

As a result, the specific legislative authority in the submission is no longer in effect. In addition to the above changes, Texas's technical and equivalency method has not identified and quantified accurately the covered fleets in the Federal and State covered areas. The Texas CFF program has excluded certain covered fleets from its total fleet aggregation in the El Paso and Houston/Galveston nonattainment areas. Without an adequate determined fleet baseline for comparison, the SIP revision's technical evaluation is not sufficiently comprehensive to determine equivalency with the Federal CFF program. These and additional concerns with the State CFF program and broad compliance exemptions lead EPA to conclude that the State has not made a convincing and compelling demonstration of equivalency with the Federal CFF program. A more detailed discussion of the Texas CFF program elements and control strategy can be found in the Technical Support Document available from the EPA Region VI office.

III. Proposed Action

The EPA is proposing disapproval of the Texas CFF SIP revision submitted to EPA on August 6, 1996. The State's proposed substitute program is codified in 30 Texas Administrative Code, Chapter 114, Sections 114.30, 114.32 through 114.34, and 114.36 through 114.40. The EPA is soliciting public comments on the proposed action discussed in this notice. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional office listed in the **ADDRESSES** section of this notice.

The regional office, with EPA's Office of Mobile Sources has initiated efforts to help ensure that this action is consistent with the Act and will not interfere with any applicable requirement concerning attainment or any other applicable requirement of the Act.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP will be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. State Options

The following are options available to Texas in the implementation of its CFF Program. The State may choose to; adopt the Federal CFF Program; or

revise the current Texas CFF program and resubmit to EPA or substitute another State program or control strategy for the Texas CFF program. Such a substitution could be a stationary or mobile source control program, but only if it consists exclusively of provisions other than those required under the Act.

V. Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. See 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

The EPA's disapproval of the State request under section 110 and subchapter I, part D of the Act does not affect any existing requirements applicable to small entities. Any preexisting Federal requirements remain in place after this disapproval. Federal disapproval of the State submittal does not affect its State enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate or to private sectors, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that

may be significantly or uniquely impacted by the rule.

The EPA has determined that the disapproval action proposed does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and Recordkeeping requirements.

Dated: October 8, 1997.

Jerry Clifford,

Acting Regional Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

42 CFR Part 84

National Institute for Occupational Safety and Health; Certification of Respiratory Devices Used to Protect Workers in Hazardous Environments

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of priorities for rulemaking.

SUMMARY: In response to public comments received from its May 16, 1996, request (61 FR 24740), NIOSH is announcing the intended priority order for the development of the next proposed rule amendments (modules) to the current NIOSH procedures for certifying respiratory devices used to protect workers in hazardous environments. The priority order is based on the comments and data in the public record. The priority order of the planned modules is provided to help the respirator community plan for potential changes.

FOR FURTHER INFORMATION CONTACT: Roland Berry Ann, NIOSH, 1095 Willowdale Road, Morgantown, West

Virginia 26505-2888, telephone (304) 285-5907.

Availability and access of copies:

Additional copies of this notice can be obtained by calling the NIOSH toll-free information number (1-800-35-NIOSH, option 5, 9 a.m.-4 p.m. ET); the electronic bulletin board of the Government Printing Office, (202) 512-1387; and the NIOSH Home Page on the World-Wide Web (<http://www.cdc.gov/niosh/homepage.html>).

SUPPLEMENTARY INFORMATION: NIOSH intends to propose technical modules in the following areas:

1. Powered Air Purifying Respirator (PAPR)—Establishment of N, R, and P series filters; Use of active low flow or low pressure warning devices; and Addition of new duration ratings.
2. Airline Respirator—Single airline for pneumatic devices and breathing air; Airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits); Metabolic simulator tests; Air flow/pressure rate requirements; and Air flow measuring and warning devices.
3. Self Contained Breathing Apparatus (SCBA)—Maximum weight limit, with accessory definition; Upgrade of cylinder air specifications; Incorporation of National Fire Protection Association (NFPA) requirements; Non-facepiece SCBA; Metabolic simulator tests; Air flow/pressure rate requirements; and Alternatives to Department of Transportation and Compressed Gas Association requirements.
4. Gas and Vapor Respirator—Certification to a wider variety of specific substances and addition of service life categories.

NIOSH intends to propose three Administrative/Quality Assurance modules. The intended subjects for these modules are:

1. Corrections to 42 CFR part 84 and existing program policies not included in the regulations.
2. Upgrade of Quality Assurance requirements; Use of independent quality auditors in the certification program and updated fee schedule.
3. Use of independent testing laboratories in the certification program and restructured fee schedule.

I. Background

On May 16, 1996, NIOSH published a document in the **Federal Register** (61 FR 24740) to request public comments on what the agency's priorities should be in the area of respirator certification. NIOSH sought public comments on issues of privatization and fees related to possible changes in its administration of respirator certification, and comments on establishing priorities for

future rulemaking. NