f) of the proposed construction standard lists exposure control methods for selected construction operations. As discussed with regard to paragraph (f), OSHA has preliminarily determined that the engineering controls, work practices, and respiratory protection specified for each operation in Table 1 represent appropriate and effective controls for those operations. Therefore, paragraph (d)(8) of the proposed construction standard makes an exception to the general requirement for exposure assessment where employees perform operations in Table 1 and the employer has fully implemented the controls specified for that operation. This relieves the employer of the burden of performing exposure monitoring in these situations.

Where the employer elects to implement the control measures specified in Table 1 for a given construction operation, paragraph (d)(8)(ii) requires that the employer presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL, unless the employer can demonstrate otherwise in accordance with paragraph (d) of the proposed rule. So, for example, if an employer elects to implement the controls specified in Table 1 for a given construction operation that requires a respirator and does not conduct an exposure assessment to demonstrate that exposures are below the PEL, the employer would be required to provide each employee performing that operation for 30 or more days per year with medical surveillance in accordance with paragraph (h) of the proposed rule.

(e) Regulated Areas and Access Control

Under paragraph (e)(1) in the standards, employers have two options wherever an employee's exposure to airborne concentrations of respirable silica is, or can reasonably be expected to be, in excess of the PEL: (1) the establishment of regulated areas in accordance with paragraph (e)(2); or (2) the implementation of a written access control plan in accordance with paragraph (e)(3).

The purpose of a regulated area is to ensure that the employer makes employees aware of the presence of respirable crystalline silica at levels above the PEL, and to limit exposure to as few employees as possible. The establishment of a regulated area is an effective means of minimizing exposure to employees not directly involved in operations that generate respirable crystalline silica and limiting the risk of exposure to a substance known to cause adverse health effects. Because of the potentially serious results of exposure and the need for persons entering the area to be properly protected, the number of persons given access to the area should be limited to those employees needed to perform the job. Limiting access to regulated areas also has the benefit of reducing the employer's obligation to implement other provisions of this proposed standard to as few employees as possible.

Under paragraph (e)(2)(ii), regulated areas are to be demarcated from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundary of the regulated area, and minimizes the number of employees exposed to respirable crystalline silica within the regulated area. OSHA has not specified how employers are to demarcate regulated areas. Signs, barricades, lines, or textured flooring may each be effective means of demarcating the boundaries of regulated areas. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on their knowledge of the specific conditions of their workplaces. Whatever methods are chosen to establish a regulated area, the demarcation must effectively warn employees not to enter the area unless they are authorized, and then only if they are using the proper personal protective equipment. Allowing employers to demarcate and limit access to the regulated areas as they choose is consistent with recent OSHA substance-specific health standards, such as chromium (VI) (29 CFR 1910.1026) and 1,3-butadiene (29 CFR 1910.1051).

Paragraph (e)(2)(iii) describes who may enter regulated areas. In both standards, access to regulated areas is restricted to persons required by their job duties to be present in the area, as authorized by the employer. In addition, designated employee representatives exercising the right to observe monitoring procedures are allowed to enter regulated areas. For example, employees in some workplaces may designate a union representative to observe monitoring; this person would be allowed to enter the regulated area. Persons authorized under the OSH Act, such as OSHA compliance officers, are also allowed access to regulated areas.

Under paragraph (e)(2)(iv), employers must provide each employee and designated representative who enters a regulated area with an appropriate respirator in accordance with paragraph (g), and require that the employee or designated representative uses the respirator while in the regulated area. The boundary of the regulated area indicates where respirators must be donned prior to entering, and where respirators can be doffed, or removed, upon exiting the regulated area. This provision is intended to establish a clear and consistent requirement for respirator use for all employees who enter a regulated area, regardless of the duration of their presence in the regulated area. OSHA believes this proposed requirement is simple to administer and enforce, protective of employee health, and consistent with general practice in management of regulated areas.

OSHA has proposed a requirement for use of protective clothing or other measures to limit contamination of clothing for employees working in regulated areas. Paragraph (e)(2)(v) requires that, where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer must either provide appropriate protective clothing such as coveralls or similar full-bodied clothing, or else provide a means to remove excessive silica dust from contaminated clothing when exiting the regulated area. This provision is intended to limit additional respirable crystalline exposures to employees in regulated areas that could result from disturbing the dust that has accumulated on their clothing. It is also intended to protect employees in adjacent areas from exposures that could occur if employees with grossly contaminated clothing were to carry crystalline silica dust to other areas of the workplace. The purpose of this provision is not, however, to protect employees from dermal exposure to crystalline silica, as discussed further below.

In paragraph (e)(2)(v)(A), the proposal refers to ''finely divided materials.'' When using this term, the proposed standard refers to particles with very small diameters (*i.e.,* ≤ 10 μm) such that, once airborne, the particles would be considered respirable dust. ''Gross contamination'' refers to a substantial accumulation of dust on clothing worn by an employee working in a regulated area such that movement by the individual results in the release of dust from the clothing. The provision is not intended to cover any contamination of clothing, but rather those limited circumstances where significant quantities of dust are deposited on workers' clothing. Where such conditions exist, OSHA anticipates that the dust present on workers' clothing or the release of dust from the clothing would be plainly visible.

Under paragraphs (e)(2)(v)(A)(*1*)–(*2*), the employer would have the option of providing either appropriate protective clothing, such as coveralls that can be removed upon exiting the regulated area, or any other means of removing excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica. The employer may choose the approach that works best in the circumstances found in a particular workplace. The employer may choose, for example, to provide HEPA vacuums for removal of dust from clothing. It should be noted, however, that paragraph (f)(3)(ii) (paragraph(f)(4)(ii) of the standard for construction) prohibits the use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL. Paragraph (e)(2)(v) requires contaminated clothing to be either cleaned or removed upon exiting the regulated area, in order to ensure that other areas of the workplace do not become contaminated. Cleaning or removal of contaminated clothing must take place prior to removal of respiratory protection in order to ensure that any exposure to dust released from contaminated clothing is minimized.

In other substance-specific chemical standards, OSHA has typically included requirements for provision of protective clothing, as well as associated provisions addressing removal, storage, cleaning, and replacement of protective clothing. The proposed provisions for this respirable crystalline standard are more limited than other OSHA standards, in that the requirements only apply in regulated areas, and then only when there is the potential for clothing to become grossly contaminated. The employer is also given the option of providing other means to remove dust from contaminated clothing, an alternative not generally available in other OSHA standards. OSHA has proposed these more limited provisions because the Agency has made a preliminary determination that the proposed provisions will serve to reduce employee exposures, and that additional requirements for protective clothing are not reasonably necessary and appropriate.

Most other chemicals regulated under OSHA substance-specific standards either have direct dermal effects or can contribute to overall exposures through dermal absorption. OSHA is not aware of any evidence that dermal exposure is a concern for respirable crystalline silica. Moreover, dusts containing crystalline silica are ubiquitous in many of the work environments covered by this proposed standard. Therefore, the proposed silica standard focuses on those situations where contamination of clothing has the potential to contribute significantly to employee inhalation exposures. OSHA recognizes that the ASTM standards addressing occupational exposure to respirable crystalline silica do not include requirements for protective clothing. However, the Agency believes that the proposed provisions will serve to limit employee exposures in those situations where contamination of clothing contributes to inhalation exposures. OSHA also notes that the Agency's Advisory Committee on Construction Safety and Health recommended that OSHA maintain the language on protective clothing that was included in the draft provided for review under the Small Business Regulatory Enforcement Fairness Act (SBREFA). The SBREFA draft language would have required protective clothing or a means to vacuum contaminated clothing for all employees exposed above the PEL. The Agency seeks comment on the proposed provisions for protective clothing and has included this topic in the ''Issues'' section of this preamble.

OSHA's standard addressing sanitation in general industry (29 CFR 1910.141) requires that whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing shall be provided (29 CFR 1910.141(e)). The sanitation standard also includes provisions for lavatories with running water (29 CFR 1910.141(d)(2)), and prohibits storage or consumption of food or beverages in any area exposed to a toxic material (29 CFR 1910.141(g)(2)). Similar provisions are in place for construction (29 CFR 1926.51). OSHA expects that employers will comply with the provisions of the sanitation standard when required. Thus, no additional requirements for hygiene practices are included in the proposed silica standards.

The proposed standard provides two options for employers to choose between for minimizing exposure to employees not directly involved in operations that generate respirable crystalline silica. The establishment of regulated areas under paragraph (e)(2), as described above, is the first option for exposure control in workplaces, and when fully implemented will satisfy this requirement. However, OSHA recognizes that establishing regulated areas in some workplaces can be difficult. For example, in the SBREFA review process, the question was raised as to how a regulated area could be established for a highway project, where the source of exposure could be constantly moving. Some activities covered by the general industry/maritime standard may present similar difficulties, such as hydraulic fracturing operations where exposures may occur over a large area. In recognition of the practical problems that may be encountered in such circumstances, the proposed standard includes an option in paragraph (e)(3) for establishing and implementing a written access control plan in lieu of a regulated area.

Paragraph (e)(3)(ii) in the standard sets out the requirements for a written access control plan. The plan must contain provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL. It must describe how employees will be notified of the presence and location of areas where exposures are, or can reasonably be expected to be, in excess of the PEL, and how these areas will be demarcated from the rest of the workplace. For multi-employer workplaces, the plan must identify the methods that will be used to inform other employers of the presence and the location of areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL, and any precautionary measures that need to be taken to protect employees. The written plan must contain provisions for limiting access to these areas, in order to minimize the number of employees exposed and the level of employee exposure. The plan must also describe procedures for providing each employee working in areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL with an appropriate respirator in accordance with paragraph (g) of this section. Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the access control plan must include provisions for the employer to provide either appropriate protective clothing, or a means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica. The access control plan must also include provisions for removal or cleaning of such clothing.

The employer must review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary. The written access control plan must be available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

The intent of the provision for establishing written access control plans in lieu of regulated areas is to provide employers with flexibility to adapt to the particular circumstances of their worksites while maintaining equivalent protection for employees. The Agency seeks comment on this proposed approach and has included this topic in the ''Issues'' section of this preamble.

(f) Methods of Compliance

Paragraph (f)(1) of the proposed rule establishes a hierarchy of controls which employers must use to reduce and maintain exposures to respirable crystalline silica to or below the permissible exposure limit (PEL). The proposed rule requires employers to implement engineering and work practice controls as the primary means to reduce exposure to the PEL or to the lowest feasible level above the PEL. In situations where engineering and work practice controls are not sufficient to reduce exposures to or below the PEL, employers are required to supplement these controls with respiratory protection, according to the requirements of paragraph (g) of the proposed rule. OSHA proposes to require primary reliance on engineering controls and work practices because reliance on these methods is consistent with good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with the Agency's traditional adherence to a hierarchy of preferred controls.

OSHA requires adherence to this hierarchy of controls in a number of current standards, including the Air Contaminants (29 CFR 1910.1000) and Respiratory Protection (29 CFR 1910.134) standards, as well as previous substance-specific standards. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see AFL–CIO* v. *Marshall,* 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers* v. *Marshall,* 647 F.2d 1189 (DC Cir. 1980), *cert. denied,* 453 U.S. 913 (1981) (lead standard); *ASARCO* v. *OSHA,* 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel* v. *OSHA,* 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen* v. *U.S. Dep't of Labor,* 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

The Agency understands that engineering controls: (1) Control crystalline silica-containing dust particles at the source; (2) are reliable, predictable, and provide consistent levels of protection to a large number of workers; (3) can be monitored continually and relatively easily; and (4) are not as susceptible to human error as is the use of personal protective equipment. The use of engineering controls to prevent the release of silica-containing dust particles at the source also minimizes the silica exposure of other employees in surrounding work areas, especially at construction sites, who are not directly involved in the task that is generating the dust, and may not be wearing respirators.

Respirators are another important means of protecting workers from exposure to air contaminants. However, to be effective, respirators must be individually selected; fitted and periodically refitted; conscientiously and properly worn; regularly maintained; and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides to some or all of the employees. For example, certain types of respirators require the user to be clean shaven to achieve an effective seal where the respirator contacts the worker's skin. Failure to ensure a tight seal due to the presence of facial hair compromises the effectiveness of the respirator.

Respirator effectiveness ultimately relies on the good work practices of individual employees. In contrast, the effectiveness of engineering controls does not rely so heavily on actions of individual employees. Engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace as a whole, while respirators protect only the employees who are wearing them correctly. Furthermore, engineering and work practice controls permit the employer to evaluate their effectiveness directly through air monitoring and other means. It is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. OSHA therefore considers the use of respirators to be the least satisfactory approach to exposure control.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators can impose substantial physiological burdens on employees, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and odor sensations; and isolation from the workplace environment. Job and workplace factors such as the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity can also impose physiological burdens on workers wearing respirators. These stressors may interact with respirator use to increase the physiological strain experienced by employees.

Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. These medical conditions include cardiovascular and respiratory diseases (*e.g.,* a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), reduced pulmonary function caused by other factors (*e.g.,* smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (*e.g.,* epilepsy, lower back pain), and impaired sensory function (*e.g.,* a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease.

These concerns about the burdens placed on workers by the use of respirators were acknowledged in OSHA's revision of its Respiratory Protection standard, and are the basis for the requirement that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace (63 FR 1152, Jan. 8, 1998). Although experience in industry shows that most healthy workers do not have physiological problems wearing properly chosen and fitted respirators, nonetheless common health problems can cause difficulty in breathing while an employee is wearing a respirator.

In addition, safety problems created by respirators that limit vision and communication must always be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult, annoying, and fatiguing. In addition, movement of the jaw in speaking can cause leakage, thereby reducing the efficiency of the respirator and decreasing the protection afforded the employee. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to workers and can cause workers to refrain from wearing the respirator, thereby rendering it ineffective.

While OSHA acknowledges that certain types of respirators may lessen problems associated with breathing resistance and skin discomfort, OSHA does not believe that respirators provide employees with a level of protection that is equivalent to engineering controls, regardless of the type of respirator used. It is well-recognized that certain types of respirators are superior to other types of respirators with regard to the level of protection offered, or impart other advantages. OSHA has evaluated the level of protection offered by different types of respirators in the Agency's Assigned Protection Factors rulemaking (68 FR 34036, June 6, 2003). Even in situations where engineering controls are not sufficiently effective to reduce exposure levels to or below the PEL, the reduction in exposure levels benefits workers by reducing the required protection factor of the respirator, which provides a wider range of options in the type of respirators that can be used. For example, for situations in which dust concentrations are reduced through use of engineering controls to levels that are less than ten times the PEL, employers would have the option of providing approved half-mask respirators that may be lighter and easier to use when compared with full-facepiece respirators.

In summary, engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace; respirators protect only the employees who are wearing them. In addition, the effectiveness of respiratory protection always depends on the actions of employees, while the efficacy of engineering controls is generally independent of the individual. OSHA believes that engineering controls offer more reliable and consistent protection to a greater number of workers, and are therefore preferable to respiratory protection. *Engineering controls.* The engineering controls presented in this proposal can be grouped into these main categories: (1) Substitution, (2) isolation, (3) ventilation, and (4) dust suppression. Depending on the sources of crystalline silica dust and the operations conducted, a combination of control methods may reduce silica exposure levels more effectively than a single method. *Substitution.* Substitution refers to the replacement of a toxic material with another material that reduces or eliminates the harmful exposure. OSHA considers substitution to be an ideal control measure if it replaces a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects.

The technological feasibility study (PEA, Chapter 4) indicates that employers use substitutes for crystalline silica in a variety of operations. For example, some employers use substitutes in abrasive blasting operations, repair and replacement of refractory materials, operations performed in foundries, and in the railroad transportation industry. If substitutes for crystalline silica are being used in any operation not considered in the feasibility study, OSHA is requesting relevant information that contains data supporting the effectiveness, in reducing exposure to crystalline silica, of substitutes currently being used.

Before replacing a toxic material with a substitute, it is important that employers evaluate the toxicity of the substitute materials relative to the toxicity of the original material. Substitute materials that pose significant new or additional risks to workers are not a desirable means of control. Additionally, employers must comply with Section 5(a)(1) of the OSH Act, which prohibits occupational exposure to ''recognized hazards that are causing or are likely to cause death or serious physical harm.'' 29 U.S.C. 654(a)(1). Employers must also comply with applicable standards. 29 U.S.C. 654(a)(2). For example, with respect to chemical hazards, OSHA's Hazard Communication standard imposes specific requirements for employee training, material safety data sheets, and labeling. 29 CFR 1910.1200.

While the Agency's technological feasibility analysis includes information about materials that some employers use as alternatives to silica or silica-containing materials, the Agency recognizes that these substitute materials may present health risks. OSHA does not intend to imply that any particular material is an appropriate or safe substitute for silica. *Isolation.* Isolation, by means of a process enclosure, is another effective engineering control employed to reduce exposures to crystalline silica. It refers to a physical barrier normally surrounding the source of exposure and installed to contain a toxic substance within the barrier. Isolating the source of a hazard within an enclosure restricts respirable dust from spreading throughout a workplace and exposing workers who are not directly involved in dust-generating operations.

Due to the shift from manually operated to automated processes, enclosures have become more practicable. For example, forming line operators in structural clay products manufacturing can use automation for transfer of materials, allowing conveyors and milling areas to be enclosed (OSHA SEP Inspection Report 300523396). Another example can be observed in automated refractory demolition and installation methods. A ''pusher'' system installed in coreless induction furnaces allows refractory linings to be automatically pressed out by push plates installed in furnace bottoms. A representative of Foundry Products Supplier B (2000a) estimated that total worker exposure using a pusher system would be roughly half that of traditional chipping refractory removal methods and possibly as much as 80 percent less if an enclosure (tarp) was used over the end of the furnace from which the lining is extruded. At a pottery facility, the exposure for a material handler monitoring automated equipment that is adding silica-containing raw materials to a mixer was about 66 percent lower than the exposure of a material handler manually adding the material to the mixer (OSHA SEP Inspection Report 300384435). At a structural clay industry facility inspected by OSHA, an 86-percent reduction in respirable quartz exposure readings occurred after management installed an enclosed, automated sand transfer system, despite not having optimally sealed components (PEA, Chapter 4).

Workers can also be isolated from a hazardous source when they operate heavy machinery equipped with enclosed cabs. In such cases, a cab that is well sealed and equipped with ventilation and a high-efficiency particulate air (HEPA) filter can minimize the potential for exposure from the dust created outside the cab.

MSHA (1997) recommended the following controls to maximize the effectiveness of an enclosed cab: keeping the cab interior's horizontal and vertical surfaces and areas clean and free of debris; inspecting door seals and closing mechanisms to ensure they work properly; ensuring that seals around windows, power line entries, and joints in the walls and floors of the cab are tightly sealed; ensuring that air conditioners are designed so that air comes in from the outdoors to create positive pressure and passes first through a pre-filter (those with an American Society of Heating, Refrigeration and Air-Conditioning Engineers efficiency rating of 90 percent are common) and then through a HEPA filter; and ensuring that HEPA filters are changed when they reach the manufacturer's final resistance value (MSHA, 1997).

Tractors, front-end loaders, and other mobile material-handling equipment equipped with properly enclosed, sealed, and ventilated operator cabs (*i.e.,* no leaks, positive pressure, and effective air filtration) can substantially reduce silica exposures associated with the use of such equipment. Direct-reading instruments show that fine particle (0.3 micron (μm) in size) concentrations inside operator cabs can be reduced by an average of 96 percent when cabs are clean, sealed, and have a functionally adequate filtration and pressurization system. Gravimetric sampling instruments found an average cab efficiency of about 93 percent when comparing dust levels outside and inside the cab (Cecala et al., 2005). Similarly, NIOSH investigators reported respirable dust exposure reductions of 97 and 98 percent, respectively, inside the cabin of a modified railroad ballast dumper in the railroad transportation industry (NIOSH HHE 92–0311, 2001). Other researchers have reported particle reductions inside the operator cab greater than 90 percent (Hall et al., 2002).

The Agency recognizes that although enclosed cabs have been proven to be an effective control method, they do not control exposures at the source. In many circumstances, machine operators work alongside employees who are outside the enclosed cabs and are not protected by them. As such, OSHA expects employers to apply all other feasible controls to protect those employees.

In certain situations, a process enclosure can enhance the benefits of other control methods when used simultaneously, such as when an enclosure is equipped with local exhaust ventilation (LEV). When the enclosure contains the crystalline-silica-containing dust cloud, the ventilation system is able to remove that contaminant in a more effective and timely fashion, as opposed to having it dissipate out of the ventilation system's exhaust range where there is no enclosure.

In the asphalt roofing manufacturing industry, the capture of process emissions (including dust) at the coater station is best achieved by using LEV in conjunction with an enclosure. When using a full enclosure with LEV, NIOSH recommends several practices that improve the capture efficiency of the ventilation system. OSHA believes these recommendations are beneficial whenever this control method is used in a production line. The recommendations are: (1) When process enclosures are used, the number and size of openings in the enclosure must be minimized to prevent a reduction in the capture efficiency of the ventilation system; (2) all doors should be adequately sealed and closed during operation of the line; (3) the size of the opening where the product enters and leaves the process equipment should be minimized to ensure an inward flow of air by the negative pressure within the enclosure; and (4) negative pressure must be maintained inside the enclosure to prevent leakage of process emissions into the workplace.

In the foundry industry, shakeout operators are responsible for monitoring equipment that separates the casting being produced from the molding material. This process generally involves shaking the casting, which creates dust exposure associated with respirable crystalline silica levels above the PEL. OSHA has determined that employers using this process should enclose the shakeout operations, and the most effective method to reduce exposure is installing efficient ventilation (PEA, Chapter 4).

Another example occurs in the masonry industry, when stationary saws are placed inside ventilated enclosures, and the set-up permits the operator to stand outside the enclosure. A 78-percent reduction in respirable quartz exposure was observed (from 354 μg/m^3 to 78 μg/m^3) when workers used a site-built ventilated booth outdoors as opposed to cutting with no booth (ERG–C, 2008).

Ventilation. Ventilation is another engineering control method used to minimize airborne concentrations of a contaminant by supplying or exhausting air. Two types of systems are commonly used: LEV and dilution ventilation. LEV is used to remove an air contaminant by capturing it at or near the source of emission, before the contaminant spreads throughout the workplace. Dilution ventilation allows the contaminant to spread over the work area but dilutes it by circulating large quantities of air into and out of the area. Consistent with past recommendations such as those included in the Hexavalent Chromium Rule, OSHA prefers the use of LEV systems to control airborne toxics because, if designed properly, they efficiently remove contaminants and provide for cleaner and safer work environments.

The use of effective exhaust ventilation in controlling worker exposures to crystalline silica can be illustrated by an example in the mineral processing industry. Here, the highest exposure levels obtained by OSHA were associated with bag dumping and disposal operations at a pottery clay manufacturing company (OSHA SEP Inspection Report 116178096). After the facility installed ventilated bag disposal hoppers, HEPA filters, and an enhanced LEV system, the exposure of the production workers was reduced by about 80 percent (from 221 μg/m^3 to 44 μg/m^3). A Canadian study of a rock-crushing plant also shows the effectiveness of LEV systems (Grenier, 1987); the plant, originally equipped with a general exhaust ventilation system with fabric dust collectors, processed rock containing as much as 60 percent crystalline silica. Operation of the LEV system was associated with reductions of respirable crystalline silica levels ranging from 20 to 79 percent.

LEV can be adapted to diverse sources of emissions. For workers who empty bags or mix powders that contain crystalline silica material, a portable exhaust trunk positioned near the bag-dumping hopper can capture a portion of the dust released during that activity. Additional crystalline silica exposure can occur when workers compress empty bags, an activity that can also be performed with LEV control (PEA, Chapter 4).

LEV can also be applied to operations involving portable tools. The benefits of tool-mounted LEV systems for controlling crystalline silica have been demonstrated by two NIOSH evaluations. In one evaluation, NIOSH tested two tool-mounted LEV shrouds for hand-held pneumatic chipping equipment (impact drills): one custom built, the other a commercially available model. Comparing multiple short-term exposure samples, NIOSH found that the shrouds reduced personal breathing zone (PBZ) respirable dust by 48 to 60 percent (NIOSH, 2003–EPHB 282–11a). In a separate evaluation, NIOSH collected short-term PBZ samples while workers used 25- or 30-pound jackhammers to chip concrete from inside concrete mixer truck drums. During 90- to 120-minute periods of active chipping, mean respirable silica levels decreased by 69 percent when the workers used a tool-mounted LEV shroud in these enclosed spaces (NIOSH, 2001–EPHB 247–19).

In the railroad transportation industry, dust control kits that incorporate LEV are designed to reduce the amount of ballast dust released by activities of heavy equipment during maintenance. These kits can be used with brooming equipment (mechanical sweepers) and present an alternative to relying on cab modification. Workers that operate brooming equipment have the greatest potential for elevated exposures among workers in this industry, and the Agency believes that kits would be a better control measure than cab modification because they reduce exposures at the source. Unfortunately, information regarding the effectiveness of these kits in reducing worker exposure to crystalline silica is not available from the manufacturer. OSHA is therefore requesting any relevant information that would aid the Agency in determining the potential impact of dust control kits in the railroad transportation industry (HTT, 2003; ERG–GI, 2008).

Based on the information presented in OSHA's technological feasibility analysis, many exposures in the workplace have occurred, in part, due to faulty ventilation systems and improper work practices that minimize their efficiency. In many cases, exposures can be reduced with the proper use and maintenance of ventilation systems (PEA, Chapter 4).

Dust suppression. Dust suppression methods are generally effective in controlling respirable crystalline silica dust, and they can be applied to many different operations such as material handling, rock crushing, abrasive blasting, and operation of heavy equipment (Smandych et al., 1998). Dust suppression can be accomplished by one of three systems: (1) wet dust suppression, in which a liquid or foam is applied to the surface of the dust-generating material; (2) airborne capture, in which moisture is dispensed into a dust cloud, collides with particles, and causes them to drop from the air; and (3) stabilization, which holds down dust particles by physical or chemical means (lignosulfonate, calcium chloride, and magnesium chloride are examples of stabilizers).

The most common dust suppression controls encountered during the technological feasibility review correspond to wet methods (PEA, Chapter 4). Water is generally an inexpensive and readily available resource and has been proven an efficient engineering control method to reduce exposures to airborne crystalline silica-containing dust. Dust, when wet, is less able to become or remain airborne.

In its analysis of technological feasibility, OSHA demonstrated that wet methods are effective in a wide variety of operations. For example, respirable quartz exposures for masonry cutters using stationary saws were substantially lower when wet cutting was performed instead of dry cutting (mean levels of 42 $\mu g/m^3$ versus 345 $\mu g/m^3$). Also, the exposure level for fabricators in the stone and stone products industry, who produce finished stone products from slabs, can be reduced substantially by applying wet method controls. Simcox et al. (1999) shows that exposures of fabricators at granite-handling facilities were reduced by 88 percent (490 $\mu g/m^3$ to 60 $\mu g/m^3$) when all dry-grinding tools used on granite were either replaced or modified to be water-fed.

Regarding the application of wet methods to operations involving portable equipment, recent studies show that using wet methods to control respirable dust released during chipping with hand-held equipment can reduce worker exposure substantially. NIOSH (2003–EPHB 282–11a) investigated a water-spray dust control used by construction workers breaking concrete with 60- and 90-pound jackhammers. A spray nozzle was fitted to the body of the chipping tool, and a fine mist was directed at the breaking point. Compared with uncontrolled pavement breaking, PBZ respirable dust concentrations were between 72 and 90 percent lower when the water spray was used. Williams and Sam (1999) also reported that a water-spray nozzle mounted on a hand-held pneumatic chipper decreased respirable dust by approximately 70 percent in the worker's breathing zone.

Washing aggregate also reduces the amount of fine particulate matter generated during subsequent use or handling. Burgess (1995) reports that the use of washed sand, from which a substantial portion of the fine particles have been removed, results in respirable crystalline silica exposures that are generally lower than when sand is not pre-washed. Plinke et al. (1992) also report that increasing moisture content decreases the amount of dust generated and state that it is often most efficient to apply water sprays to material before it reaches a transfer point so that the dust has time to absorb water before being disturbed.

For the railroad transportation industry, OSHA is recommending that ballast be washed before it is loaded into hopper cars. Ballast wetted at the supplier's site might dry prior to reaching the dumping site (NIOSH HETA–92–0311, 2001). In this circumstance, applying an additional layer of blanketing foam or other sealing chemical suppressant on top of the rail car can reduce water evaporation and provide an additional type of dust suppression (ECS, 2007). *Work practice controls.* Work practice controls systematically modify how workers perform an operation, and often involve workers' use of engineering controls. For crystalline silica exposures, OSHA's technological feasibility analysis shows that work practice controls are generally applied complementary to engineering controls, to adjust the way a task is performed. For work practice controls to be most effective, it is essential that workers and supervisors are fully aware of the exposures generated by relevant workplace activities and the impact of the engineering controls installed. Work practice controls are preferred over the use of personal protective equipment since work practice controls can address the exposure of silica at the source of emissions, thus protecting nearby workers.

Work practice controls can enhance the effects of engineering controls. For example, to ensure that LEV is working effectively, a worker would position it so that it captures the full range of dust created, thus minimizing silica exposures.

A good example of adequate work practice controls can be found in ready-mixed concrete operations. Exposure data available to OSHA indicate that all truck drivers or other workers who remove residual concrete inside ready-mixed truck mixer drums have silica exposures greater than the proposed PEL, with some exposures approaching 10,000 μg/m³. The Agency recommends wet methods and ventilation as appropriate engineering controls and also gives priority to performing a particular work practice that can reduce exposures. Specifically, this work practice involves the timely rinsing of drum mixers. One report (Williams and Sam, 1999) concluded that heavy build-up of concrete inside truck mixer drums results in higher concentrations of worker exposure to crystalline silica during cleaning because a greater amount of time is required to remove the build-up. Rinsing the drum with water immediately after each load helps minimize build-up and the resulting dust exposure. The same cleaning methods are used, such as water pressure and scraping, independently of how often rinsing is performed. However, by rinsing the tanks with more frequency, the employer is modifying the nature of the cleaning operation because less concrete will be present, and thus less respirable dust created, during each cleaning.

Another example of good work practices can be observed in the porcelain enameling industry. One facility stated that porcelain applicators can ensure that they are making optimal use of LEV by avoiding positioning themselves between the enamel spray and the ventilation system. For large items, workers can use a turntable support to rotate the item so that it can be sprayed on all sides while the worker maintains the spray direction pointing into the ventilated booth (Porcelain Industries, 2004a).

Combined control methods. Exposure documentation obtained by the Agency demonstrates that for many operations, a combination of engineering and work practice controls reduces silica exposure levels more effectively than a single control method. The following examples represent preliminary feasibility conclusions for several industries.

In the dental equipment and supplies industry, OSHA has found that employers can limit the exposure of most workers to 50 μg/m³ or less by implementing a combination of engineering controls, including improving ventilation systems (at bag-dumping stations, weighing and mixing equipment, and packaging machinery) and designing workstations to minimize spills, and encouraging work practices that maximize the effect of engineering controls. One facility that implemented these controls reduced median exposure levels by 80 percent, from 160 μg/m³ to 32 μg/m³ (OSHA SEP Inspection Report 122252281).

Based on the exposure profile for the rock and concrete drilling industry, construction sites have already achieved compliance with the proposed PEL for about half of the workers operating drilling rigs through a combination of controls, including wet dust suppression methods, shrouds, and hoods connected to dust extraction equipment, and management of dust collection dump points (PEA, Chapter 4).

An example from a routine cupola relining in the ferrous foundry industry also demonstrates the benefit of a combination of controls. Samples taken before and after additional controls were installed reflect a 90-percent reduction of the median worker exposures (OSHA SEP Inspection Report 122209679). The modifications included using refractory material with reduced silica and greater moisture content, improving equipment and materials to reduce malfunction and task duration, wetting refractory material before removal, and assigning a consistent team of trained workers to the task.

Burmeister (2001) also reported on the benefits of multiple controls on another refractory relining activity. Initially, a full-shift crystalline silica result of 2.74 times the current calculated PEL was obtained while a worker chipped away the old refractory lining and then mixed the replacement refractory material. The foundry responded by holding a training meeting and seeking worker input on abatement actions, implementing a water control system to reduce dust generated during the pneumatic chipping process, purchasing chisel retainers that eliminated the need for workers to reach into the ladle during chipping, and purchasing a vacuum to remove dust and chipped material from the ladle. With these changes in place, a consultant found that exposure was reduced to 87 percent of the calculated PEL, representing a 70-percent reduction in worker exposure.

These examples illustrate the importance and value of maintaining an effective set of engineering controls alongside work practice controls to optimize silica exposure reduction. The proposed requirements are consistent with ASTM E 1132–06 and ASTM E 2625–09, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these standards has explicit requirements for methods of compliance. These requirements include use of properly designed engineering controls such as ventilation or other dust suppression methods and enclosed workstations such as control booths and equipment cabs; requirements for maintenance and evaluation of engineering controls; and implementation of certain work practices such as not working in areas where visible dust is generated from respirable crystalline silica containing materials without use of respiratory protection. OSHA has elected to propose a performance standard for general industry in which particular engineering and work practice controls are not specified. Instead, the standard requires that employers use engineering and work practice controls to achieve the PEL. In this case the use of properly designed, maintained, and regularly inspected engineering controls is implied by the ongoing ability of the employer to achieve the PEL. The national consensus standard for construction (ASTM E 2625–09) includes task-based control strategies for situations where exposures are known from empirical data. This approach is consistent with the alternative approach for construction operations in paragraph (f)(2) described below.

Paragraph (f)(2) of the proposed rule provides an alternative approach to achieve compliance with paragraph (f), Methods of Compliance, for construction operations. Under this paragraph, employers that implement the specific engineering controls, work practices, and, if required, respiratory protection described in Table 1 (please refer to paragraph (f) of the proposed rule) are considered to be in compliance with the requirements for engineering and work practice controls in paragraph (f)(1) of the proposed rule. An advantage of complying with Table 1 is that the employer need not make a determination of the hierarchy of controls, because the table incorporates that determination for each job operation listed. Furthermore, proposed paragraph (d)(8)(i) specifies that if an employer chooses to follow Table 1, the employer need not conduct exposure assessments required by paragraph (d) of the proposed rule. Rather, for those operations in Table 1 where respirator use is required, proposed paragraph (d)(8)(ii) requires employers to presume that workers engaged in those operations are exposed above the PEL; in those cases, the employer would be required to comply with all provisions of the standard that apply to exposures above the PEL except for monitoring. For instance, when Table 1 requires workers to use respirators, the employer relying on Table 1 must: establish a regulated area or access control plan pursuant to proposed paragraph (e); comply with the cleaning methods provisions in proposed paragraph (f)(4); comply with the prohibition of employee rotation as specified in proposed paragraph (f)(5); establish a respiratory protection program pursuant to proposed paragraph (g)(2); and provide medical surveillance pursuant to paragraph (h) if workers are exposed for 30 or more days per year.

Table 1 was developed using recommendations made by small entity representatives through the Small Business Regulatory Enforcement Fairness Act (SBREFA) process. The SBREFA panel asked OSHA to develop a provision that detailed what specific controls to use for each construction operation covered by the rule in order to achieve compliance with paragraph (f)(1). Additionally, the Advisory Committee for Construction Safety and Health (ACCSH) has recommended that OSHA proceed with the development of Table 1. The table provides a list of 13 construction operations that expose workers to respirable crystalline silica as well as control strategies (engineering controls, work practices, and respirators) that reduce those exposures.

In developing control strategies for each of the 13 construction operations in Table 1, OSHA relied upon information from a variety of sources including scientific literature, NIOSH reports, OSHA site visits, and compliance case files (SEP reports). For several of the listed operations and controls, the Agency requests additional information from the public that will allow the Agency to determine whether the operations, corresponding control strategies, and conditions of use should be modified or removed from Table 1. OSHA also requests comment on the degree of specificity used for engineering and work practice controls for tasks identified in Table 1, including maintenance requirements.

Table 1 implements a novel approach for OSHA. The Agency believes that the table will provide significant benefits to workers and employers by ensuring that workers are adequately protected, providing specific approaches for complying with paragraph (f) requirements, and reducing the monitoring and sampling burden.

The table divides operations according to duration into ''less than or equal to'' four-hours-per-day tasks and ''greater than'' four-hours-per-day tasks. The Agency recognizes that some activities do not last a full work shift, and often some activities are performed for half-shifts or less. The duration of a task influences the extent of worker exposure and the selection of appropriate control strategies. OSHA followed its hierarchy of controls to develop these control strategies. Respiratory protection has been included in Table 1 for operations in which the specified engineering and work practice controls may not maintain worker exposures at or below the proposed PEL for all workers and at all times. Employers who comply with Table 1 need not assess employee exposures as otherwise required under paragraph (f), and workers in these circumstances will not have the benefit of conventional exposure data to characterize their exposures. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the Agency is proposing to require respiratory protection in situations where overexposures may occur even with the implementation of engineering and work practice controls. The Agency is requesting comments regarding the appropriateness of the use and selection of respirators in several operations.

If an employer anticipates that a worker will perform a single operation listed in Table 1 for four hours or less during a single shift, then the employer must ensure that the worker uses whichever respirator is specified in the ''≤4 hr/day'' column in the table. For example, if an employer anticipates that a worker will operate a stationary masonry saw for four hours or less, and the worker does not perform any other operation listed in Table 1, the worker would not be required to use respiratory protection because there is no respirator requirement for that entry in the table.

If an employer anticipates that a worker will perform a single operation listed in Table 1 for more than four hours, then the employer must ensure that the worker uses the respirator specified in the ''>4 hr/day'' column in Table 1 for the entire duration of the operation. For example, if an employer anticipates that a worker will operate a stationary masonry saw for more than four hours, and the worker does not perform any other operation listed in Table 1, the worker would be required to wear a half-mask respirator for the entire duration of the operation (refer to Table 1).

Additionally, for workers who engage in two or more discrete operations from Table 1 for a total of more than four hours during a single work shift, employers that rely on Table 1 must provide, for the entire duration of each operation performed, the respirator specified in the ''>4 hr/day'' column for that operation, even if the duration of that operation is less than four hours. If no respirator is specified for an operation in the ''>4 hr/day'' column, then respirator use would not be required for that part of a worker's shift.

For example, if a worker is using a stationary masonry saw for three hours and engages in tuckpointing for two hours in the same the shift, the employer would be required to ensure that the worker uses a half-mask respirator for the three hours engaged in sawing, and a tight-fitting, full-face PAPR for the two hours engaged in tuckpointing work. In other words, if a worker uses a stationary saw and engages in a tuckpointing operation for a total of more than four hours in a single work shift, the worker would be required to use a half-mask respirator for the entire time he or she operates the stationary saw and a tight-fitting, full-face PAPR for the tuckpointing work, regardless of how long each task is performed.

The following paragraphs describe the engineering controls, work practices and respirators selected for each of the operations listed in Table 1. In addition, the Agency describes the information that it has relied upon to develop the control strategies.

For most control strategies in the table, OSHA is proposing to require additional specifications to ensure that the strategies are effective. The most frequently required additional specifications are:

• Changing water frequently when using water delivery systems, to avoid silt build-up in the water and prevent wet slurry from accumulating and drying. This prevents silica from becoming airborne when the water becomes aerosolized by the rotation of equipment or when the water dries and leaves residual respirable silica-containing dust.

• Operating equipment such that no visible dust is emitted from the process. Visible dust may be an indication that the controls are not operating effectively. The absence of visible dust does not necessarily indicate that workers are protected, but visible dust is a clear indication of a potential problem.

• Providing sufficient ventilation to prevent build-up of visible airborne dust when working indoors or in enclosed spaces. Stagnant air in an enclosed environment may increase worker exposures.

• Ensuring that saw blades and abrasive discs are not excessively worn. Excessive wear tends to increase respirable silica emissions and worker exposures.

• Using dust collectors according to manufacturers' specifications. Manufacturer specifications are often based on operation-specific designs.

Use of stationary masonry saws. For workers operating stationary masonry saws, OSHA is proposing to require that the saws be equipped with an integrated water delivery system that is operated and maintained to minimize dust emissions. The exposure profile created for this operation shows that cutting with wet methods offers a clear reduction to exposures, as opposed to dry cutting with no controls or with a mix of administrative or other engineering controls. The Agency obtained 12 samples for workers dry cutting with no engineering controls, 9 samples for workers dry cutting with a mix of controls, and 7 samples for workers operating the saws with water at the point of operation. The mean, median, and range values were all lower for workers using wet methods:

• Median of 33 μg/m³ (a 34-percent reduction from dry cutting and 63-percent reduction from dry cutting with some controls).

• Mean of 42 μg/m³ (an 88-percent reduction from dry cutting and 80-percent reduction from dry cutting with some controls).

• A maximum value of 93 μg/m³, as opposed to a maximum value of 2,005 μg/m³ for dry cutting, and 824 μg/m³ for dry cutting with some controls.

The Agency concludes, based on this information and the analysis discussed in the exposure profile for this operation (PEA, Chapter 4), that the water delivery system specified in Table 1 consistently reduces worker exposures to or below the proposed PEL when the saws are used for four hours or less. As a result, respiratory protection is not included in the control strategy for these operations. OSHA believes that, even when workers operate stationary masonry saws for eight hours, wet methods will reduce 8-hour exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, the maximum TWA value measured for a stationary masonry saw operator is 93 μg/m³, equivalent to a 4-hr exposure of 47 μg/m³ (*see* Chapter 4 of the PEA). Thus, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who use stationary masonry saws for more than four hours.

Use of hand-operated grinders. The table provides employers with two different control strategies.

Option 1: Use water-fed grinders that continuously feed water to the cutting surface, operated and maintained to minimize dust emissions. For operations lasting less than four hours, OSHA is proposing that respirators will not be required. For operations lasting four hours or more, OSHA is proposing the use of half-mask respirators to ensure workers are protected.

For its technological feasibility analysis, OSHA did not obtain any sample results where wet grinding occurred. Information available to the Agency suggests that overexposures still occur when using wet methods and that there are additional challenges such as limited applications. OSHA has decided to include this control strategy based on the use of water systems on similar tools used in the cut stone and stone products manufacturing industry that have shown a reduction of exposures to well below 100 μg/m³ (OSHA 3362–05). The Agency believes that similar reductions can be achieved for grinding operations because the amount of respirable dust produced in these operations is comparable. Based on this inference, OSHA believes that wet methods alone will provide sufficient protection for shifts lasting four hours or less, and is proposing to require the use of half-mask respirators with an APF of 10 for shifts lasting more than four hours.

The Agency requests comments and additional information regarding wet grinding and the adequacy of this control strategy.

Option 2: Use hand-operated grinders with commercially available shrouds and dust collection systems operated and maintained to minimize dust emission. The dust collector must be equipped with a HEPA filter and must operate at 25 cubic feet per minute (cfm) or greater airflow per inch of blade diameter. OSHA is proposing to require the use of half-mask respirators at all times, for outdoor and indoor operations alike, to ensure workers are protected.

OSHA's exposure profile for this operation contains 13 samples associated with the use of LEV. Two of these samples are associated with outdoor activities (40 μg/m³ and 53 μg/m³), and 11 samples are associated with indoor work (a range of 12 μg/m³ to 208 μg/m³). Overall, exposure samples show that outdoor exposures are lower than indoor exposures. The mean, median, and range values for these operations are:

• Median of 47 μg/m³ for outdoor operations with LEV, and 107 μg/m³ for indoor operations with LEV.

• Mean of 46 μg/m³ for outdoor operations with LEV, and 96 μg/m³ for indoor operations with LEV.

• A maximum value of 53 μg/m³ for outdoor operations with LEV, and 208 μg/m³ for indoor operations with LEV.

These values suggest that workers would sometimes achieve levels below the proposed PEL with LEV. However, the Agency recognizes that elevated exposures occur even with the use of LEV in these operations based on the fact that 8 out of 13 samples collected exceed the proposed PEL, with 6 samples ranging from 100 μg/m³ to 250 μg/m³. Based on this information, OSHA is proposing that employers apply the engineering control specified and equip workers with half-mask respirators at all times. It is important to note that OSHA has preliminarily concluded that the LEV control outlined in the table will not reduce and maintain exposures to the proposed PEL for all workers. However, these controls will reduce exposures within the APF of 10 offered by half-mask respirators. The Agency seeks additional information to confirm that the control strategy (including the use of half-mask respirators) listed in the table will reduce workers' exposure to or below the PEL.

Tuckpointing. OSHA is proposing to require employers to equip grinding tools with commercially available shrouds and dust collection systems, operated and maintained to minimize dust emissions. The grinder must be operated flush against the working surface, with grinding operations performed against the natural rotation of the blade (*i.e.,* mortar debris must be directed into the exhaust). Employers would be required to use vacuums that provide at least 80 cubic feet per minute (cfm) to 85 cfm airflow through the shroud and include filters that are at least 99 percent efficient.

Recent dust control efforts for tuckpointing have focused on using a dust collection hood, or shroud, which encloses most of the grinding blade. It is used with a vacuum cleaner system that exhausts air from these hood systems and collects dust and debris. These shroud and vacuum combinations capture substantial amounts of debris, but air monitoring results summarized in OSHA's exposure profile for this operation show that even with this control in place, silica exposures often continue to exceed 100 μg/m³, with many of the results exceeding 250 μg/m³.

The highest exposure obtained for outdoor work with LEV (6,196 μg/m³), and many other exposures, suggest that there are circumstances in which the protection factor offered by a PAPR will be needed to reduce worker exposure to below 50 μg/m³. OSHA is aware that some exposures may be effectively controlled with the LEV system and a respirator with an APF of 10, but is proposing to require the use of the LEV system with respirators that provide an APF of 50 to ensure that the control strategy protects those workers with extremely elevated exposures. Based on this information, OSHA estimates that a substantial percentage of the worker population will need respiratory protection in the form of a powered air-purifying respirator (PAPR) with a loose-fitting helmet or a negative-pressure full-facepiece respirator regardless of task duration.

Furthermore, OSHA is stressing the importance of sufficient air circulation in enclosed or indoor environments to maximize the effect of the control strategy outlined. Elevated results are reported for tuckpointers in operations performed in areas with limited air circulation (including indoors). As such, the Agency is proposing to require employers to provide for ventilation to prevent the accumulation of airborne dust during operations performed in enclosed spaces, in addition to requiring equipment to be operated so that no visible dust is emitted from the process.

Use of jackhammers and other impact drillers. The table provides employers with two different control strategies.

Option 1: Apply a continuous stream or spray of water at the point of operation.

Results in OSHA's exposure profile show that the wet methods attempted in the five samples obtained were not effective at all in reducing exposures; in fact, the statistical values are higher than those under baseline conditions. Based on the best available information, OSHA believes that no single wet method was applied effectively and consistently throughout these operations, and the data obtained for wet methods is reflective of that inconsistency (ERG–C, 2008; PEA, Chapter 4). The three highest results for the samples corresponding to wet methods show respirable dust levels higher than the mean respirable dust value for comparable uncontrolled operations, indicating that the wet method control was not applied effectively, as it was not reducing total respirable dust levels.

Conversely, however, OSHA has obtained information from individual employers, NIOSH, and an informal consortium of New Jersey organizations interested in controlling silica during road construction activities that have all tested wet dust suppression methods with chipping and breaking equipment. The results of these tests indicate that wet dust suppression is effective in reducing respirable crystalline silica exposures.

The Agency obtained a reading for a jackhammer operator breaking concrete outdoors, where a continuous stream of water was directed at the breaking point. When compared with the median value in the exposure profile for outdoor and uncontrolled operations, the result represents a 77-percent exposure reduction in respirable quartz (OSHA SEP Inspection Report 106719750).

NIOSH provided similar findings when it completed several studies evaluating water spray devices to suppress dust created while workers used chipping and breaking equipment. Compared with concentrations during uncontrolled pavement breaking, respirable dust results were between 72 and 90 percent lower when the water spray was used (NIOSH EPHB–282–11a, 2003). A follow-up NIOSH study reported a similar 77-percent reduction in silica concentration during 60-minute trials with a solid cone nozzle producing water mist (NIOSH EPHB–282–11c–2, 2004).

Two other findings also show that water spray systems are effective in reducing respirable dust concentrations. Williams and Sam (1999) evaluated a shop-built water spray system attached to a hand-held pneumatic chipper used by a worker removing hardened concrete from inside a mixing truck drum. Although this task is not typically performed by construction workers, it represents a worst-case environment (in a confined space or indoors) for construction concrete chipping and breaking jobs. Water spray decreased respirable dust by about 70 percent in the worker's breathing zone, again showing that a water spray system offers substantial reduction in silica-containing dust generated.

Additionally, the New Jersey Laborers Health and Safety Fund, NIOSH, and the New Jersey Department of Health and Senior Services have collaborated in publishing simple instructions for developing spray equipment for jackhammers. A design tested in New Jersey involving a double water spray—one on each side of the breaker blade—reduced peak dust concentrations by approximately 90 percent compared with the peak concentration measured for uncontrolled breaking (Hoffer, 2007; NIOSH 2008–127, 2008; NJDHSS, no date).

OSHA believes that, even when workers perform impact drilling for eight hours, wet methods will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who perform impact drilling for more than four hours.

OSHA notes that applying the lowest exposure reduction of the values reported in the studies would reduce the highest range of exposures to within an APF of 10 provided by a half-mask respirator and, thus, consistently and adequately protect workers for a full shift. Additionally, for impact drilling operations lasting four hours or less, OSHA is proposing to allow workers to use water delivery systems without the use of respiratory protection, as the Agency believes that this dust suppression method alone will provide consistent, sufficient protection. OSHA is requesting comments and additional information that address the appropriateness of this control strategy.

It is important to mention that the highest exposures in the profile were obtained during indoor work, with a maximum value of 3,059 μg/m³. OSHA believes that these elevated results are in part due to poor air circulation in enclosed environments. The Agency believes that it is particularly important to ensure adequate air circulation during indoor work, so that airborne dust does not accumulate and contribute to higher exposures. As such, the proposed Table 1 includes a specification that directs employers to provide adequate ventilation during indoor work so as to prevent build-up of visible airborne dust.

Option 2: Use tool-mounted shroud and HEPA-filtered dust collection system, operated and maintained to minimize dust emissions.

Based on available information, LEV systems are also able to effectively reduce respirable airborne silica dust. NIOSH tested two tool-mounted LEV shrouds during work with chipping hammers intended for chipping vertical concrete surfaces. Comparing multiple short–term samples, NIOSH found that the shrouds reduced respirable dust by 48 to 60 percent (Echt et al., 2003; NIOSH EPHB 282–11a, 2003). In a separate evaluation, NIOSH showed that this type of LEV system controls dust equally well for smaller chipping equipment. Mean silica levels decreased 69 percent when the workers used a tool-mounted LEV shroud in enclosed spaces (NIOSH EPHB 247–19, 2001). In this study, a combination of LEV and general exhaust ventilation provided additional dust control, resulting in a 78 percent decrease in silica readings. This finding further supports OSHA's proposal to ensure that additional ventilation is provided during indoor work to prevent the accumulation of airborne dust.

OSHA believes that, even when workers perform impact drilling for eight hours, these controls will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who perform impact drilling for more than four hours. OSHA believes that that LEV systems will reduce the highest range of airborne respirable silica concentrations (in the exposure profile) to within an APF provided by a half-mask respirator for operations lasting a full shift. For operations lasting four hours or less, OSHA is proposing to allow workers to use the shroud and HEPA vacuum system without respirators, as the Agency believes that this control alone will provide consistent, sufficient protection. The highest exposure values were obtained during indoor work, and the Agency is proposing that employers provide appropriate air circulation in order to maximize the effectiveness of the proposed control strategy.

Use of rotary hammers or drills (except overhead use). Table 1 requires that drills be equipped with a hood or cowl and a HEPA-filtered dust collector, operated and maintained to minimize dust emissions. The proposed control strategy also directs employers to eliminate blowing or dry sweeping drilling debris from working surfaces.

Of the 14 respirable quartz readings summarized in the exposure profile for this operation, seven represent hole drilling indoors under uncontrolled conditions. The highest reading obtained for workers in this job category, 286 μg/m³, was recorded for a worker drilling holes with a ¾-inch bit in the floor of a concrete parking garage where air circulation was poor (Lofgren, 1993). The other seven results, most of which were collected during outdoor drilling of brick and rock, are also spread over a wide range but tend to be lower than (less than half) the indoor values, with a maximum of 130 μg/m³ (NIOSH HETA–2003–0275–2926).

Shepherd et al. (2009) found that compared with uncontrolled drilling, using dust collection cowls connected to portable vacuums reduced silica exposures by 91 to 98 percent. The researchers tested four commercially available combinations of two cowls and two vacuums indoors. Although investigators note that results might vary for different drill types and drill bit sizes, OSHA estimates that the proposed control strategy will consistently maintain exposures below the proposed PEL even during periods of intense drilling. OSHA is proposing that employers ensure that dust collectors are used according to manufacturer's specifications in order to maximize dust reduction, and that the vacuums used are appropriate for the nature of the task to provide the adequate suction rate.

Based on the percent reductions documented in the Shepherd study, using a drill equipped with a hood or cowl and a HEPA-filtered dust collector reduces the highest exposure reading in the profile to levels below the proposed PEL. As such, OSHA anticipates that this control strategy alone will reduce or maintain exposures below 50 μg/m³ for workers using rotary hammers or drills for durations up to 8 hours (excluding overhead work).

Hallin (1983) indicates a greater potential for overexposure during overhead drilling. A test run reported that drilling for 120 minutes into a concrete ceiling with a percussion drill and a hammer drill gave respirable quartz concentrations of 1,740 μg/m³ and 720 μg/m³, respectively. The percussion drill was later fitted with a dust collector, and a 180-minute test run produced a value of 80 μg/m³. This type of drilling was not addressed in the Shepherd report; therefore, OSHA cannot confirm that using the cowl and dust collector would sufficiently protect workers. The Agency has no additional information that would indicate that exposures resulting from overhead work might be consistently reduced below the proposed PEL. Based on these factors, OSHA is proposing to exclude this particular task from Table 1. Furthermore, the Agency concurs with the recommendation made by Hallin (1983) that overhead drilling is ergonomically stressful and should not be performed consistently for a full shift.

Use of vehicle-mounted earth-drilling rigs for rock and concrete. Although the equipment used for each type of drilling varies, OSHA has addressed workers using drilling rigs of all types for rock, earth, and concrete together in the same section of the technological feasibility analysis. This is because the worker activities have much in common and the general methods of silica control are also similar. Specifically, these workers control the vehicle-mounted or rig-based drills from more than an arm's length from the drill bit(s). They also perform certain intermittent tasks near the drilling point, such as fine-tuning the bit position, moving debris away from the drill hole, and working directly or indirectly with compressed air to blow debris from deep within the holes.

When drilling rock, workers typically use rigs that are vertically oriented and equipped to produce a deep hole through the addition of bit extensions. This operation generally involves the drilling of one hole for an extended period of time, with minimal interruption. In contrast, when drilling concrete, workers often use rigs that consist of an array of one or many drills fixed to the maneuverable arm of a construction vehicle or purpose-built mobile machine, which permits the operator to produce a series of precisely spaced mid-size holes. This process requires operators to frequently start and stop the drilling process.

Based on these differences, OSHA is proposing to require separate additional specifications for rock drilling and concrete drilling, with both types of drilling using LEV at the point of operation and water to suppress dust from the dust collector exhaust. The Agency estimates that these control strategies will protect workers from overexposures, as consistent use of dust extraction shrouds or hoods reduces worker exposures at both rock and concrete drilling sites. The control strategies for rock drilling and concrete drilling are discussed below.

OHSA recognizes that enclosed cabs are available for concrete and rock drilling rigs, and operators who work in enclosed cabs will experience exposure reductions (ERG–C, 2008). OSHA is proposing that respirators will not be required for these operators, regardless of length of shift. Although cabs benefit operators while in the cab, they do not affect workers' exposure during positioning or hole-tending activities. To effectively control exposures of all workers involved in the operation, employers must apply the engineering controls outlined in Table 1 to manage exposure sources.

In order for the cabs to work optimally, OSHA is proposing that cabs have the following characteristics: (1) Air conditioning and positive pressure is maintained at all times, (2) incoming air is filtered through a pre-filter and a HEPA filter, (3) the cab interior is maintained as free as practicable from settled dust, and (4) door seals and closing mechanisms are working properly. Cecala et al. (2005) studied modifications designed to lower respirable dust levels in an enclosed cab on a 20-year-old surface drill at a silica sand operation. The study found that effective filtration and cab integrity (*e.g.,* new gaskets, sealed cracks to maintain a positive-pressure environment) are the two key components necessary for dust control in an enclosed cab. OSHA believes that the cab specifications outlined will promote proper air filtration and cab integrity. *Rock drilling.* The control strategy for this operation specifies the use of a dust collection system around the drill bits as well as a water spray to wet the exhaust, operated and maintained to minimize dust emissions. Respiratory protection will not be required unless work is being performed under the shroud at the point of operation.

Modern shroud designs, which are commercially available, have been shown to consistently achieve respirable dust reductions (Reed et al., 2008; Drilling Rig Manufacturer A, 2009). Moreover, NIOSH has quantified reductions in dust emissions associated with LEV used with a dowel drilling machine. For these concrete drilling rigs, NIOSH found that close-capture dust collection hoods reduced respirable dust concentrations by 89 percent compared with drilling without the hoods. OSHA believes that similar reductions are achievable on rock drilling machines equipped with dust collection systems, as the quantity of airborne dust generated is comparable for both types of drilling.

Additionally, OSHA believes it is important for employers to use dust collectors in accordance with manufacturer specifications. NIOSH has shown that dust collector efficiency is improved when workers use an appropriate suction rate, maintain the shroud in good condition, and keep the shroud positioned to fully enclose the bit as it enters the hole. The Agency is also proposing to include a visible dust specification, which employers can use as a tool to identify potential problems with controls.

Due to the nature of rock drilling, workers often have to work under the shroud to clear tailings and dust from in or around the hole. When this work is performed, workers do not receive the same amount of protection from the control system, and they have to work closer to the point of dust generation. As such, OSHA believes that workers will experience higher exposures. In order to ensure that workers are adequately protected, OSHA is proposing that employers ensure that workers use half-mask respirators when working under shrouds at the point of operation. The Agency is seeking comments and additional information that address the appropriateness of this specification.

The Agency is also proposing to require employers to use a water delivery system to suppress dust emanating from the dust collector exhaust. Research shows that in the vicinity of a rock-drilling rig, dust collector dumping operations are the largest single contributor of airborne respirable particulates. Maksimovic and Page has shown that in rock-drilling rigs, this source contributed 38 percent of the respirable dust emissions, while the deck shroud contributed 24 percent (reported in Reed et al., 2008). NIOSH reports that modifications (involving water delivery systems) to dust collector discharge areas have reduced exposures from this source by 63 to 89 percent, which means that overall airborne particles can be reduced by at least 24 percent.

For example, a result of 54 μg/m³ was obtained for a worker who operated a rig equipped with a vacuum dust collection system. This overexposure resulted from the lack of dust suppression while dust was being dumped from the second filter of the collector—not from the actual drilling operation. Information from the inspection shows that the collector had two filters, and water was used to suppress dust from dumping operations from the first filter only (OSHA SEP Inspection Report 300340908). OSHA believes that adding a water delivery system to suppress dust from the discharge at the second filter would have resulted in a lower exposure. This result indicates that the control strategy outlined, when applied effectively, will adequately protect workers during a full work shift without requiring respirators.

Concrete drilling. The control strategy for this operation specifies the use of a dust collection system around the drill bits as well as a low-flow water spray to wet the exhaust, operated and maintained to minimize dust emissions.

NIOSH has recommended several modifications to typical concrete drilling rig dust collection equipment (NIOSH EPHB 334–11a, 2008). OSHA anticipates that these upgrades will help ensure that optimal dust collection efficiency is maintained over time. As such, the Agency is proposing to require these additional specifications:

- Using smooth ducts and maintaining a duct transport velocity of 4,000 feet per minute to prevent duct clogging
- Providing duct clean-out points to aid in duct maintenance and prevent clogging, and
- Installing pressure gauges across dust collection filters so the operator can clean or change the filter at an appropriate time

Furthermore, Minnich 2009 demonstrated that a dust plume originated from the point of operation after a worker activated a drill and LEV system simultaneously. OSHA believes that the overall collection efficiency would be improved by activating the exhaust suction prior to initiating drilling and deactivating it after the drill bit stops rotating, and is proposing to require that employers operate their LEV systems in this manner.

Similar to rock drilling, OSHA believes it is important for employers to use dust collectors in accordance with manufacturer specifications based on the NIOSH findings described in the rock drilling section. The Agency is also proposing to include a visible dust specification for concrete drilling, as it will help employers identify potential problems with controls.

While the available data do not specifically characterize the effects of controls for concrete drilling rigs in all circumstances, the Agency has substantial data on the effectiveness of controls in rock drilling, and based on the similarities of these operations (refer to PEA, Chapter 4). OSHA estimates that these controls provide similar protection in concrete drilling and are able to reduce and maintain exposures to the proposed PEL most of the time. Implementing the additional specifications listed in Table 1 will also provide protection. However, OSHA cannot rule out the possibility that silica exposures will occasionally exceed the PEL, when workers perform this operation outside of an enclosed cab for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who perform concrete drilling outside of an enclosed cab for more than four hours.

OSHA seeks additional data to describe the efficacy of the controls described above in reducing exposures for workers who operate concrete drilling rigs. Additionally, the Agency is requesting comments and additional information regarding the adequacy of the control strategy described in Table 1.

Use of drivable milling machines. Table 1 proposes that employers use water-fed systems that deliver water continuously at the cut point to suppress dust, operated and maintained to minimize dust emissions. The table also includes a visible dust provision, which helps employers identify potential problems with the control strategy. The Agency is proposing that no respiratory protection will be required for shifts lasting four hours or less, and that half-mask respirators be used for operations lasting more than four hours.

Some machines are equipped with water delivery systems that are specifically designed to suppress dust. However, water is more generally applied to the cutting drum of milling machines to prevent mechanical overheating. OSHA believes that improved water delivery systems will help reduce exposures for the worker population that remains overexposed. For example, a study conducted in the Netherlands with a novel dust emission suppression system shows the potential impact of a water-delivery system (combined with an additive) as a control strategy. Compared with a standard milling machine that uses cooling water only on the blade, the use of an aerosolized water and foam dust suppression system reduced the mean exposure for drivers and tenders by about 95 and 98 percent, respectively (Van Rooij and Klaasse, 2007). The same study also reported results for the use of aerosolized water without the additive. Aerosolized water alone provided a substantial benefit, reducing the mean exposure for drivers and tenders by about 88 and 84 percent, respectively.

Based on the exposure profile, OSHA anticipates that the vast majority of workers already experience exposure levels below the proposed PEL for operations lasting four hours or less. With water delivery systems designed specifically to suppress dust, the Agency expects that workers will be consistently protected against respirable crystalline silica exposures. With this control strategy in place, OSHA believes that respirators will not be necessary for operations lasting four hours or less.

OSHA believes that, even when workers operate drivable milling machines for eight hours, water delivery systems will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, OSHA cannot rule out the possibility that silica exposures will occasionally exceed the PEL under certain circumstances, when workers operate these machines for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who operate drivable milling machines for more than four hours.

Based on the range of exposures in the exposure profile (*see* Chapter 4 of the PEA), OSHA anticipates that properly designed water delivery systems to suppress dust and half-mask respirators will provide sufficient protection (the highest exposure measured for any worker is 340 μg/m³, with no dust suppression controls in place). As such, the Agency believes that using wet methods and half-mask respirators is a control strategy that consistently protects workers for operations lasting more than four hours.

Walking behind milling machines. For walk-behind milling machines, Table 1 provides workers with two options for controlling exposures to crystalline silica.

The first option directs employers to use water-fed equipment that continuously feeds water to the cutting surface to suppress dust, operated and maintained to minimize dust emissions.

The exposure profile for this operation contains six samples, with the highest exposure being the only one above the proposed PEL. The two lowest exposures in the profile (both are 12 μg/m³) were obtained for workers that used water-fed machines (ERG–C, 2008), indicating that the wet method effectively controls silica exposure.

If the highest exposure in the profile is weighted for four hours, the adjusted exposure is less than the proposed PEL. Thus, OSHA anticipates that for operations lasting four hours or less, workers will be consistently protected by wet methods.

OSHA believes that, even when workers operate walk-behind milling machines for eight hours, water delivery systems will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers operate these machines for more than four hours, silica exposures may occasionally exceed the PEL under certain circumstances. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who operate walk-behind milling machines for more than four hours. The Agency believes the use of a half-mask respirator will ensure consistent worker protection.

The second option is to use tools equipped with commercially available shrouds and dust collection systems, which are operated and maintained to minimize dust emissions. The dust collector must be equipped with a HEPA filter and must operate at an adequate airflow to minimize airborne visible dust. Additionally, the dust collector must be used in accordance with manufacturer specifications including the airflow rate.

To date OSHA has not been able to quantify the effectiveness of currently available LEV in controlling respirable quartz levels associated with walk-behind milling operations; however, OSHA believes that evidence from similar construction tasks supports its value for workers performing milling. OSHA believes that the LEV dust control option will work at least as effectively for milling machines as for tuckpointing grinders. Although the tuckpointers using LEV still experienced a geometric mean result of 60 μg/m³, walk-behind milling machine operators have the advantages of lower uncontrolled exposure levels, greater distance between the tool and their breathing zone, and equipment that is self-supporting (the milling drum enclosure more easily kept sealed against the floor), rather than hand-held. Therefore, an LEV system with an appropriately sized vacuum will similarly reduce most walk-behind milling machine operator exposures.

Based on the exposure samples analyzed, OSHA estimates that most workers already have exposures under the proposed PEL for operations lasting four hours or less, and is not proposing to require respirator use.

For operations lasting more than four hours, the Agency believes that at most the workers will be protected by using LEV alone, as described Chapter 4 of the PEA. However, the Agency cannot rule out the possibility that workers who operate these machines for more than four hours will occasionally receive exposures that exceed the PEL, under certain circumstances. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who operate drivable milling machines for more than four hours.

Use of hand-held masonry saws. Table 1 provides employers with two different control strategies. Along with the engineering controls listed in Table 1, OSHA is proposing the additional specifications that will aid employers in using the engineering controls optimally.

- Prevent wet slurry from accumulating and drying. The accumulation and drying of wet slurry can lead to settled dust that is easily resuspended and can contribute to worker exposures.
- Ensure that the equipment is operated such that no visible dust is emitted from the process. When controls are functioning properly, visible dust should not be observed. This specification will help employers identify potential problems with the control strategy.
- When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. Proper airflow prevents air from becoming stagnant and dilutes the levels of respirable crystalline silica.
- Use dust collectors in accordance with manufacturer specifications. Selecting the correct system and flow rates will consistently reduce exposure.

Option 1: Employers use a water-fed system that delivers water continuously at the cut point, operated and maintained to minimize dust emissions.

The exposure profile for outdoor cutting with wet methods shows that for shift lasting four hours or less, workers consistently experience exposure below the proposed PEL. The Agency believes that wet methods alone will provide protection and is proposing to require that employers apply the wet method control without the use of respiratory protection.

OSHA believes that, even when workers operate hand-held masonry saws outdoors for eight hours, wet methods will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, on the basis of the two highest sample results in the exposure profile (*see* Chapter 4 of the PEA), the Agency believes that silica exposures may occasionally exceed the PEL under certain circumstances, when workers perform these operations outdoors for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who operate hand-held masonry saws outdoors for more than four hours.

Similarly, the highest readings in the exposure profile for operations using wet methods indoors suggest that silica exposures may sometimes exceed the PEL even for workers who perform these activities for less than four hours. Therefore, the Agency is proposing to require the use of a half-mask respirator with an APF of 10 for workers who operate hand-held masonry saws indoors or within a partially sheltered area, regardless of task duration.

Option 2: Use a saw equipped with a local exhaust dust collection system, operated and maintained to minimize dust emissions.

While the exposure profile does not contain any samples for work involving hand-held masonry saws conducted with LEV in place, several studies have shown the general effectiveness of LEV to reduce silica concentrations. Meeker et al. (2009) shows that LEV can reduce respirable silica exposures to levels near 100 μg/m³ during short-term periods of active cutting outdoors. Since most workers cut intermittently even during times of active cutting (*e.g.,* 10 or 20 seconds using the saw followed by a longer period—up to several minutes—of measuring and moving materials or equipment), 8-hour TWA values are likely to be considerably lower (Flanagan et al., 2001). However, OSHA has not been able to confirm that LEV methods offer the same degree of exposure reduction to workers currently experiencing more modest, but still elevated, exposures.

Thus, the Agency cannot rule out the possibility that silica exposures will sometimes exceed the PEL, even when workers perform these operations for less than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who use LEV to control exposures while operating hand-held masonry saws outdoors.

While OSHA does not have exposure data to specifically describe indoor operations using LEV controls, Thorpe et al. (1999) and Meeker et al. (2009) reported exposure reductions by 88 to 93 percent for outdoor operation. OSHA believes that these exposure reductions would be similar in indoor operations because there is no added general ventilation in these environments such as natural air circulation outdoors and airborne dust tends to become more stagnant indoors. Given the very high uncontrolled exposures documented in the Chapter 4 of the PEA, even the projected exposure reduction from LEV does not rule out the possibility that exposures above 500 μg/m³ will occasionally occur under certain circumstances. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide full face-piece respirators to workers who operate hand-held masonry saws indoors or in partially enclosed areas, regardless of task duration.

Use of portable walk-behind or drivable masonry saws. Table 1 directs employers to use a water-fed system that delivers water continuously at the cut point, operated and maintained to minimize dust emissions with the following specifications:

- Prevent wet slurry from accumulating and drying. The accumulation and drying of wet slurry can lead to settled dust that is easily resuspended and can contribute to worker exposures.
- Ensure that the equipment is operated such that no visible dust is emitted from the process. When controls are functioning properly, visible dust should not be observed. This specification will help employers identify potential problems with the control strategy.
- When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. Proper airflow prevents air from becoming stagnant and dilutes the levels of respirable crystalline silica.

The exposure profile for this operation shows that of the 12 respirable silica results associated with wet-cutting concrete outdoors using walk-behind saws, only 1 measurement exceeded the proposed PEL, while 8 were less than the LOD. These results suggest that for outdoor operations, water-fed walk-behind saws provide adequate protection for workers.

Based on this information, OSHA believes that by using the wet method controls as specified, workers will be provided with consistent, adequate protection and is proposing to not require the use of a respirator when working outdoors.

Flanagan et al. (2001) reported higher 8-hour TWA respirable silica levels for operators and their assistants who used water-fed walk-behind saws indoors for most of their shift (the worst-case conditions resulted in four 8-hour TWA values between 130 μg/m³ and 710 μg/m³). The author noted that factors such as inadequate ventilation or poor wet vacuum capture efficiency contributed to the higher indoor respirable silica levels.

By applying the additional specifications and engineering controls outlined in Table 1, OSHA believes that indoor exposures will be reduced to levels where respiratory protection with an APF of 10 will provide adequate protection. OSHA is proposing to require the use of a half-mask respirator for tasks of all duration when working indoors or in partially shielded areas.

Rock crushing. Table 1 provides employers with two control strategies to protect employees not working in enclosed cabs. Both options (described below) require the use of half-mask respirators regardless of task duration.

For equipment operators working within an enclosed cab, OSHA is proposing that cabs have the following characteristics: (1) air conditioning and positive pressure is maintained at all times, (2) incoming air is filtered through a pre-filter and a HEPA filter, (3) the cab is maintained as free as practicable from settled dust, and (4) door seals and closing mechanisms are working properly. Cecala et al. (2005) studied modifications designed to lower respirable dust levels in an enclosed cab on a 20-year-old surface drill at a silica sand operation. The study found that effective filtration and cab integrity (*e.g.,* new gaskets, sealed cracks to maintain a positive-pressure environment) are the two key components necessary for dust control in an enclosed cab. OSHA believes that the cab specifications outlined will promote proper air filtration and cab integrity. OSHA is proposing that operators who work in enclosed cabs meeting these specifications will not be required to wear respirators.

OSHA is also proposing an additional specification, which requires that dust control equipment be operated such that no visible dust is emitted from the process. When controls are functioning properly visible dust should not be observed, and this specification will help employers identify potential problems with the control strategy.

Option 1: Use wet methods or dust suppressants.

Based on available information, OSHA believes that water or other dust suppression is used during rock crushing activities but that the application may be either inconsistent or inefficient (ERG–C, 2008). However, the Agency has obtained other information that shows that dust suppression systems have been effective in reducing exposures. For example, a silica result of 54 μg/m³ was obtained for the operator of a stationary crusher at a concrete recycling facility using fine mist water spray (ERG-concr-crush-A, 2001). It is important to note that this machine operator spent much of the shift in a poorly sealed booth directly over the crusher, but left the booth frequently to tend to other activities. Due to the lack of information regarding the workshift, OSHA cannot asses the full extent of the impact that water dust control had on the worker exposure.

Gottesfeld et al. (2008) summarized a study conducted in India at several rock crushing facilities. The study demonstrates that after water spray installation, 70 percent of the breathing zone and area results were less than 50 μg/m³, and just one result exceeded 250 μg/m³. In contrast, before the water mist system was added, all results exceeded 50 μg/m³, and 60 percent were greater than 250 μg/m³, a condition similar to those in OSHA's exposure profile for workers associated with rock crushing machines. OSHA acknowledges that worksites may different in the United States, but believes that similar exposure reductions can be achieved with rock crushers in the U.S.

Wet dust suppression options that can offer a substantial benefit include water expanded into foam, steam, compressed water fog, and wetting agents (surfactants added to water to reduce surface tension) (ERG–C, 2008). OSHA believes that when used properly and consistently, these dust suppressants could reduce silica concentrations at least as effectively as and more consistently than directional water mist spray alone, achieving exposure reductions of 70- to 90-percent.

OSHA acknowledges that available data is inadequate to indicate whether water mist or other dust suppressants alone are sufficient to reduce these workers' silica exposures below 50 μg/m³. However, based on the best available information, OSHA estimates that by consistently using properly directed water mist spray (or other dust suppression methods), the vast majority of rock crushers can achieve consistent results in a range that is compatible with use of a half-mask respirator with an APF of 10.

Option 2: Use local exhaust ventilation systems at feed hoppers and along conveyor belts, operated and maintained to minimize dust emissions.

Information available to OSHA indicates that LEV is capable of reducing silica concentrations. For example, Ellis Drewitt (1997) reported a reading of 300 μg/m³ for a worker in Australia using a dust extraction system (when compared to the uncontrolled mean of 798 μg/m³ in the exposure profile).

Another international report from Iran describes a site where workers used rock crushers with LEV (Bahrami et al., 2008). The report demonstrated that LEV systems were associated with a marked decrease in respirable dust. Among 20 personal silica samples for process workers and hopper-filling workers associated with rock crushers after LEV was installed, the mean PBZ respirable quartz results were 190 μg/m³ to 400 μg/m³, respectively. It is important to note that the bulk samples of this rock contained 85 to 97 percent quartz. The Agency believes that these levels would likely have been lower if the rock had not been nearly pure silica. If the respirable dust sample had contained the more typical 12 percent silica on the filter, OSHA estimates that the corresponding airborne silica concentrations would have been 92 μg/m³ to 178 μg/m³. The Agency recognizes that exposures may be higher than this estimate, but does not possess additional information that more clearly characterizes worker exposures with the implementation of LEV controls.

As such, OSHA believes that a fully functioning LEV system can control exposures for most workers to within the protection factor offered by a half-mask respirator. OSHA is aware of the difficulties present in applying LEV to rock crushing operations, and is requesting additional information addressing the appropriateness and practicability of this control strategy.

Drywall finishing (with silica-containing material). The main source of exposure for drywall finishing operations occurs when dust is generated while sanding dried, silica-containing joint compound (ERG–C, 2008). Fourteen of the 15 samples collected for the exposure profile for this operation show exposures below the proposed PEL, with 7 samples below the LOD. The one overexposure, 72 μg/m³, was obtained for a worker performing overhead sanding (NIOSH HETA 94–0078–2660, 1997). Table 1 provides employers with two control strategies; neither option requires the use of respirators.

Option 1: Use pole sander or hand sander equipped with a dust collection system, operated and maintained to minimize dust emissions. Use dust collectors according to manufacturer specifications.

NIOSH tested the effectiveness of five off-the-shelf ventilated sanding systems during drywall finishing: three designed to control dust during pole sanding, and two to control dust during hand sanding. Total dust area sample results revealed that all five systems were effective for reducing total airborne dust by at least 80 percent, ranging up to 97 percent (NIOSH ECTB–208–11a, 1995). This effectiveness was confirmed in a study by Young-Corbett and Nussbaum (2009a), which found that using a ventilated sander during drywall sanding reduced respirable dust in the PBZ by 88 percent compared with a block sander (no controls).

Silica exposures were not measured explicitly in these studies, but OSHA estimates that based on the reported total dust reductions, even the highest exposure in the profile can be reduced to levels below the proposed PEL. The Agency reasonably estimates that this control strategy will adequately protect workers without the need for respirators.

Although ventilated sanders are the most effective exposure control option for silica-containing joint compound, and they offer indirect benefits to workers and managers (NIOSH Appl. Occup. Environ. Hyg. 15, 2000), there are many perceived barriers to their adoption in the workplace (NIOSH ECTB–208–11a, 1995; Young-Corbett and Nussbaum, 2009b). Hence, Option 2 is provided to employers as a way to comply with paragraph (f)(1) of the proposed rule.

Option 2: Use wet methods to smooth or sand the drywall seam.

Young-Corbett and Nussbaum (2009a) found that a wet sponge sander reduces respirable dust in the PBZ by 60 percent compared with a block sander (no controls). Other wet methods include wiping a clean, damp sponge over the still-damp joint compound to smooth the seam and rinsing the sponge in a bucket of water as it becomes loaded with compound, or wetting dried joint compound with a spray bottle and sanding with sandpaper (NIOSH ECTB–208–11a, 1995).

Again, silica exposures were not explicitly measured in the Young-Corbett and Nussbaum study. Based on the reported respirable dust reduction, however, OSHA estimates that even the highest exposure in the profile can be reduced and maintained below the proposed PEL. As such, the Agency believes that using wet methods will offer adequate protection without requiring respirators.

Use of heavy equipment during earthmoving. The exposure profile for this operation ranges from 11 μg/m³ to 170 μg/m³, with about 13 percent of the values exceeding the proposed PEL. Table 1 provides for the option of operating equipment from enclosed cabs to control exposures. It specifies that workers operate equipment from within enclosed cabs that have the following characteristics:

- Air conditioning with positive pressure maintained at all times;
- Incoming air filtered through a pre-filter and a HEPA filter;
- Having the cab be as free as practicable from settled dust; and
- Door seals and closing mechanisms that are working properly.

Based on published research, ERG–C (2008) found that effective enclosed cabs generally have these four characteristics, and extensive literature suggests that the exposure reductions can range from 80 to more than 90 percent in this industry (Rappaport et al., 2003; Pannel and Grogin, 2000; Cecala et al., 2005; NIOSH 528, 2007).

The exposure profile shows that of the 19 results for which the status of the cab was established, 17 were for unenclosed cabs. Both of the operations involving enclosed cabs had exposures of about 12 μg/m³, while operations involving several of the unenclosed cabs were associated with worker exposures greater than 50 μg/m³ and up to 87 μg/m³. This information allows OSHA to determine that operators using enclosed cabs as proposed by this option will effectively protect workers. Respiratory protection will not be needed.

Concerning abrasive blasting operations, paragraph (f)(2) of the general industry/maritime proposed rule and paragraph (f)(3) of the construction proposed rule direct employers to comply with the requirements of 29 CFR 1910.94 (Ventilation), and for shipyard employment 29 CFR 1915.34 (Mechanical Paint Removers) and 29 CFR part 1915, subpart I (Personal protective equipment). These standards apply to abrasive blasting operations that involve crystalline silica-containing blasting agents or substrates. Employers should consult these other standards to ensure that they comply with personal protective equipment, ventilation, and other operation-specific safety requirements.

OSHA is aware of current and past efforts of domestic and international entities to ban silica sand as an abrasive blasting agent. Given the best available information to date, the Agency does not believe that banning silica sand is the most appropriate course of action, as OSHA has concerns about potential harmful exposures to other substances that the alternatives might introduce in a workplace. Further toxicity data are necessary before the Agency can reach any conclusions about the hazards of these substitutes relative to the hazards of silica. The following paragraphs provide further information regarding abrasive blasting agents.

The annual use of silica sand for abrasive blasting operations has decreased from about 1.5 million tons in 1996 to 0.5 million tons in 2007, which roughly represents a 67-percent reduction (Greskevitch and Symlal, 2009)). This reduction might reflect the use of alternative blasting media, the increased use of high-pressure water-jetting techniques, and the use of cleaning techniques that do not require open sand blasting. Several substitutes for silica sand are available for abrasive blasting operations, and current data indicate that the abrasive products with the highest U.S consumptions are: coal slag, copper slag, nickel slag, garnet, staurolite, olivine, steel grit, and crushed glass.

A NIOSH study compared the short-term pulmonary toxicity of several abrasive blasting agents (NIOSH, Blasting Abrasives: Health Hazard Comparison, 2001). This study reported that specular hematite and steel grit presented less short-term in vivo toxicity and respirable dust exposure in comparison to blast sand. Overall, crushed glass, nickel glass, staurolite, garnet, and copper slag were similar to blast sand in both categories. Coal slag and olivine showed more short-term in vivo toxicity than blast sand and were reported as similar to blast sand regarding respirable dust exposure. This study did not examine long-term hazards or non-lung effects.

Hubbs et al. (2005) mention that of the nine alternatives to silica sand, NIOSH has identified five of them–coal slag, steel grit, specular hematite, garnet, and crushed glass–for further testing to determine the relative potential of these agents to induce lung fibrosis in rats exposed to whole-body inhalation. These abrasive materials were selected for study based on high production, number of workers exposed, short-term intratracheal instillation [39] relative toxicity studies, and inadequacy of available current data (Hubbs et al., 2005). The National Toxicology Program is performing long-term (39 weeks), in

[39] Intratracheal instillation is an alternative to inhalation exposure studies. Test material is delivered in a bolus aqueous solution to the lung through a syringe and ball-tipped needle into the tracheal (Phalen, 1984).

vivo, toxicity studies of these abrasive blasting agents.

Additionally, another NIOSH study (KTA-Tator, 1998) monitored exposures to several OSHA-regulated toxic substances that were created by the use of silica sand and substitute abrasive blasting materials. The study showed that several substitutes create exposures or potential exposures to various OSHA-regulated substances. The study showed exposures or potential exposures to: (1) Arsenic, when using steel grit, nickel slag, copper slag and coal slag; (2) beryllium, when using garnet, copper slag, and coal slag; (3) cadmium, when using nickel slag and copper slag; (4) chromium, when using steel grit, nickel slag, and copper slag; and (5) lead, when using copper slag.

Since these studies were performed, the Agency has learned that specular hematite is not being manufactured in the United States due to patent-owner specification. In addition, the elevated cost of steel has a substantial impact on the availability to some employers to use substitutes like steel grit and steel shot.

Elevated silica exposures have been found during the use of low-silica abrasives as well, even when blasting on non-silica substrates. For example, the use of the blasting media Starblast XL (staurolite), which contains less than 1 percent quartz according to its manufacturer, resulted in a respirable quartz level of 1,580 μg/m³. The area sample (369-minute) was taken inside a containment structure erected around two steel tanks. The elevated exposure occurred because the high levels of abrasive generated during blasting in containment overwhelmed the ventilation system (NIOSH, 1993b). This example emphasizes the impact of control methods in specific working environments. In order to reduce elevated exposures closer to the PEL in situations like these, employers should examine the full spectrum of available controls, and how these controls perform in specific working conditions. Employers may find, for example, that they would have to provide supplementary respiratory protection to adequately protect workers that perform abrasive blasting in areas where the accumulation of dust remains stagnant (*e.g.* confined spaces) in a worker's personal breathing zone and overwhelms exhaust ventilation systems. Other engineering controls the same employer may consider would be wet and/or automated blasting.

Paragraph (f)(4) of the construction proposed rule, and Paragraph (f)(3) of the general industry/maritime proposed rule specify that accumulations of crystalline silica in the work place are to be cleaned by HEPA-filter vacuums or wet methods. This section also prohibits the use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica. These requirements are being proposed to help regulate the amount of crystalline silica that becomes airborne, thus providing effective control of worker exposure. The requirements of paragraph (f)(4) are consistent with general industry standards for hazardous substances, such as cadmium and asbestos, which specify that work surfaces be cleaned wherever possible by vacuuming with a HEPA-filtered vacuum. Much documentation shows that moving from compressed air blowing and dry sweeping to HEPA-filtered vacuums and the application of wet methods effectively reduces worker exposures during cleaning activities (PEA, Chapter 4).

A study of Finnish construction workers compared the respirable crystalline silica levels during dry sweeping or when using alternative cleaning methods. Compared with dry sweeping, estimated worker exposures were about three times lower when workers used wet sweeping and five times lower when they used vacuums. In the asphalt roofing industry, NIOSH and OSHA both recommended vacuuming with HEPA-filtered vacuums as a method to minimize exposure. In five Health Hazard Evaluations at asphalt roofing manufacturing facilities, NIOSH recommended vacuuming as opposed to compressed air for cleaning dust out of equipment (ERG–GI, 2008).

OSHA's technological feasibility analysis points to numerous other instances where cleaning methods are of particular importance in reducing worker exposures. In the rock and concrete drilling industry, OSHA recommends that workers use HEPA-filtered vacuums instead of compressed air to clean holes in order to reduce–or even eliminate–substantial exposure during hole-tending activities. In the porcelain enameling industry, a facility has used a vacuum fitted with a HEPA filter for all cleaning. To minimize generating airborne dust, workers avoid dry sweeping and only shovel or scrape materials that are damp (Porcelain Industries, 2004a; 2004b).

For millers using portable or mobile equipment, Echt et al. (2002) reported that cleanup is critical for engineering controls to work most effectively for walk-behind milling machines. The study reported that airborne dust increased when a scabbler passed over previously milled areas. It was recommended that debris be cleaned using a HEPA-filtered vacuum prior to making a second pass over an area. This step enhanced LEV capability and prevented debris from being re-suspended.

Several facilities have adopted the recommended cleaning methods as part as an overall effort to reduce exposures. For example, in the jewelry and dental laboratories industries, additional controls to reduce exposures below the proposed PEL include LEV, wet methods, substitution, isolation, work practices, and improved housekeeping such as the use of a HEPA-filtered vacuum for cleaning operations. These examples again also show the value of applying a combination of controls to reduce exposures below the PEL.

Paragraph (f)(5) of the construction proposed rule, and Paragraph (f)(4) of the general industry/maritime proposed rule specify that the employer must not rotate workers to different jobs to achieve compliance with the PEL. OSHA proposes this prohibition because silica is a carcinogen, and the Agency assumes that any level of exposure to a carcinogen places a worker at risk. With worker rotation, the population of exposed workers increases.

This provision is not a general prohibition of worker rotation wherever workers are exposed to crystalline silica. It is only intended to restrict its use as a compliance method for the proposed PEL; worker rotation may be used as deemed appropriate by the employer in activities such as to provide cross-training and to allow workers to alternate physically demanding operations with less arduous ones. This same provision was used for the asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101), hexavalent chromium (29 CR 1910.1026), butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1926.60) OSHA standards.

(g) Respiratory Protection

During situations where employee exposure to respirable crystalline silica is expected to be above the PEL, paragraph (g) requires the employer to protect employees' health through the use of respirators. Specifically, in areas where exposures exceed the PEL, respirators are required during the installation and implementation of engineering and work practice controls; during work operations where engineering and work practice controls are not feasible; when all feasible engineering and work practice controls have been implemented but are not sufficient to reduce exposure to or below the PEL; and during periods when any employee is in a regulated area or an area for which an access control plan indicates that use of respirators is necessary.

These limitations on the required use of respirators are generally consistent with other OSHA health standards, such as methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). They reflect the Agency's determination, discussed above in section (f) (Methods of compliance), that respirators are inherently less reliable than engineering and work practice controls in reducing employee exposure to respirable crystalline silica. OSHA has therefore proposed to allow reliance on respirators only in certain designated situations.

Proposed paragraph (g)(1)(i) requires the use of respirators in areas where exposures exceed the PEL during periods when engineering and/or work practice controls are being installed or implemented. OSHA recognizes that respirators may be essential to achieve the PEL under these circumstances. During these times, employees would have to use respirators for temporary protection until the hierarchy of controls has been implemented.

OSHA anticipates that engineering controls will be in place by the start-up date specified in paragraph (k)(2)(ii) of the construction and the general industry/maritime proposed standards. The Agency realizes that in some cases employers may commence operations, install new or modified equipment, or make other workplace changes that result in new or additional exposures to crystalline silica after the effective date as defined by paragraph (k)(1). In these cases, a reasonable amount of time may be needed before appropriate engineering controls can be installed and proper work practices implemented. When employee exposures exceed the PEL in these situations, employers must provide their employees with respiratory protection and require its use.

Proposed paragraph (g)(1)(ii) requires respiratory protection in areas where exposures exceed the PEL during work operations in which engineering and work practice controls are not feasible. OSHA anticipates that there will be few situations where no feasible engineering or work practice controls are available to limit employee exposure to respirable crystalline silica. In situations where respirators are used as the sole form of protection to achieve compliance with the PEL, the employer will be required to demonstrate that engineering and work practice controls are not feasible.

Proposed paragraph (g)(1)(iii) requires the use of respirators for supplemental protection in circumstances where feasible engineering and work practice controls alone cannot reduce exposure levels to or below the PEL. Examples include some tuckpointing, jackhammering, and abrasive blasting operations. The employer must always install and implement engineering and work practice controls whenever they are feasible, even if these controls alone cannot reduce employee exposures to or below the PEL. Whenever respirators are used as supplemental protection to achieve compliance with the PEL, the burden is on the employer to demonstrate that engineering and work practice controls alone are insufficient to achieve the PEL.

Under proposed paragraph (g)(1)(iv), employers have to provide respiratory protection during periods when any employee is in a regulated area. Proposed paragraph (e) in the general industry/maritime standard and proposed paragraph (e)(2) in the construction standard would require employers to establish a regulated area wherever an unprotected employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL. OSHA has included the provision requiring respirator use in regulated areas in the proposed rule to make it clear that each employee is required to wear a respirator when present in a regulated area, regardless of the duration of time spent in the area. Because of the potentially serious results of exposure, OSHA believes that this provision is necessary and appropriate because it would have the effect of limiting unnecessary exposures to employees who enter regulated areas, even if they are only in a regulated area for a short period of time.

Proposed paragraph (e)(3) gives the employer the option of developing an access control plan as a means of minimizing exposures to employees not directly involved in operations that generate respirable crystalline silica. This written access control plan would serve as an alternative to setting up regulated areas under paragraph (e)(2). An access control plan must include procedures for providing and requiring the use of respiratory protection in areas where exposures can reasonably be expected to exceed the PEL. Proposed paragraph (g)(1)(v) of the construction standard requires the use of respiratory protection when specified by the access control plan.

Proposed paragraph (g)(2) requires the employer to implement a comprehensive respiratory protection program in accordance with the Agency's respiratory protection standard (29 CFR 1910.134) whenever respirators are used to comply with the requirements of the respirable crystalline silica standard. The respiratory protection program is designed to ensure that respirators are properly used in the workplace and are effective in protecting workers. The program must include: procedures for selecting respirators for use in the workplace; medical evaluation of employees required to use respirators; fit-testing procedures for tight-fitting respirators; procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; procedures and schedules for maintaining respirators; procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of employees in respiratory hazards to which they might be exposed and the proper use of respirators; and procedures for evaluating the effectiveness of the program.

In 2006, OSHA revised the respiratory protection standard (29 CFR 1910.134) to include assigned protection factors (71 FR 50122, Aug. 24, 2006). Assigned protection factor means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a respiratory protection program under 29 CFR 1910.134. The revised standard includes a table (Table 1—Assigned Protection Factors) that employers must use to select sufficiently protective respirators for employees who may be exposed to respirable crystalline silica.

Proposed paragraph (g)(3) for the construction standard indicates that, for the operations listed in Table 1 in paragraph (f) of the construction standard, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with the requirements for selection of respirators in 29 CFR 1910.134 paragraph (d). Paragraph (d) of 29 CFR 1910.134 requires the employer to evaluate respiratory hazards in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. There is no need for the employer to complete this process when following Table 1, because Table 1 specifies the type of respirator required for a particular operation.

(h) Medical Surveillance

In paragraph (h)(1)(i), OSHA proposes to require that each employer covered by this rule make medical surveillance available at no cost, and at a reasonable time and place, for all employees who are occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

There is a general consensus that medical surveillance is necessary for employees exposed to respirable crystalline silica. Medical surveillance for workers exposed to respirable crystalline silica is included in standards developed by ASTM International (ASTM, 2006; 2009) as well as in guidance or recommendations developed by the American College of Occupational and Environmental Medicine (ACOEM, 2006), the Building and Construction Trades Department, AFL–CIO (BCTD, 2001), the Industrial Minerals Association/Mine Safety and Health Administration (IMA/MSHA, 2008), National Industrial Sand Association (NISA, 2010), and the World Health Organization (WHO, 1996). Although the specific recommendations made by these organizations differ in certain respects, they are consistent in indicating that regular medical examinations are appropriate for workers with substantial exposures to respirable crystalline silica.

The purposes of medical surveillance for respirable crystalline silica include the following: to determine, where reasonably possible, if an individual can be exposed to respirable crystalline silica in his or her workplace without experiencing adverse health effects; to identify respirable crystalline silica-related adverse health effects so that appropriate intervention measures can be taken; and to determine the employee's fitness to use personal protective equipment such as respirators. The proposal is consistent with Section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)) which requires that, where appropriate, medical surveillance programs be included in OSHA standards to determine whether the health of workers is adversely affected by exposure to the hazard addressed by the standard. Other OSHA health standards, such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027), also include medical surveillance requirements.

The proposed standard is intended to encourage participation by requiring that medical examinations be made available by the employer without cost to employees (also required by Section 6(b)(7) of the Act), and at a reasonable time and place. If participation requires travel away from the worksite, the employer is required to bear the cost. Employees must be paid for time spent taking medical examinations, including travel time.

OSHA is proposing that medical surveillance be made available to employees exposed to respirable crystalline silica above the PEL for 30 or more days a year. In contrast, the ASTM standards (Section 4.6.1) require medical surveillance for workers with actual or anticipated exposures to respirable crystalline silica at concentrations that exceed the occupational exposure limit for 120 or more days a year (ASTM, 2006; 2009). The OSHA proposal for medical surveillance of employees exposed to respirable crystalline silica above the PEL for 30 or more days per year is more comprehensive than the ASTM recommendation. Both the OSHA proposal and the ASTM standard use exposure above the occupational exposure limit as the trigger for medical surveillance. However, the OSHA proposal is more protective than the ASTM standard because it calls for medical surveillance of workers exposed for a shorter duration of time.

OSHA believes that the proposed cutoffs, based both on exposure level and on the number of days per year that an employee is exposed to respirable crystalline silica, are a reasonable and administratively convenient basis for providing medical surveillance benefits to respirable crystalline silica-exposed workers. With the exception of the asbestos standard (29 CFR 1910.1001), which doesn't specify an action level, medical surveillance in OSHA standards such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027) is triggered by exposure at or above action level. However, OSHA notes that employees exposed at or below the PEL, or exposed above the PEL for only a few days in a year, will be at lower risk of developing respirable crystalline silica-related disease than employees who are exposed above the PEL for 30 or more days per year. Medical surveillance triggered by exposures above the PEL covers employees who face the highest risk of developing disease related to respirable crystalline silica exposure. OSHA estimates that approximately 351,000 employees would be exposed above the proposed PEL for more than 30 days per year, and therefore require medical surveillance under the proposed standard. For comparison, OSHA estimates approximately 1,026,000 employees would be exposed above the proposed action level of 25 ug/μ^3 but at or below the proposed PEL, a difference of 675,000 employees. The total number of medical exams required, which takes into account turnover in the work force, would be similarly affected. For example, in the first year following promulgation, approximately 454,000 exams would be required under the proposed standard. If medical surveillance was triggered at the action level rather than the PEL, over 1,280,000 exams would be required. Under the proposed standard, periodic medical exams would be required on a triennial basis, increasing over time the total number of medical exams. Thus, requiring medical surveillance only for employees exposed above the proposed PEL reduces the burden on employers and focuses resources on the employees at highest risk. OSHA solicits comments on the approporate trigger for medical surveillance in the issues section of the NPRM.

Paragraph (h)(1)(ii) of the proposal requires that the medical examinations made available under the rule be performed by a physician or other licensed health care professional (PLHCP). The term ''PLHCP,'' as discussed further in section (b) (Definitions), above, refers to individuals whose legal scope of practice allows them to provide, or be delegated responsibility to provide, some or all of the health care services required by the medical surveillance provisions. The determination of who qualifies as a PLHCP is thus determined on a state-by-state basis. OSHA considers it appropriate to allow any professional to perform medical examinations and procedures made available under the standard when they are licensed by state law to do so. This provision provides flexibility to the employer, and reduces cost and compliance burdens. The proposed requirement is consistent with the approach of other recent OSHA standards, such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and respiratory protection (29 CFR 1910.134).

The proposed standard also specifies how frequently medical examinations are to be offered to those employees covered by the medical surveillance program. Under paragraph (h)(2), employers are required to make available to covered employees an initial (baseline) examination within 30 days after initial assignment unless the employee has received a medical examination provided in accordance with the standard within the past three years. The proposed requirement that a medical examination be offered at the time of initial assignment is intended to determine if an individual will be able to work in the job involving respirable crystalline silica exposure without adverse effects. It also serves the useful function of establishing a health baseline for future reference. Where an examination that complies with the requirements of the standard has been provided in the past three years, that previous examination would serve these purposes, and an additional examination would not be needed. For example, some employees may work short-term jobs associated with construction projects and other activities of limited duration. In these circumstances, an employee may work for several different employers over the course of a three-year period. In such cases, each employer who hires the employee within three years of the employee's last medical examination would not have to make available an initial medical examination, but could rely on a written medical opinion from an examination provided in the past three years, if the examination complied with the requirements of the standard.

Proposed paragraphs (h)(2)(i)-(vi) specify that the baseline medical examination provided by the PLHCP must consist of: medical and work history; physical examination with special emphasis on the respiratory system; chest X-ray or equivalent diagnostic study; pulmonary function test; latent tuberculosis test; and other tests deemed appropriate by the PLHCP. Special emphasis is placed on the portions of the medical and work history focusing on exposure to respirable-crystalline silica or other agents affecting the respiratory system, history of respiratory system dysfunction (including signs and symptoms such as shortness of breath, coughing, and wheezing), history of tuberculosis, and smoking.

Medical and work histories are required because they are an efficient and inexpensive means for collecting information that can aid in identifying individuals who are at risk because of hazardous exposures (ACOEM, 2006; WHO, 1996). Information on present and past work exposures, medical illnesses, and symptoms can lead to the detection of diseases at early stages when preventive measures can be taken. Recording of symptoms is important because, in some cases, symptoms indicating onset of disease can occur in the absence of abnormal laboratory test findings.

The physical exam focuses on the respiratory system, which is known to be susceptible to respirable crystalline silica toxicity. Aspects of the physical exam, such as visual inspection, palpation, tapping, and listening with a stethoscope, would allow the PLHCP to detect abnormalities in chest shape or lung sounds that are associated with compromised lung function (WHO, 1996; IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006). The ASTM standards do not specifically address a physical exam as part of medical surveillance, but physical exams are included in other recommendations (IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006; BCTD, 2001). OSHA's proposal for a physical exam provides for a more comprehensive medical evaluation than that required by the ASTM standards.

OSHA proposes that an X-ray or an equivalent diagnostic study be made available at the first medical examination. An initial chest X-ray, although not useful for preventing silicosis, can be useful for diagnosing silicosis, for detecting mycobacterial disease, and for detecting large opacities associated with cancer (IMA/MSHA 2008). It also provides baseline data upon which to assess any subsequent changes. X-rays are the standard medical test to diagnose respirable crystalline silica-related lung diseases. However, the proposal allows for an equivalent diagnostic study in place of the chest X-ray. This is intended to allow for use of technologically advanced imaging techniques in place of conventional X-rays.

An example of a diagnostic study that is equivalent to an X-ray is a digital chest radiograph. Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Digital imaging systems offer a number of advantages over conventional film-based X-rays, including more consistent image quality, faster results, increased ability to share images with multiple readers, simplified storage of images, and reduced risk for technicians and the environment due to the elimination of chemicals for developing film (Attfield and Weissman, 2009).

The proposed standard calls for an X-ray size of no less than 14 x 17 inches and no more than 16 x17 inches at full inspiration, which is consistent with the X-ray film size required in NIOSH specifications for medical examination of underground coal miners (42 CFR part 37). The proposed standard also specifies interpretation and classification of X-rays according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader. The ILO recently made standard digital radiographic images available and has published guidelines on the interpretation and classification of digital radiographic images (ILO 2011). Therefore, digital radiographic images can now be evaluated according to the same ILO guidelines as X-ray films and are considered equivalent diagnostic tests. The ILO guidelines require that digital images be displayed on a medical-grade flat-panel monitor designed for diagnostic radiology. ILO specifications for those monitors include a minimal diagonal display of 21 inches per image, a maximum to minimum luminance ratio of at least 50, a maximum luminance of no less than 250 candelas per square meter, a pixel pitch not to exceed 210 μm, and a resolution no less than 2.5 line-pairs per millimeter. NIOSH (2011) has published guidelines for conducting digital radiography and displaying digital radiographic images in a manner that will allow for classification according to ILO guidelines. Hard copies printed from digital images are not recommended for classification because they give the appearance of more opacities compared to films or digital images (Franzblau et al., 2009).

The ILO system was designed to assess X-ray and digital radiographic image quality and to describe radiographic findings of pneumoconiosis in a simple and reproducible way (NISA, 2010; WHO, 1996; IMA/MSHA, 2008). The procedure involves scoring opacities according to shape, size, location, and profusion. Opacities are first classified as either small or large, with small opacities representing simple silicosis and large opacities representing complicated silicosis. The best indicator of silicosis severity is profusion, which is the B reader's assessment of the amount of small opacities seen in the lung fields (NISA, 2010; IMA/MSHA, 2008). Using a standard set of ILO X-ray films or digital radiographic images, the B reader compares the workers' X-rays or digital radiographic images with the ILO films or digital radiographic images and rates the profusion of small opacities. The numbers 0, 1, 2, or 3 are used to indicate increasing amounts of small opacities. A 12-point profusion scale is employed, in which the B reader gives a first choice and then a second choice profusion rating.

A NIOSH-certified B reader is a physician who has demonstrated competency in the ILO classification system by passing proficiency and periodic recertification examinations (NIOSH, 2011a). The NIOSH certification procedures were designed to improve the proficiency of X-ray and digital radiographic image readers and minimize variability of readings. Standardized procedures for the evaluation of X-ray films and digital images by certified, qualified individuals is warranted by the prevalence and seriousness of silicosis. As of February 12, 2013, there were 242 certified B readers in the United States.

Other radiological test methods that may be useful are computed tomography (CT) or high resolution computed tomography (HRCT) scans. Two older studies reported that CT or HRCT scans were not more sensitive than X-rays for detecting silicosis but were more sensitive than X-rays at distinguishing between early and advanced stages of silicosis (Bégin *et al.,* 1987a; Talini *et al.,* 1995). More recent studies and reviews reported that CT or HRCT may be superior to chest X-ray in the early detection of silicosis and the identification of progressive massive fibrosis (PMF) (Sun *et al.,* 2008; Lopes *et al.,* 2008; Blum *et al.,* 2008). However, the value of CT or HRCT scans should be balanced with risks and disadvantages of those methods, which include higher radiation doses (WHO, 1996).

CT or HRCT scans could be considered ''equivalent diagnostic studies'' under paragraph (h)(2)(iii) of the proposed standard. However, standardized methods for interpreting and reporting the results of CT or HRCT scans are not currently available. The Agency seeks comment on whether CT and HRCT scans should be considered ''equivalent diagnostic studies'' under the standard, and has included this topic in the ''Issues'' section of this preamble.

Paragraph (h)(2)(iv) of the proposed OSHA standard calls for spirometry testing (forced vital capacity [FVC], forced expiratory volume at one second [FEV_1], and FEV_1/FVC ratio) by a spirometry technician with current certification from a NIOSH-approved spirometry course as part of the baseline medical examination. Pulmonary function tests, such as spirometry, are optional under the ASTM standards (ASTM, 2006; 2009). ASTM (2006, 2009) and others point to a lack of evidence that routine spirometry testing is useful for detecting early stages of respirable crystalline silica-related disease. They indicate that most abnormalities detected by spirometry screening are not related to respirable crystalline silica-related diseases but rather to factors such as smoking and non-occupationally related diseases. There are also a number of obstacles to widespread use of spirometry including inadequate training of medical personnel, technical problems with some spirometers, and lack of standardization for testing methodologies and procedures (ACOEM, 2011; IMA/MSHA, 2008; ATS/ERS, 2005; NISA, 2010). However, ACOEM, (2011), IMA/MSHA (2008), American Thoracic Society/European Respiratory Society (ATS/ERS, 2005), and NISA (2010) go on to note that properly conducted spirometry is considered a useful part of respiratory medical surveillance programs.

Because quality lung function tests are useful for obtaining information about the employee's lung capacity and respiratory flow rate, OSHA proposes to require spirometry as part of the baseline medical examination. Information provided by spirometry is useful for determining baseline lung function status upon which to assess any subsequent lung function changes and for evaluating any loss of lung function. This information may also be useful in assessing the health of employees who wear respirators. The proposed requirement is consistent with the approach of other OSHA standards, such as those for asbestos (29 CFR 1910.1001) and cadmium (29 CFR 1910.1027).

Because it is imperative that spirometry be conducted according to strict standards for quality control and for results to be consistently interpreted, OSHA proposes that spirometry be administered by a spirometry technician with current certification from a NIOSH-approved spirometry course. The NIOSH-approved spirometry training is based upon procedures and interpretation standards developed by the ATS/ERS and European Respiratory Society and addresses topics such as instrument calibration, testing performance, data quality, and interpretation of results (NIOSH, 2011b). Requiring spirometry technicians to have current certification from a NIOSH-approved spirometry course will improve their proficiency in generating quality results that are consistently interpreted. Similar recommendations are included in the ASTM standards (Section 4.6.5.4) (ASTM 2006; 2009).

In paragraph (h)(2)(v), OSHA proposes testing for latent tuberculosis infection at the baseline medical examination. In contrast, the ASTM standards (Section 4.6.5.3) recommend tuberculosis testing only when an X-ray shows evidence of silicosis (ASTM, 2006; 2009). NISA (2010) recommends baseline tuberculosis testing and periodic testing in workers who have chest X-ray readings of 1/0 or higher or more than 25 years of exposure to respirable crystalline silica. OSHA believes that a general requirement for testing during the initial medical examination will serve to protect workers exposed to respirable crystalline silica by identifying latent tuberculosis infection so it can be treated before active (infectious) tuberculosis develops.

In 2008, there were almost 13,000 new cases of active tuberculosis in the U.S. Although incidence of tuberculosis continues to decrease in the U.S., the ultimate goal of tuberculosis control and prevention in the U.S. is the elimination of tuberculosis (CDC, 2009). Active tuberculosis cases are prevented by identifying and treating those with latent tuberculosis disease.

As described in OSHA's Health Effects analysis and summarized in Section V of this preamble, the risk of developing active tuberculosis infection is higher in individuals with silicosis than those without silicosis (Balmes, 1990; Cowie, 1994; Hnizdo and Murray, 1998; Kleinschmidt and Churchyard, 1997; Murray et al., 1996). Moreover, there is evidence that exposure to silica increases the risk for pulmonary tuberculosis, independent of the presence of silicosis (Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude et al., 2006). OSHA therefore preliminarily concludes that it is in the best interest of both the employer and the affected worker to identify latent tuberculosis prior to silica exposure. The increased risk of developing active pulmonary tuberculosis places not only the worker, but also his or her co-workers and family members at increased risk of acquiring this potentially fatal infectious disease. Early treatment of latent disease would eliminate this risk. Testing for latent tuberculosis infection will identify cases of this disease and alert affected workers, so that the necessary treatment can be obtained from their local public health department or other health care provider. OSHA's proposed requirement is consistent with the recommendations of ACOEM (2006), which recommends tuberculosis screening for all silica-exposed workers. The Centers for Disease Control and Prevention recommends that tuberculosis testing target populations who are at the highest risk of developing the disease, including those with silicosis (CDC, 2000). The Agency seeks comment on its preliminary determination that all workers receiving an initial medical exam should receive testing for latent tuberculosis infection, and has included this topic in the ''Issues'' section of this preamble.

Paragraph (h)(2)(vi) of the proposal gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate. While the tests conducted under this section are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding (IMA/MSHA, 2008). For example, the PLHCP may decide that additional tests are needed to address abnormal findings in a pulmonary function test. OSHA believes that the PLHCP is in the best position to decide if any additional medical tests are necessary for each individual examined. Where additional tests are deemed appropriate by the PLHCP, the proposed standard would require that they be made available.

In paragraph (h)(3)(i), OSHA proposes periodic examinations including medical and work history, physical examination emphasizing the respiratory system, chest X-rays and pulmonary function tests, and other tests deemed to be appropriate by the PLHCP. The examinations would be required every three years under paragraph (h)(3) of this proposal, unless the PLHCP recommends that they be made available more frequently. The specific requirements for the examinations and the value of the examinations for screening workers exposed to respirable crystalline silica were addressed above. The proposed requirement for examinations every three years is consistent with the ASTM standards (Section 4.6.5), which recommend that medical surveillance be conducted no less than every three years (ASTM, 2006; 2009). Other standards recommend periodic evaluations at intervals ranging from two to five years, depending on duration of exposure (IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006; BCTD, 2001).

The main goal of periodic medical surveillance for workers is to detect adverse health effects at an early and potentially reversible stage. Based on the Agency's experience, OSHA believes that surveillance every three years would strike a reasonable balance between the need to diagnose health effects at an early stage and the limited number of cases likely to be identified through surveillance.

The proposed requirement that employers offer a chest X-ray or an equivalent diagnostic test as part of the periodic medical examination conducted every three years is an important aspect of early disease detection. As indicated above, X-rays are appropriate tools for detecting and monitoring the progression of silicosis, possible complications such as mycobacterial disease, and large opacities related to cancer (IMA/MSHA 2008). Detection of simple silicosis by periodic X-ray could allow for implementation of exposure reduction methods that are likely to decrease the risk of disease progression (ACOEM, 2006). X-rays would also allow the detection of treatable conditions, such as mycobacterial infections (ACOEM, 2006).

X-rays conducted every three years as part of the triennial medical examinations are appropriate considering the long latency period of most respirable crystalline silica-related diseases. The proposed three-year frequency for chest X-rays represents a simplified approach that balances a reasonable time frame for detecting disease and administrative convenience. Under paragraph (h)(3)(ii) of the proposed standard, the PLHCP can request X-rays more frequently. The proposed frequency is consistent with the ASTM standards, as well as ACOEM recommendations (ASTM, 2006; 2009; ACOEM, 2006). Other groups recommend X-rays at intervals ranging from every two to five years, depending on exposure duration (IMA/MSHA, 2008; NISA, 2010; WHO, 1996). OSHA is interested in comments on the proposed X-ray frequency and has raised this topic in the ''Issues'' section of this preamble.

Proposed paragraph (h)(3) also requires that spirometry (FVC, FEV_1, and FEV_1/FVC ratio) be offered by a spirometry technician with current certification from a NIOSH-approved spirometry course, as part of the medical examination conducted every three years. As noted above, spirometry is optional in the ASTM standards (ASTM, 2006; 2009). However, OSHA believes that periodic spirometry is a potentially valuable tool for detecting respirable crystalline silica-related disease and monitoring the health of exposed workers.

Periodic spirometry that adheres to strict quality standards is useful for monitoring progressive lung function changes to identify individual workers or groups of workers with abnormal lung function changes. Quality longitudinal spirometry testing that compares workers' lung function to their baseline levels is useful for detecting excessive declines in lung function that could lead to severe impairment over time. For example, recent studies have shown that excessive decline in lung function can be an early warning sign for risk of COPD development (Wang et al., 2009). Identifying workers who are at risk of developing severe decrements in lung function would allow for interventions to prevent further progression of disease. OSHA is proposing a medical examination including a lung function test every three years because exposure to respirable crystalline silica does not usually cause severe declines in lung function over short time periods. The proposed frequency is consistent with ACOEM (2006) and BCTD (2001), which recommend lung function testing every two to three years. WHO (1996) and NISA (2010) recommend annual pulmonary function testing, but WHO (1996) states that if this is not feasible, it can be conducted at the same frequency as chest X-rays (every two to five years). Paragraph (h)(3) of the proposed standard gives the PLHCP the authority to request lung function testing more frequently. The PLHCP might recommend such a test because of age, tenure, exposure level, or abnormal results. The Agency seeks comment on the proposed frequency of pulmonary function testing and has raised this topic in the ''Issues'' section of this preamble.

Paragraph (h)(4) of the proposed standard would require the employer to ensure the examining PLHCP has a copy of the standard, and to provide the following information to the PLHCP: a description of the affected employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer. Making this information available to the PLHCP will aid in the evaluation of the employee's health in relation to assigned duties and fitness to use personal protective equipment, when necessary. The results of exposure monitoring are part of the information that would be supplied to the PLHCP responsible for medical surveillance. These results contribute valuable information to assist the PLHCP in determining if an employee is likely to be at risk of harmful effects from respirable crystalline silica exposure. A well-documented exposure history also assists the PLHCP in determining if a condition (*e.g.,* compromised pulmonary function) may be related to respirable crystalline silica exposure. Where the employer does not have information directly indicating an employee's exposure (*e.g.,* where the employer uses Table 1 in the proposed construction standard and does not perform exposure monitoring), an indication of the presumed exposure associated with the operation (*i.e.,* at or above the action level, above the PEL) would fulfill this requirement.

Proposed paragraph (h)(5)(i) requires that the employer obtain a written medical opinion from the PLHCP within 30 days of each medical examination. The purpose of this requirement is to provide the employer with a medical basis to aid in the determination of placement of employees and to assess the employee's ability to use protective clothing and equipment. OSHA believes the 30-day period will provide the PLHCP sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The proposed requirement that the opinion be in written form is intended to ensure that employers and employees receive the benefit of this information.

Paragraphs (h)(5)(i)(A)–(D) of the proposal specify what must be included in the PLHCP's opinion. The standard first proposes that the PLHCP's written medical opinion describe the employee's health condition as it relates to exposure to respirable crystalline silica, including any conditions that would put the employee at increased risk of material impairment of health from further exposure to respirable crystalline silica. The standard also proposes that the PLHCP's written medical opinion include recommended limitations for the employee's exposure to respirable crystalline silica or use of personal protective equipment such as respirators. These proposed requirements are consistent with the overall goals of medical surveillance: to determine if an individual can be exposed to respirable crystalline silica present in his or her workplace without experiencing adverse health effects, to identify respirable crystalline silica-related adverse health effects so that appropriate intervention measures can be taken, and to determine the employee's fitness to use personal protective equipment such as respirators.

Paragraph (h)(5)(i)(C) proposes that the PLHCP must include in the written medical opinion a statement that the employee should be examined by a pulmonary specialist if the X-ray is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP. As described above, paragraph (h)(2)(iii) of the proposed standard requires that X-rays be interpreted according to the ILO Classification of Radiographs of Pneumoconioses. The ASTM standards recommend that workers with profusion opacities greater than 1/1 (profusion similar to that shown on a standard category 1 radiograph) be evaluated at a frequency determined by a physician qualified in pulmonary disease (Section 4.7.1) and receive annual counseling by a physician or other person knowledgeable in occupational safety and health (Section 4.7.2) (ASTM, 2006; 2009). The proposed OSHA standard addresses pneumoconiosis at an earlier stage than the ASTM standards, thus allowing for intervention at an earlier indication of possibly abnormal findings.

Paragraph (h)(5)(i)(D) of the proposal would require that the PLHCP include in the written medical opinion a statement that the PLHCP has explained to the employee the medical examination results, including conditions related to respirable crystalline silica exposure that require further evaluation or treatment and any recommendations related to use of protective clothing or equipment. Under this provision, OSHA anticipates that the employee will be informed directly by the PLHCP of all results of his or her medical examination, including conditions of nonoccupational origin. Direct consultation between the PLHCP and employee ensures that the employee will receive all information about health status, including non-occupationally related conditions, that are not communicated to the employer.

Under proposed paragraph (h)(5)(ii), the employer must ensure that the PLHCP does not include findings unrelated to crystalline silica exposure in the written opinion provided to the employer or otherwise reveal such findings to the employer. OSHA has proposed this provision to ensure confidentiality of medical information and to reassure employees participating in medical surveillance that they will not be penalized or embarrassed as a result of the employer obtaining information about them not directly pertinent to occupational exposure to respirable crystalline silica. Paragraph (h)(5)(iii) of the proposed standard requires the employer to provide a copy of the PLHCP's written opinion to the employee within two weeks after the employer receives it, to ensure that the employee has been informed of the results of the examination in a timely manner.

OSHA is aware of concerns that the written medical opinion may divulge confidential information regarding an employee's medical condition, or may otherwise divulge information that may adversely affect an individual's employment status. The Building and Construction Trades Department, AFL–CIO has expressed the view that, except in limited circumstances, any decision to disclose medical information to an employer should be left to the employee (BCTD, 2009). OSHA respects concerns for medical privacy and is aware of how disclosure of medical information could potentially impact workers. The proposed requirements are intended to balance employee privacy with employers' need for information to assess possible health effects or risks related to respirable crystalline silica exposure by employees. OSHA seeks comment on the proposed requirement for the employer to obtain a written medical opinion, and has raised this topic in the ''Issues'' section of this preamble.

Proposed paragraph (h)(6)(i) requires that an examination by a pulmonary specialist be offered when indicated in the PLHCP's written opinion. This requirement is intended to ensure that individuals with abnormal findings are seen by a professional with expertise in respiratory disease who can provide not only expert medical judgment, but also counseling regarding work practices and personal habits that could affect these individuals' respiratory health. In this respect the proposed provision is conceptually consistent with the provision in the ASTM standards (4.7.2) for counseling by a physician or other person qualified in occupational safety and health. Data presented by the American Board of Internal Medicine (ABIM) indicate that as of February 5, 2013, 13,138 physicians in the United States had valid certificates in pulmonary disease (ABIM, 2013). ABIM does not report how many of these physicians are currently practicing. However, ABIM does report that 4,378 new certificates in pulmonary disease were issued in the period from 2001–20010 (ABIM, 2012). Because physicians are likely to practice in the field for some time after receiving their certification, this figure indicates that a substantial number of pulmonary specialists are available to perform examinations required under the proposed standard.

Paragraph (h)(6)(i) further proposes that these additional examinations by pulmonary specialists must be made available within 30 days following receipt of the PLHCP's recommendation that examination by such a specialist is indicated. OSHA proposes, under paragraph (h)(6)(ii), that the employer provide the pulmonary specialist with the same information that is provided to the original PLHCP (*i.e.,* a copy of the standard; a description of the affected employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer). The reasons why the pulmonary specialist should receive this information are the same as those for the PLHCP and were addressed above.

Proposed paragraph (h)(6)(iii) requires the employer to obtain a written medical opinion from the pulmonary specialist comparable to the written opinion obtained from the original PLHCP, including a description of the employee's health condition as it relates to respirable crystalline silica exposure, the pulmonary specialist's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to respirable crystalline silica, and any recommended limitations on the employee's exposure to respirable crystalline silica or use of personal protective equipment. The pulmonary specialist would also need to state in the written opinion that these findings were explained to the employee. The reasons why the pulmonary specialist should provide this information to the employer are the same as those for the PLHCP and were addressed above.

Some OSHA health standards contain a provision for medical removal protection (MRP). MRP typically requires that the employer temporarily remove an employee from exposure when such an action is recommended in a written medical opinion. During the time of removal, the employer is required to maintain the total normal earnings, as well as all other employee rights and benefits, of the removed employee. However, MRP is not intended to serve as a workers' compensation system. The primary reason MRP was included in previous standards was to encourage employee participation in medical surveillance. By protecting employees who are removed on a temporary basis from economic loss, this potential disincentive to participating in medical surveillance is alleviated. Previous standards also included MRP requirements to prevent the onset of disease and to detect and minimize the extent of existing disease. For example, OSHA's cadmium standard (29 CFR 1910.1026) provides for MRP based on criteria such as biological monitoring results and evidence of cadmium-related disease. Removal from exposure can allow for biological monitoring results to return to acceptable levels, or for improvement in the employee's health condition.

OSHA has made a preliminary determination that MRP is not reasonably necessary or appropriate for respirable crystalline silica-related health effects. Thus, the proposed rule does not include a provision for MRP. The Agency believes that respirable crystalline silica-related health effects (*e.g.,* silicosis) are generally chronic conditions that are not remedied by temporary removal from exposure. Since situations where temporary removal would be appropriate are not anticipated to occur, OSHA does not believe that MRP is necessary. The Agency seeks comment on this preliminary determination, and has included this topic in the ''Issues'' section of this preamble.

(i) Communication of Respirable Crystalline Silica Hazards to Employees

The proposed standard includes requirements intended to ensure that the dangers of respirable crystalline silica exposure are communicated to employees by means of labels, safety data sheets, and employee information and training. OSHA believes that it is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and in safety data sheets. These written forms of communication will be effective and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects.

OSHA has proposed to revise its existing hazard communication standard (HCS) (29 CFR 1910.1200) to conform with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Revision 3. (*See* 74 FR 50280, Sept. 30, 2009.) The hazard communication requirements of the proposed crystalline silica rule are designed to be consistent with the revised HCS, while including additional specific requirements needed to protect employees exposed to respirable crystalline silica. OSHA intends for the requirements of the respirable crystalline silica rule to conform with the final hazard communication standard. The proposed requirements are also consistent with the worker training and education provisions of ASTM International's standards addressing control of occupational exposure to respirable crystalline silica (Section 4.8 in both E 1132–06 and E 2625–09) (ASTM, 2006; 2009).

In the HCS rulemaking, OSHA proposed to revise substance-specific health standards by referencing the HCS requirements for labels, safety data sheets, and training and by identifying the hazards that need to be addressed in the employer's written hazard communication program. Accordingly, proposed paragraph (i)(1) of the silica rule requires compliance with the HCS requirements and lists cancer, lung effects, immune system effects, and kidney effects as hazards that need to be addressed in the employer's hazard communication program. These are the health effects that OSHA has preliminarily determined to be associated with respirable crystalline silica exposure.

Proposed paragraph (i)(2)(i) requires the employer to ensure that each affected employee can demonstrate knowledge of the specified training elements (discussed below). When using the term ''affected employee'' in this context, OSHA is referring to any employee who may be exposed to respirable crystalline silica under normal conditions of use or in a foreseeable emergency. Employee knowledge of the specified training elements could be determined through methods such as discussion of the required training subjects, written tests, or oral quizzes. In order to ensure that employees comprehend the material presented during training, it is critical that trainees have the opportunity to ask questions and receive answers if they do not fully understand the material that is presented to them. When videotape presentations or computer-based programs are used, this requirement may be met by having a qualified trainer available to address questions after the presentation, or providing a telephone hotline so that trainees will have direct access to a qualified trainer.

Proposed paragraphs (i)(2)(i)(A) and (B), which require training on specific operations in the workplace that could result in respirable crystalline silica exposure and specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, closely parallel the HCS. OSHA has included these elements in the proposed respirable crystalline silica rule to ensure that both employers and employees understand the sources of potential silica exposure and control measures used to reduce exposure. Workers have a particularly important role in controlling silica exposures because work practices often play a crucial role in controlling exposures, and engineering controls frequently require action on the part of workers to function effectively. For example, stationary masonry saws using wet methods to control dust may require adjustment of the nozzle and the water flow rate to ensure that an adequate volume of water reaches the cutting area. Water filters may need to be rinsed or replaced at regular intervals, and basin water may need to be replaced on a regular basis to prevent clogging of the nozzles. Similarly, the effectiveness of local exhaust ventilation systems, another common method used to control exposures to respirable crystalline silica, is often enhanced by the use of proper work practices. When tuckpointing, for instance, workers should ensure that the shroud surrounding the grinding wheel remains flush against the working surface to minimize the amount of dust that escapes from the collection system. Operating the grinder in one direction (counter to the direction of blade rotation) is effective in directing mortar debris into the exhaust system, and backing the blade off before removing it from the slot permits the exhaust system to clear accumulated dust. Workers' implementation of work practices such as these is often necessary to ensure that they are adequately protected, and OSHA has preliminarily concluded that the importance of recognizing potential exposures and understanding appropriate work practices merits including these provisions in the proposed silica rule.

Proposed paragraph (i)(2)(i)(C) requires training on the contents of the respirable crystalline silica rule, and proposed paragraph (i)(2)(ii) requires that the employer make a copy of the standard readily available to employees without cost. OSHA believes that it is important for employees to be familiar with and have access to the proposed respirable crystalline silica standard and the employer's obligations to comply with it.

Proposed paragraph (i)(2)(i)(D) requires employers to provide training to workers on the purpose and description of the medical surveillance program found at paragraph (h) of the proposed silica rule. Such training should cover the signs and symptoms of respirable crystalline silica-related adverse health effects including cancer, lung effects, immune system effects, and kidney effects. This information will help to ensure that employees are able to effectively participate in medical surveillance, which is discussed above in section (h) (Medical surveillance).

OSHA intends for the training requirements under the proposed silica standard, like those in the hazard communication standard, to be performance-oriented. The Agency has therefore written proposed section (i) in terms of objectives, which are meant to ensure that employees are made aware of the hazards associated with respirable crystalline silica in their workplace and how they can help to protect themselves. The proposed standard also lists the subjects, which are in addition to or reiterate those covered by the HCS, that must be addressed in training, but not the specific ways in which the training is to be accomplished. OSHA believes that the employer is in the best position to determine how the training can most effectively be accomplished. Hands-on training, videotapes, slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program in each specific workplace.

In order for the training to be effective, the employer must ensure that it is provided in a manner that the employee is able to understand. OSHA has consistently required that employee training required by OSHA standards be presented in a manner that employees can understand. This position was recently reiterated in a memorandum to OSHA Regional Administrators from Assistant Secretary David Michaels (OSHA, 2010). Employees have varying educational levels, literacy, and language skills, and the training must be presented in a language, or languages, and at a level of understanding that accounts for these differences in order to meet the proposed requirement in paragraph (i)(2) that individuals being trained understand the specified elements. This may mean, for example, providing materials, instruction, or assistance in Spanish rather than English if the workers being trained are Spanish-speaking and do not understand English. The employer is not required to provide training in the employee's preferred language if the employee understands both languages; as long as the employee is able to understand the material in the language used, the intent of the proposed standard would be met.

The frequency of training under the proposed standard is determined by the needs of the workplace. At the time of initial assignment to a position involving exposure to respirable crystalline silica, each employee needs to be trained sufficiently to understand the specified training elements. Additional training may be needed periodically to refresh and reinforce the memories of employees who have previously been trained or to ensure that employees are informed of new developments in the workplace that may result in new or additional exposures to respirable crystalline silica. Additional training might also be necessary after new engineering controls are installed to ensure that employees are able to properly use the new controls and implement work practices relating to those controls. Further, employees might need additional training in the use of new personal protective equipment. Such training would ensure that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

(j) Recordkeeping

Paragraph (j) of the proposed standard requires employers to maintain air monitoring data, objective data, and medical surveillance records. The recordkeeping requirements are proposed in accordance with section 8(c) of the OSH Act (29 U.S.C. 657(c)), which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.

Proposed paragraph (j)(1)(i) requires employers to keep accurate records of all air monitoring results used or relied on to assess employee exposure to respirable crystalline silica. Paragraph (j)(1)(ii) requires that such records include the following information: the date of measurement for each sample taken; the operation monitored; sampling and analytical methods used; the number, duration, and results of samples taken; the identity of the laboratory that performed the analysis; the type of personal protective equipment, such as respirators, worn by the employees monitored; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored. These requirements are generally consistent with those found in other OSHA standards, such as methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). OSHA has proposed an additional requirement in this rulemaking—recording the identity of the laboratory that performed the analysis of exposure measurements—because of the importance of ensuring that laboratories performing analyses of respirable crystalline silica samples conform with the requirements specified in paragraph (d)(5) of the proposed rule.

Proposed paragraph (j)(2)(i) requires employers who rely on objective data, pursuant to proposed paragraph (d)(2)(ii)(B) or (d)(3)(ii), to keep accurate records of the objective data. Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product, material, process, operation, or activity.

Proposed paragraph (j)(2)(ii) requires the record to include: the crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; a description of the process, operation, or activity involved and how the data support the assessment; and other data relevant to the process, operation, activity, material, or employee exposures. Since objective data may be used to exempt the employer from provisions of the proposal or provide a basis for selection of respirators, it is critical that the use of objective data be carefully documented. Reliance on objective data is intended to provide the same degree of assurance that employee exposures have been correctly characterized as air monitoring would. The records should demonstrate a reasonable basis for the conclusions drawn from the objective data.

Proposed paragraph (j)(3)(i) requires the employer to establish and maintain an accurate record for each employee subject to medical surveillance under paragraph (h) of the proposed standard. Paragraph (j)(3)(ii) lists the categories of information that an employer would be required to record: the name and social security number of the employee; a copy of the PLHCP's and pulmonary specialist's written opinions about the employee; and a copy of the information provided to the PLHCPs and pulmonary specialists as required by proposed paragraph (h)(4). The information provided to the PLHCPs and pulmonary specialists includes the employee's duties as they relate to crystalline silica exposure, crystalline silica exposure levels, descriptions of personal protective equipment used by the employee, and information from employment-related medical examinations previously provided to the employee (*see* paragraph (h)(4)).

OSHA believes that medical surveillance records, like exposure records, are necessary and appropriate for protection of employee health, enforcement of the standard, and development of information regarding the causes and prevention of occupational illnesses. Employee access to medical surveillance records helps protect employees because such records contribute to the evaluation of employees' health and enable employees and their health care providers to make informed health care decisions. These records are especially important when an employee's medical conditions place him or her at increased risk of health impairment from further exposure to respirable crystalline silica. Furthermore, the employer could evaluate medical surveillance data for indications that workplace conditions are associated with increased risk of illness and take corrective actions. Finally, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to respirable crystalline silica exposure, evaluate compliance programs, and assess the efficacy of the standard.

Proposed paragraphs (j)(1)(iii), (j)(2)(iii), and (j)(3)(iii) require employers to maintain and provide access to air monitoring, objective data, and medical surveillance records, respectively, in accordance with OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020). That standard, specifically 29 CFR 1910.1020(d), requires employers to ensure the preservation and retention of exposure and medical records. Air monitoring data and objective data are considered employee exposure records that must be maintained for at least 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii). Medical records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i).

The maintenance and access provisions incorporated from 29 CFR 1910.1020 ensure that records are available to employees so that they may examine the employer's exposure assessments and assure themselves that they are being adequately protected. Moreover, compliance with the requirement to maintain records of exposure data will enable the employer to show, at least for the duration of the retention-of-records period, that the exposure assessment was accurate and conducted in an appropriate manner. The lengthy record retention period is necessitated in this case by the long latency period commonly associated with silica-related diseases. Furthermore, determining causality of disease in employees is assisted by, and in some cases requires, examining present and past exposure data as well as the results of present and past medical examinations.

(k) Dates

Under paragraph (k)(1) of the proposed standard, the final crystalline silica rule becomes effective 60 days after its publication in the **Federal Register**. This period is intended to allow affected employers the opportunity to familiarize themselves with the standard. Under paragraph (k)(2)(i), employer obligations to comply with most requirements of the final rule begin 180 days after the effective date (240 days after publication of the final rule). This additional time period after the effective date is designed to allow employers to complete initial exposure assessments, establish regulated areas or access control plans, provide initial medical examinations, and comply with other provisions of the rule.

Paragraph (k)(2)(ii) allows additional time for employers to implement the engineering controls required under paragraph (f) of the proposed rule. Engineering controls need to be in place within one year after the effective date. This is to allow affected employers sufficient time to design, obtain, and install the necessary control equipment. During the period before engineering controls are implemented, employers must provide respiratory protection to employees under proposed paragraph (g)(1)(i).

Paragraph (k)(2)(iii) specifies that the laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date. OSHA recognizes that the requirements for monitoring in the proposed rule will increase the demand for analysis of respirable crystalline silica samples. A two year start-up period is proposed to allow time for laboratories to achieve compliance with the proposed requirements, particularly with regard to requirements for accreditation and round robin testing.

OSHA solicits comment on the adequacy of these proposed start-up dates. OSHA would like to ensure that engineering controls and medical surveillance are implemented as quickly as possible, while also ensuring that employers have sufficient time to complete these processes. OSHA is also interested in ensuring that laboratories comply with the requirements of the standard as quickly as possible, while also ensuring that sufficient laboratory capacity is available to meet the needs of employers. In addition, the Agency is interested in mitigating impacts on firms complying with the rule, and seeks comment on approaches that would phase in requirements of the rule based on industry, employer size, or other factors. The Agency has included these topics in the ''Issues'' section of this preamble.

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List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Cancer, Chemicals, Cristobalite, Crystalline silica, Hazardous substances, Health, Occupational safety and health, Quartz, Reporting and recordkeeping requirements, Silica, Tridymite.

XVIII. Authority and Signature

This document was prepared under the direction of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

The Agency issues the proposed sections under the following authorities: sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 4–2010 (75 FR 55355, September 10, 2010); and 29 CFR part 1911.

Signed at Washington, DC, on August 23, 2013.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons set forth in the preamble, OSHA proposes to amend chapter XVII of title 29, parts 1910, 1915, and 1926, of the Code of Federal Regulations as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—[AMENDED]

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), or 4–2010 (75 FR 55355), as applicable; and 29 CFR part 1911. All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653. Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

■ 2. In § 1910.1000, Table Z–1—Limits for Air Contaminants, remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust''; and add ''Silica, crystalline, respirable dust; see 1910.1053'' in alphabetical order, to read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm [(a) 1]	mg/m^3 [(b) 1]	Skin designation
* * * * * * *				
Silica, crystalline, respirable dust; see 1910.1053.				
* * * * * * *				

* * * * *

■ 3. In § 1910.1000, Table Z–3—Mineral Dusts, the entry ''Silica:'' is revised to read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–3—MINERAL DUSTS

Substance	mppcf [a]	mg/m^3
Silica:		
Amorphous, including natural diatomaceous earth	20	$\frac{80\ mg/m^3}{\%SiO_2}$
* * * * * * *		

■ 4. A new § 1910.1053 is added, to read as follows:

§ 1910.1053 Respirable crystalline silica.

(a) *Scope and application.* (1) This section applies to all occupational exposures to respirable crystalline silica, except:

(2) Construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926; and

(3) Agricultural operations covered under 29 CFR part 1928.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 micrograms per cubic meter of air (25 μg/m³), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Competent person means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Respirable crystalline silica means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

This section means this respirable crystalline silica standard, 29 CFR 1910.1053.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m³, calculated as an 8-hour TWA.

(d) *Exposure assessment.* (1) *General.* (i) Each employer covered by this section shall assess the exposure of employees who are or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level.

(ii) The employer shall determine employee exposures from breathing zone air samples that reflect the 8-hour TWA exposure of each employee.

(iii) The employer shall determine 8-hour TWA exposures on the basis of one or more air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same job tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(2) *Initial exposure assessment.* (i) Except as provided for in paragraph (d)(2)(ii) of this section, each employer shall perform initial monitoring of employees who are, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level.

(ii) The employer may rely on existing data to satisfy this initial monitoring requirement where the employer:

(A) Has monitored employee exposures after [INSERT DATE 12 MONTHS PRIOR TO EFFECTIVE DATE OF FINAL RULE] under conditions that closely resemble those currently prevailing, provided that such monitoring satisfies the requirements of paragraph (d)(5)(i) of this section with respect to analytical methods employed; or

(B) Has objective data that demonstrate that respirable crystalline silica is not capable of being released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling.

(3) *Periodic exposure assessments.* If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If initial monitoring indicates that employee exposures are at or above the action level, the employer shall assess employee exposures to respirable crystalline silica either under the fixed schedule prescribed in paragraph (d)(3)(i) of this section or in accordance with the performance-based requirement prescribed in paragraph (d)(3)(ii) of this section.

(i) *Fixed schedule option.* (A) Where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months.

(B) Where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months.

(C) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring for that employee, except as otherwise provided in paragraph (d)(4) of this section.

(ii) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(4) *Additional exposure assessments.* The employer shall conduct additional exposure assessments as required under paragraph (d)(3) of this section whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level.

(5) *Method of sample analysis.* (i) The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7.

(ii) The employer shall ensure that samples are analyzed by a laboratory that:

(A) Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard

17011:2004 for implementation of quality assessment programs;

(B) Participates in round robin testing with at least two other independent laboratories at least every six months;

(C) Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

(D) Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

(E) Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis;

(F) Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

(*1*) Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

(*2*) Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

(*3*) Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever the exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(e) *Regulated areas and access control.* (1) *General.* Wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) of this section or an access control plan in accordance with paragraph (e)(3) of this section.

(2) *Regulated areas option.* (i) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(ii) *Demarcation.* The employer shall demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundaries of the area and minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(iii) *Access.* The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(iv) *Provision of respirators.* The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(v) *Protective work clothing in regulated areas.* (A) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer shall provide either of the following:

(*1*) Appropriate protective clothing such as coveralls or similar full-bodied clothing; or

(*2*) Any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica.

(B) The employer shall ensure that such clothing is removed or cleaned upon exiting the regulated area and before respiratory protection is removed.

(3) *Written access control plan option.* (i) The employer shall establish and implement a written access control plan.

(ii) The written access control plan shall contain at least the following elements:

(A) Provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL;

(B) Procedures for notifying employees of the presence and location of areas identified pursuant to paragraph (e)(3)(ii)(A) of this section, and for demarcating such areas from the rest of the workplace where appropriate;

(C) For multi-employer workplaces, the methods the employer covered by this section will use to inform other employer(s) of the presence and location of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures that need to be taken to protect employees;

(D) Provisions for limiting access to areas where respirable crystalline silica exposures may exceed the PEL to effectively minimize the number of employees exposed and the level of employee exposure;

(E) Procedures for providing each employee and their designated representative entering an area where respirable crystalline silica exposures may exceed the PEL with an appropriate respirator in accordance with paragraph (g) of this section, and requiring each employee and their designated representative to use the respirator while in the area; and

(F) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica:

(*1*) Provisions for the employer to provide either appropriate protective clothing such as coveralls or similar full-bodied clothing, or any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica; and

(*2*) Provisions for the removal or cleaning of such clothing.

(iii) The employer shall review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary.

(iv) The employer shall make the written access control plan available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Abrasive blasting.* In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply with the requirements of 29 CFR 1910.94 (Ventilation), 29 CFR 1915.34 (Mechanical paint removers), and 29 CFR part 1915, subpart I (Personal Protective Equipment), as applicable, where abrasive blasting operations are conducted using crystalline silica-containing blasting agents, or where abrasive blasting operations are conducted on substrates that contain crystalline silica.

(3) *Cleaning methods.* (i) The employer shall ensure that accumulations of crystalline silica are cleaned by HEPA-filter vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(ii) Compressed air, dry sweeping, and dry brushing shall not be used to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(4) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during work operations for which engineering and work practice controls are not feasible;

(iii) During work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL; and

(iv) During periods when the employee is in a regulated area pursuant to paragraph (e) of this section.

(v) During periods when the employee is in an area where respirator use is required under an access control plan pursuant to paragraph (e)(3) of this section.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration), interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader, or an equivalent diagnostic study;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume at one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (h)(2) (except paragraph (h)(2)(v)) of this section at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The written opinion shall contain:

(A) A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;

(B) Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators;

(C) A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) of this section if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and

(D) A statement that the PLHCP has explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

(ii) The employer shall ensure that the PLHCP does not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to respirable crystalline silica.

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(6) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a pulmonary specialist, the employer shall make available a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion.

(ii) The employer shall ensure that the examining pulmonary specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (h)(4) of this section.

(iii) The employer shall obtain a written medical opinion from the pulmonary specialist that meets the requirements of paragraph (h)(5) (except paragraph (h)(5)(i)(C)) of this section.

(i) *Communication of respirable crystalline silica hazards to employees.* (1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (i)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) *Employee information and training.* (i) The employer shall ensure that each affected employee can demonstrate knowledge of at least the following:

(A) Specific operations in the workplace that could result in exposure to respirable crystalline silica, especially operations where exposure may exceed the PEL;

(B) Specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, including appropriate work practices and use of personal protective equipment such as respirators and protective clothing;

(C) The contents of this section; and

(D) The purpose and a description of the medical surveillance program required by paragraph (h) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each affected employee.

(j) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all exposure measurement results used or relied on to characterize employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, operation, or activity and how the data support the assessment; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's and pulmonary specialist's written opinions; and

(C) A copy of the information provided to the PLHCPs and pulmonary specialists as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(k) *Dates.* (1) *Effective date.* This section shall become effective November 12, 2013

(2) *Start-up dates.* (i) All obligations of this section, except engineering controls required by paragraph (f) of this section and laboratory requirements in paragraph (d)(5)(ii) of this section, commence 180 days after the effective date.

(ii) Engineering controls required by paragraph (f) of this section shall be implemented no later than one year after the effective date.

(iii) Laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date.

Appendix A to § 1910.1053—Medical Surveillance Guidelines (Non-Mandatory)

Introduction

The purpose of this non-mandatory Appendix is to provide helpful information about complying with the medical surveillance provisions of the Respirable Crystalline Silica standard, as well as to provide other helpful recommendations and information. Medical screening and surveillance allow for early identification of exposure-related health effects in individual workers and groups of workers, respectively, so that actions can be taken to both avoid further exposure and prevent adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences. Thus, medical surveillance of silica-exposed workers requires involvement of clinicians with thorough knowledge of silica-related health effects and a public health perspective.

This Appendix is divided into four sections. Section I reviews silica-related diseases, appropriate medical responses, and public health responses. Section II outlines the components of the medical surveillance program for workers exposed to silica. Section III describes the roles and responsibilities of the clinician implementing the program and of other medical specialists and public health providers. Section IV provides additional resources.

I. Recognition of Silica-Related Diseases

Overview. Silica refers specifically to the compound silicon dioxide (SiO_2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with a number of adverse health effects. Exposure to respirable crystalline silica can occur in foundries, industries that have abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing.

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined.

A. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is as follows:

1. Symptoms—shortness of breath and cough, although workers may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as mycobacterium tuberculosis infection (TB) or lung cancer. Workers with these symptoms should immediately receive further evaluation and treatment.

2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

3. Spirometry—may be normal or may show only mild restriction or obstruction.

4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ‘‘eggshell calcifications’’ are seen.

5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease.

Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Additionally, a case of acute or accelerated silicosis indicates a significant breakdown in prevention. Urgent communication with the employer is warranted to review exposure levels and protect other workers.

B. Accelerated Silicosis. Accelerated silicosis occurs within 2–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is as follows:

1. Symptoms—shortness of breath, cough, and sometimes sputum production. Workers with accelerated silicosis are at high risk of tuberculosis, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis, and fatigue, may herald one of these infections or the onset of lung cancer.

2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe disease.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

5. Clinical Course—accelerated silicosis has a rapid, severe course. Referral to a physician who is American Board of Medical Specialties (ABMS)-Certified in Pulmonary Medicine should be made whenever the diagnosis of accelerated silicosis is being considered. Referral to the appropriate specialist should be made if signs or symptoms of tuberculosis, other silica-related infections, or lung cancer are observed. As noted above, the clinician should also alert the employer of the need for immediate review of exposure controls in the worksite in order to protect other workers.

C. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of very high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include weight loss, fatigue, productive cough, hemoptysis, and pleuritic chest pain.

2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ‘‘ground glass’’ appearance of interstitial fibrosis will appear.

5. Clinical Course—workers with acute silicosis are at high risk of tuberculosis, atypical mycobaterial infections, and fungal superinfections. Because this disease is immediately life-threatening and indicates a profoundly high level of exposure, it constitutes an immediate medical and public health emergency. The worker must be urgently referred to a physician ABMS-certified in Pulmonary Medicine. As noted above, the clinician should also alert the employer of the need for immediate exposure controls in the worksite in order to protect other workers.

During medical surveillance examinations, clinicians should be alert for other silica-related health outcomes as described below.

D. Chronic Obstructive Pulmonary Disease (COPD). COPD, including chronic bronchitis and emphysema, has also been documented in silica-exposed workers, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each worker for progressive changes consistent with the development of COPD. Additionally, collective spirometry data for groups of workers should be evaluated for declines in lung function, thereby providing a mechanism to detect insufficient silica control measures for groups of workers.

E. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Early studies noted an association between workers with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks, 2007).

F. Tuberculosis (TB). Silica-exposed workers with latent TB are 3–30 times more likely to develop active pulmonary TB infection (ATS, 1997; Rees, 2007). Although silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics are known to be associated with increased rates of latent TB infection. The clinician should review the latest CDC information on TB incidence rates and high risk populations. Additionally, silica-exposed workers are at increased risk for contracting atypical mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii.*

G. Lung Cancer. The International Agency for Research on Cancer (IARC, 1997) classified silica as Group I (*carcinogenic to humans*). Additionally, several studies have indicated that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive (Brown, 2009).

II. Medical Surveillance

Clinicians who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section I of this Appendix. At each clinical encounter, the clinician should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. The following guidance includes components of the medical surveillance examination that are required under the Respirable Crystalline Silica standard, noted below in *italics.*

A. History. A complete work and medical history must be performed on the initial examination and every three years thereafter. Some of the information for this history must also be provided by the employer to the clinician. A detailed history is particularly important in the initial evaluation. Include the following components in this history:

1. Previous and Current Employment
   a. *Past, current, and anticipated exposures to respirable crystalline silica or other toxic substances*
   b. *Exposure to dust and other agents affecting the respiratory system*
   c. *Past, current, and anticipated work duties relating to exposures to respirable crystalline silica*
   d. *Personal protective equipment used, including respirators*
   e. *Previous medical surveillance*
2. Medical History
   a. All past and current medical conditions
   b. *Review of symptoms, with particular attention to respiratory symptoms*
   c. *History of TB infection and/or positive test for latent TB*
   d. *History of other respiratory system dysfunction such as obstructive pulmonary disease or lung cancer*
   e. History of kidney disease, connective tissue disease, and other immune disease/suppression
   f. Medications and allergies
   g. *Smoking status and history*
   f. Previous surgeries and hospitalizations

B. Physical Examination. A physical examination must be performed on the initial examination and every three years thereafter. The physical examination must emphasize the respiratory system and should include an examination of the cardiac system and an extremity examination for clubbing, cyanosis, or edema.

C. Tuberculosis (TB) Testing. Baseline testing for latent or active tuberculosis must be done on initial examination. Current CDC guidelines (*www.cdc.gov*) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained clinicians. Individuals with a positive TST result and those with uncertain test results should be referred to a local public health specialist. Clinicians may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek et al, 2010). Current CDC guidelines for acceptable tests for latent TB infection should be reviewed. Clinicians may perform periodic (*e.g.,* annual) TB testing as appropriate, based on individual risk factors. The diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS, 1997). Current CDC guidance on risk factors for TB should be reviewed periodically (*www.cdc.gov*). Workers who develop active pulmonary TB should be referred to the local public health department. Workers who have evidence of latent TB infection may be referred to the local public health department for evaluation and treatment.

D. Spirometry. Spirometry must be performed on the initial examination and every three years thereafter. Spirometry provides information about individual respiratory status, tracks an individual's respiratory status over time, and is a valuable surveillance tool to track individual and group respiratory function. However, attention should be paid to quality control (ACOEM 2011; ATS/ERS Task Force 2005). Abnormal spirometry results warrant further clinical evaluation and possible work restrictions and/or treatment.

E. Radiography. A chest roentgenogram, or an equivalent diagnostic study, must be performed on the initial examination and every three years thereafter. Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. *An International Labor Organization (ILO) reading must be performed by a NIOSH-certified "B" reader. If the B reading indicates small opacities in a profusion of 1/0 or higher, the worker must be referred to a physician who is certified by ABMS in pulmonary medicine.* Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Until the ILO endorses the use of digital standards, conventional chest radiographs are needed for classification using the ILO system. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed periodically on the ILO (*www.ilo.org*) or NIOSH (*www.cdc.gov/NIOSH*) Web sites.

F. Other Testing. It may be appropriate to include additional testing in a medical surveillance program such as baseline renal function tests (*e.g.,* serum creatinine and urinalysis) and annual TST testing for silica-exposed workers.

III. Roles and Responsibilities

A. The Physician or other Licensed Health Care Professional (PLHCP). The PLHCP designation refers to an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by the Respirable Crystalline Silica standard. The legally permitted scope of practice is determined by each State. Those licensed for independent practice may include physicians, nurse practitioners, or physician assistants, depending on the State. A medical surveillance program for workers exposed to silica should be directed by a health care professional licensed for independent practice. Health care professionals who provide clinical services for a silica medical surveillance program should have a thorough knowledge of the many silica-related diseases and health effects. Primary care practitioners who suspect a diagnosis of silicosis, advanced COPD, or other respiratory conditions causing impairment should promptly refer the affected individuals to a physician who is certified by ABMS in pulmonary medicine.

1. The PLHCP is responsible for providing the employer with a written medical opinion within 30 days of an employee medical examination. The written opinion must include the following information:

a. *A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to respirable crystalline silica.* The employer should be notified if a health condition likely to have been caused by recent occupational exposure has been detected. *Medical diagnoses and conditions that are not related to silica exposure must not be disclosed to the employer. Latent TB infection is not caused by silica exposure and must not be disclosed to the employer.* All cases of active pulmonary TB should be referred to the Public Health Department.

b. *Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators. Again, medical diagnoses not directly related to silica exposure must not be disclosed to the employer.* Guidelines regarding ethics and confidentiality are available from professional practice organizations such as the American College of Occupational and Environmental Medicine.

c. *A statement that the employee should be examined by a physician who is certified by ABMS in pulmonary medicine, where such a referral is necessary. Referral to a pulmonary specialist is required for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate.* A referral to the Public Health Department should not be disclosed to the employer. If necessary, a public health professional will contact the employer to discuss work-related conditions and/or to perform additional medical evaluations.

d. *A statement that the clinician has explained the results of the medical examination to the employee, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.*

2. State Reporting Requirements. Health care providers should be aware that some States require them to report cases of silicosis to the State Department of Health or to the State Department of the Environment.

B. Medical Specialists. *The Silica standard requires that all workers with chest X-ray B readings of 1/0 or higher be referred to an American Board Certified Specialist in Pulmonary Disease. The employer must obtain a written opinion from the specialist that includes the same required information as outlined above under IIIA1a, b, and d.* Employers should receive any information concerning evidence of silica-related risk in their workplace (*e.g.,* evidence of accelerated or acute silicosis tied to recent exposures), so that the employer can investigate and implement corrective measures if necessary. *The employer must receive any information about an examined employee concerning work restrictions, including restrictions related to use of protective clothing or equipment. Employers must not receive other medical diagnoses or confidential health information.*

C. Public Health Providers. Clinicians should refer latent and active TB cases to their local Public Health Department. In addition to diagnosis and treatment of individual cases, public health providers promptly evaluate other potentially affected persons, including coworkers. Because silica-exposed workers are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel findings. In addition to the local and state health departments, the National Institute of Occupational Safety and Health (NIOSH) can provide assistance upon request through their Health Hazard Evaluation program.

IV. Resources and References

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National Institute of Occupational Safety and Health (NIOSH) B reader Program. Access online for more information on interpretation of X-rays for silicosis and a list of certified B-readers. *http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html.*

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Screening and Surveillance of workers exposed to mineral dust; Gregory R. Wagner, Director, Division of Respiratory Diseases, NIOSH, Morgantown, WV, U.S.A.; WHO, Geneva 1996.

PART 1915—OCCUPATIONAL SAFETY AND HEALTH FOR SHIPYARD EMPLOYMENT

■ 5. The authority citation for 29 CFR part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), or 4–2010 (75 FR 55355), as applicable; 29 CFR part 1911.

Section 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

■ 6. In § 1915.1000, Table Z—Shipyards:

■ a. remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';

■ b. add ''Silica, crystalline, respirable dust; see 1910.1053'' in alphabetical order; and

■ c. revise the entry ''SILICA:'' under ''Mineral Dusts'', to read as follows:

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.d	ppm a *	mg/m 3 b *	Skin designation
* * *	*	*	*	*
Silica, crystalline, respirable dust; See 1910.1053				
* * *	*	*	*	*

MINERAL DUSTS

Substance	mppcf (j)
SILICA:	
Amorphous, including natural diatomaceous earth	20

* * * * *

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

■ 7. The authority citation for 29 CFR part 1926 is revised to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 et seq.); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), or 4–2010 (75 FR 55355), as applicable; and 29 CFR part 1911.

■ 8. In Appendix A to § 1926.55:

■ a. Remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';

■ b. add ''Silica, crystalline, respirable dust; see 1926.1053'' in alphabetical order; and
■ c. revise the entry ''SILICA:'' under ''Mineral Dusts'', to read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

Appendix A to § 1926.55—1970 American Conference of Governmental Industrial Hygienists' Threshold Limit Values of Airborne Contaminants

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.[d]	ppm[a]	mg/m^3 [b]	Skin designation
* * *	*	*	*	*
Silica, crystalline, respirable dust; see 1926.1053	....	....	....	....
* * *	*	*	*	*

MINERAL DUSTS

Substance	mppcf [j]
SILICA:	
Amorphous, including natural diatomaceous earth	20

* * * * *

■ 9. Add a new § 1926.1053, to read as follows:

§ 1926.1053 Respirable crystalline silica.

(a) *Scope and application.* (1) This section applies to all occupational exposures to respirable crystalline silica in construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 micrograms per cubic meter of air (25 $\mu g/m^3$), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Competent person means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Respirable crystalline silica means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

This section means this respirable crystalline silica standard, 29 CFR 1926.1053.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 $\mu g/m^3$, calculated as an 8-hour TWA.

(d) *Exposure assessment.* (1) *General.* (i) Except as provided for in paragraph (d)(8) of this section, each employer covered by this section shall assess the exposure of employees who are or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level.

(ii) The employer shall determine employee exposures from breathing zone air samples that reflect the 8-hour TWA exposure of each employee.

(iii) The employer shall determine 8-hour TWA exposures on the basis of one or more air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same job tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(2) *Initial exposure assessment.* (i) Except as provided for in paragraph (d)(2)(ii) of this section, each employer shall perform initial monitoring of employees who are, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level.

(ii) The employer may rely on existing data to satisfy this initial monitoring requirement where the employer:

(A) Has monitored employee exposures after [INSERT DATE 12 MONTHS PRIOR TO EFFECTIVE DATE OF FINAL RULE] under conditions that closely resemble those currently prevailing, provided that such monitoring satisfies the requirements of paragraph (d)(5)(i) of this section with respect to analytical methods employed; or

(B) Has objective data that demonstrate that respirable crystalline silica is not capable of being released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling.

(3) *Periodic exposure assessments.* If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If initial monitoring indicates that employee exposures are at or above the action level, the employer shall repeat air monitoring to assess employee exposures to respirable crystalline silica either under the fixed schedule prescribed in paragraph (d)(3)(i) of this section or in accordance with the performance-based requirement prescribed in paragraph (d)(3)(ii) of this section.

(i) *Fixed schedule option.* (A) Where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months.

(B) Where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months.

(C) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring for that employee, except as otherwise provided in paragraph (d)(4) of this section.

(ii) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(4) *Additional exposure assessments.* The employer shall conduct additional exposure assessments as required under paragraph (d)(3) of this section whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level.

(5) *Method of sample analysis.* (i) The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7.

(ii) The employer shall ensure that samples are analyzed by a laboratory that:

(A) Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard 17011:2004 for implementation of quality assessment programs;

(B) Participates in round robin testing with at least two other independent laboratories at least every six months;

(C) Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

(D) Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

(E) Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis;

(F) Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

(*1*) Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

(*2*) Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

(*3*) Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

(6) *Employee notification of assessment results.* (i) Within five working days after completing an exposure assessment in accordance with paragraph (d) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever the exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(8) *Specific operations.* (i) Where employees perform operations listed in Table 1 in paragraph (f) of this section and the employer has fully implemented the engineering controls, work practices, and respiratory protection specified in Table 1 for that operation, the employer is not required to assess the exposure of employees performing such operations.

(ii) For the purposes of complying with all other requirements of this section, the employer must presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL, unless the employer can demonstrate otherwise in accordance with the exposure assessment requirements of paragraph (d) of this section.

(e) *Regulated areas and access control.* (1) *General.* Wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) of this section or an access control plan in accordance with paragraph (e)(3) of this section.

(2) *Regulated areas option.* (i) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(ii) *Demarcation.* The employer shall demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundaries of the area and minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(iii) *Access.* The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(iv) *Provision of respirators.* The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(v) *Protective work clothing in regulated areas.* (A) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer shall provide either of the following:

(*1*) Appropriate protective clothing such as coveralls or similar full-bodied clothing; or

(*2*) Any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica.

(B) The employer shall ensure that such clothing is removed or cleaned upon exiting the regulated area and before respiratory protection is removed.

(3) *Written access control plan option.* (i) The employer shall establish and implement a written access control plan.

(ii) The written access control plan shall contain at least the following elements:

(A) Provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL;

(B) Procedures for notifying employees of the presence and location of areas identified pursuant to paragraph (e)(3)(ii)(A) of this section, and for demarcating such areas from the rest of the workplace where appropriate;

(C) For multi-employer workplaces, the methods the employer covered by this section will use to inform other employer(s) of the presence and location of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures that need to be taken to protect employees;

(D) Provisions for limiting access to areas where respirable crystalline silica exposures may exceed the PEL to effectively minimize the number of employees exposed and the level of employee exposure;

(E) Procedures for providing each employee and their designated representative entering an area where respirable crystalline silica exposures may exceed the PEL with an appropriate respirator in accordance with paragraph (g) of this section, and requiring each employee and their designated representative to use the respirator while in the area; and

(F) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica:

(*1*) Provisions for the employer to provide either appropriate protective clothing such as coveralls or similar full-bodied clothing, or any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica; and

(*2*) Provisions for the removal or cleaning of such clothing.

(iii) The employer shall review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary.

(iv) The employer shall make the written access control plan available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Specific operations.* For the operations listed in Table 1, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with paragraph (f)(1) of this section. (NOTE: The employer must comply with all other obligations of this section, including the PEL specified in paragraph (c) of this section.)

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
Using Stationary Masonry Saws.	Use saw equipped with integrated water delivery system. **Note:** Additional specifications: • Change water frequently to avoid silt build-up in water. • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Ensure saw blade is not excessively worn.	None	Half-Mask (10).

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
Using Hand-Operated Grinders.	Use water-fed grinder that continuously feeds water to the cutting surface.	None	Half-Mask (10).
	OR		
	Use grinder equipped with commercially available shroud and dust collection system, operated and maintained to minimize dust emissions. Collector must be equipped with a HEPA filter and must operate at 25 cubic feet per minute (cfm) or greater airflow per inch of blade diameter.	Half-Mask (10)	Half-Mask (10).
	Note: Additional specifications (wherever applicable): • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.		
Tuckpointing	Use grinder equipped with commercially available shroud and dust collection system. Grinder must be operated flush against the working surface and work must be performed against the natural rotation of the blade (*i.e.,* mortar debris must be directed into the exhaust). Use vacuums that provide at least 80 cfm airflow through the shroud and include filters at least 99 percent efficient.	Powered air-purifying respirator (PAPR) with loose-fitting helmet or negative pressure full facepiece (25).	Powered air-purifying respirator (PAPR) with loose-fitting helmet or negative pressure full facepiece (25).
	Note: Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working in enclosed spaces, provide sufficient ventilation to prevent build-up of visible airborne dust.		
Using Jackhammers and Other Impact Drillers.	Apply a continuous stream or spray of water at the point of impact.	None	Half-Mask (10).
	OR		
	Use tool-mounted shroud and HEPA-filtered dust collection system.	None	Half-Mask (10).
	Note: Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.		
Using Rotary Hammers or Drills (except overhead).	Use drill equipped with hood or cowl and HEPA-filtered dust collector. Eliminate blowing or dry sweeping drilling debris from working surface.	None	None.
	Note: Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Use dust collector in accordance with manufacturer specifications.		
Operating Vehicle-Mounted Drilling Rigs for Rock.	Use dust collection system around drill bit and provide a low-flow water spray to wet the dust discharged from the dust collector.	None	None.
	Note: Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • Half-mask respirator is to be used when working under the shroud. • Use dust collector in accordance with manufacturer specifications.		
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained. • Incoming air is filtered through a prefilter and HEPA filter.	None	None.

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
	• Cab is maintained as free as practicable from settled dust. • Door seals and closing mechanisms are working properly.		
Operating Vehicle-Mounted Drilling Rigs for Concrete.	Use dust collection system around drill bit and provide a low-flow water spray to wet the dust discharged from the dust collector. **Note:** Additional specifications: • Use smooth ducts and maintain duct transport velocity at 4,000 feet per minute. • Provide duct clean-out points. • Install pressure gauges across dust collection filters. • Activate LEV before drilling begins and deactivate after drill bit stops rotating. • Operate equipment such that no visible dust is emitted from the process. • Use dust collector in accordance with manufacturer specifications.	None	Half-Mask (10).
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained. • Incoming air is filtered through a prefilter and HEPA filter. • Cab is maintained as free as practicable from settled dust. • Door seals and closing mechanisms are working properly.	None	None.
Milling	For drivable milling machines:. Use water-fed system that delivers water continuously at the cut point to suppress dust. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the drum box and conveyor areas.	None	Half-Mask (10).
	For walk-behind milling tools: Use water-fed equipment that continuously feeds water to the cutting surface.	None	Half-Mask (10).
	OR Use tool equipped with commercially available shroud and dust collection system. Collector must be equipped with a HEPA filter and must operate at an adequate airflow to minimize airborne visible dust. **Note:** Additional specifications: • Use dust collector in accordance with manufacturer specifications including airflow rate.	None	Half-Mask (10).
Using Handheld Masonry Saws.	Use water-fed system that delivers water continuously at the cut point.		
	Used outdoors	None	Half-Mask (10).
	Used indoors or within partially sheltered area	Half-Mask (10)	Half-Mask (10).
	OR Use saw equipped with local exhaust dust collection system.		
	Used outdoors	Half-Mask (10)	Half-Mask (10).
	Used indoors or within partially sheltered area	Full Facepiece (50)	Full Facepiece (50).
	Note: Additional specifications: • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Use dust collector in accordance with manufacturer specifications.		
Using Portable Walk-Behind or Drivable Masonry Saws.	Use water-fed system that delivers water continuously at the cut point.		

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
	Used outdoors	None	None.
	Used indoors or within partially sheltered area	Half-Mask (10)	Half-Mask (10).
	Note: Additional specifications: • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.		
Rock Crushing	Use wet methods or dust suppressants	Half-Mask (10)	Half-Mask (10).
	OR		
	Use local exhaust ventilation systems at feed hoppers and along conveyor belts. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the process.	Half-Mask (10)	Half-Mask (10).
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained; • Incoming air is filtered through a prefilter and HEPA filter; • Cab is maintained as free as practicable from settled dust; and • Door seals and closing mechanisms are working properly.	None	None.
Drywall Finishing (with silica-containing material).	Use pole sander or hand sander equipped with a dust collection system. Use dust collector in accordance with manufacturer specifications.	None	None.
	OR		
	Use wet methods to smooth or sand the drywall seam	None	None.
Use of Heavy Equipment During Earthmoving.	Operate equipment from within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained; • Incoming air is filtered through a prefilter and HEPA filter; • Cab is maintained as free as practicable from settled dust; and • Door seals and closing mechanisms are working properly.	None	None.

NOTE 1: For the purposes of complying with all other requirements of this section, the employer must presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL.

NOTE 2: Where an employee performs more than one operation during the course of a day, and the total duration of all operations combined is > 4 hr/day, the required air-purifying respirator for each operation is the respirator specified for > 4 hr/day. If the total duration of all operations combined is ≤ 4 hr/day, the required air-purifying respirator for each operation is the respirator specified for ≤ 4 hr/day.

(3) *Abrasive blasting.* In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply with the requirements of 29 CFR 1926.57 (Ventilation) where abrasive blasting operations are conducted using crystalline silica-containing blasting agents, or where abrasive blasting operations are conducted on substrates that contain crystalline silica.

(4) *Cleaning methods.* (i) The employer shall ensure that accumulations of crystalline silica are cleaned by HEPA-filter vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(ii) Compressed air, dry sweeping, and dry brushing shall not be used to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(5) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during work operations for which engineering and work practice controls are not feasible;

(iii) During work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) During periods when the employee is in a regulated area; and

(v) During periods when the employee is in an area where respirator use is required under an access control plan pursuant to paragraph (e)(3) of this section.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(3) *Specific operations.* For the operations listed in Table 1 in paragraph (f) of this section, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with the requirements for selection of respirators in 29 CFR 1910.134 paragraph (d).

(h) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration), interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader, or an equivalent diagnostic study;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume at one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (h)(2) (except paragraph (h)(2)(v)) of this section at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The written opinion shall contain:

(A) A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;

(B) Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators;

(C) A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) of this section if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and

(D) A statement that the PLHCP has explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

(ii) The employer shall ensure that the PLHCP does not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to respirable crystalline silica.

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(6) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a pulmonary specialist, the employer shall make available a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion.

(ii) The employer shall ensure that the examining pulmonary specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (h)(4) of this section.

(iii) The employer shall obtain a written medical opinion from the pulmonary specialist that meets the requirements of paragraph (h)(5) (except paragraph (h)(5)(i)(C)) of this section.

(i) *Communication of respirable crystalline silica hazards to employees.* (1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (i)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) *Employee information and training.* (i) The employer shall ensure that each affected employee can demonstrate knowledge of at least the following:

(A) Specific operations in the workplace that could result in exposure to respirable crystalline silica, especially operations where exposure may exceed the PEL;

(B) Specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, including appropriate work practices and use of personal protective equipment such as respirators and protective clothing;

(C) The contents of this section; and

(D) The purpose and a description of the medical surveillance program required by paragraph (h) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each affected employee.

(j) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all exposure measurement results used or relied on to characterize employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, operation, or activity and how the data support the assessment; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's and pulmonary specialist's written opinions; and

(C) A copy of the information provided to the PLHCPs and pulmonary specialists as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(k) *Dates.* (1) *Effective date.* This section shall become effective [INSERT DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(2) *Start-up dates.* (i) All obligations of this section, except engineering controls required by paragraph (f) of this section and laboratory requirements in paragraph (d)(5)(ii) of this section, commence 180 days after the effective date.

(ii) Engineering controls required by paragraph (f) of this section shall be implemented no later than one year after the effective date.

(iii) Laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date.

Appendix A to § 1926.1053—Medical Surveillance Guidelines (Non-Mandatory) Introduction

The purpose of this non-mandatory Appendix is to provide helpful information about complying with the medical surveillance provisions of the Respirable Crystalline Silica standard, as well as to provide other helpful recommendations and information. Medical screening and surveillance allow for early identification of exposure-related health effects in individual workers and groups of workers, respectively, so that actions can be taken to both avoid further exposure and prevent adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences. Thus, medical surveillance of silica-exposed workers requires involvement of clinicians with thorough knowledge of silica-related health effects and a public health perspective.

This Appendix is divided into four sections. Section I reviews silica-related diseases, appropriate medical responses, and public health responses. Section II outlines the components of the medical surveillance program for workers exposed to silica. Section III describes the roles and responsibilities of the clinician implementing the program and of other medical specialists and public health providers. Section IV provides additional resources.

I. Recognition of Silica-Related Diseases

Overview. Silica refers specifically to the compound silicon dioxide (SiO_2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with a number of adverse health effects. Exposure to respirable crystalline silica can occur in foundries, industries that have abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing.

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined.

A. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is as follows:

1. Symptoms—Shortness of breath and cough, although workers may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as mycobacterium tuberculosis infection (TB) or lung cancer. Workers with these symptoms should immediately receive further evaluation and treatment.

2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

3. Spirometry—may be normal or may show only mild restriction or obstruction.

4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ''eggshell calcifications'' are seen.

5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease.

Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Additionally, a case of acute or accelerated silicosis indicates a significant breakdown in prevention. Urgent communication with the employer is warranted to review exposure levels and protect other workers.

B. Accelerated Silicosis. Accelerated silicosis occurs within 2–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is as follows:

1. Symptoms—shortness of breath, cough, and sometimes sputum production. Workers with accelerated silicosis are at high risk of tuberculosis, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis, and fatigue, may herald one of these infections or the onset of lung cancer.

2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe disease.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

5. Clinical Course—accelerated silicosis has a rapid, severe course. Referral to a physician who is American Board of Medical Specialties (ABMS)-Certified in Pulmonary Medicine should be made whenever the diagnosis of accelerated silicosis is being considered. Referral to the appropriate specialist should be made if signs or symptoms of tuberculosis, other silica-related infections, or lung cancer are observed. As noted above, the clinician should also alert the employer of the need for immediate review of exposure controls in the worksite in order to protect other workers.

C. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of very high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include weight loss, fatigue, productive cough, hemoptysis, and pleuritic chest pain.

2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ''ground glass'' appearance of interstitial fibrosis will appear.

5. Clinical Course—workers with acute silicosis are at high risk of tuberculosis, atypical myco-baterial infections, and fungal superinfections. Because this disease is immediately life-threatening and indicates a profoundly high level of exposure, it constitutes an immediate medical and public health emergency. The worker must be urgently referred to a physician ABMS-certified in Pulmonary Medicine. As noted above, the clinician should also alert the employer of the need for immediate exposure controls in the worksite in order to protect other workers.

During medical surveillance examinations, clinicians should be alert for other silica-related health outcomes as described below.

D. Chronic Obstructive Pulmonary Disease (COPD). COPD, including chronic bronchitis and emphysema, has also been documented in silica-exposed workers, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each worker for progressive changes consistent with the development of COPD. Additionally, collective spirometry data for groups of workers should be evaluated for declines in lung function, thereby providing a mechanism to detect insufficient silica control measures for groups of workers.

E. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Early studies noted an association between workers with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks, 2007).

F. Tuberculosis (TB). Silica-exposed workers with latent TB are 3–30 times more likely to develop active pulmonary TB infection (ATS, 1997; Rees, 2007). Although silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics are known to be associated with increased rates of latent TB infection. The clinician should review the latest CDC information on TB incidence rates and high risk populations. Additionally, silica-exposed workers are at increased risk for contracting atypical mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii.*

G. Lung Cancer. The International Agency for Research on Cancer (IARC, 1997) classified silica as Group I (*carcinogenic to humans*). Additionally, several studies have indicated that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive (Brown, 2009).

II. Medical Surveillance

Clinicians who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section I of this Appendix. At each clinical encounter, the clinician should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. The following guidance includes components of the medical surveillance examination that are required under the Respirable Crystalline Silica standard, noted below in *italics.*

A. History. A complete work and medical history must be performed on the initial examination and every three years thereafter. Some of the information for this history must also be provided by the employer to the clinician. A detailed history is particularly important in the initial evaluation. Include the following components in this history:

1. Previous and Current Employment
   - a. *Past, current, and anticipated exposures to respirable crystalline silica or other toxic substances*
   - b. *Exposure to dust and other agents affecting the respiratory system*
   - c. *Past, current, and anticipated work duties relating to exposures to respirable crystalline silica*
   - d. *Personal protective equipment used, including respirators*
   - e. *Previous medical surveillance*
2. Medical History
   - a. All past and current medical conditions
   - b. *Review of symptoms, with particular attention to respiratory symptoms*
   - c. *History of TB infection and/or positive test for latent TB*
   - d. *History of other respiratory system dysfunction such as obstructive pulmonary disease or lung cancer*
   - e. History of kidney disease, connective tissue disease, and other immune disease/suppression
   - f. Medications and allergies
   - g. *Smoking status and history*
   - f. Previous surgeries and hospitalizations

B. Physical Examination. A physical examination must be performed on the initial examination and every three years thereafter. The physical examination must emphasize the respiratory system and should include an examination of the cardiac system and an extremity examination for clubbing, cyanosis, or edema.

C. Tuberculosis (TB) Testing. Baseline testing for latent or active tuberculosis must be done on initial examination. Current CDC guidelines (*www.cdc.gov*) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained clinicians. Individuals with a positive TST result and those with uncertain test results should be referred to a local public health specialist. Clinicians may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek et al, 2010). Current CDC guidelines for acceptable tests for latent TB infection should be reviewed. Clinicians may perform periodic (*e.g.,* annual) TB testing as appropriate, based on individual risk factors. The diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS, 1997). Current CDC guidance on risk factors for TB should be reviewed periodically (*www.cdc.gov*). Workers who develop active pulmonary TB should be referred to the local public health department. Workers who have evidence of latent TB infection may be referred to the local public health department for evaluation and treatment.

D. Spirometry. Spirometry must be performed on the initial examination and every three years thereafter. Spirometry provides information about individual respiratory status, tracks an individual's respiratory status over time, and is a valuable surveillance tool to track individual and group respiratory function. However, attention should be paid to quality control (ACOEM 2011; ATS/ERS Task Force 2005). Abnormal spirometry results warrant further clinical evaluation and possible work restrictions and/or treatment.

E. Radiography. A chest roentgenogram, or an equivalent diagnostic study, must be performed on the initial examination and every three years thereafter. Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. *An International Labor Organization (ILO) reading must be performed by a NIOSH-certified "B" reader. If the B reading indicates small opacities in a profusion of 1/0 or higher, the worker must be referred to a physician who is certified by ABMS in pulmonary medicine.* Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Until the ILO endorses the use of digital standards, conventional chest radiographs are needed for classification using the ILO system. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed periodically on the ILO (*www.ilo.org*) or NIOSH (*www.cdc.gov/NIOSH*) Web sites.

F. Other Testing. It may be appropriate to include additional testing in a medical surveillance program such as baseline renal function tests (*e.g.,* serum creatinine and urinalysis) and annual TST testing for silica-exposed workers.

III. Roles and Responsibilities

A. The Physician or other Licensed Health Care Professional (PLHCP). The PLHCP designation refers to an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by the Respirable Crystalline Silica standard. The legally permitted scope of practice is determined by each State. Those licensed for independent practice may include physicians, nurse practitioners, or physician assistants, depending on the State. A medical surveillance program for workers exposed to silica should be directed by a health care professional licensed for independent practice. Health care professionals who provide clinical services for a silica medical surveillance program should have a thorough knowledge of the many silica-related diseases and health effects. Primary care practitioners who suspect a diagnosis of silicosis, advanced COPD, or other respiratory conditions causing impairment should promptly refer the affected individuals to a physician who is certified by ABMS in pulmonary medicine.

1. The PLHCP is responsible for providing the employer with a written medical opinion within 30 days of an employee medical examination. The written opinion must include the following information:

a. *A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to respirable crystalline silica.* The employer should be notified if a health condition likely to have been caused by recent occupational exposure has been detected. *Medical diagnoses and conditions that are not related to silica exposure must not be disclosed to the employer. Latent TB infection is not caused by silica exposure and must not be disclosed to the employer.* All cases of active pulmonary TB should be referred to the Public Health Department.

b. *Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators. Again, medical diagnoses not directly related to silica exposure must not be disclosed to the employer.* Guidelines regarding ethics and confidentiality are available from professional practice organizations such as the American College of Occupational and Environmental Medicine.

c. *A statement that the employee should be examined by a physician who is certified by ABMS in pulmonary medicine, where such a referral is necessary. Referral to a pulmonary specialist is required for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate.* A referral to the Public Health Department should not be disclosed to the employer. If necessary, a public health professional will contact the employer to discuss work-related conditions and/or to perform additional medical evaluations.

d. *A statement that the clinician has explained the results of the medical examination to the employee, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.*

2. State Reporting Requirements. Health care providers should be aware that some States require them to report cases of silicosis to the State Department of Health or to the State Department of the Environment.

B. Medical Specialists. *The Silica standard requires that all workers with chest X-ray B readings of 1/0 or higher be referred to an American Board Certified Specialist in Pulmonary Disease. The employer must obtain a written opinion from the specialist that includes the same required information as outlined above under IIIA1a, b, and d.* Employers should receive any information concerning evidence of silica-related risk in their workplace (*e.g.,* evidence of accelerated or acute silicosis tied to recent exposures), so that the employer can investigate and implement corrective measures if necessary. *The employer must receive any information about an examined employee concerning work restrictions, including restrictions related to use of protective clothing or equipment. Employers must not receive other medical diagnoses or confidential health information.*

C. Public Health Providers. Clinicians should refer latent and active TB cases to their local Public Health Department. In addition to diagnosis and treatment of individual cases, public health providers promptly evaluate other potentially affected persons, including coworkers. Because silica-exposed workers are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel findings. In addition to the local and state health departments, the National Institute of Occupational Safety and Health (NIOSH) can provide assistance upon request through their Health Hazard Evaluation program.

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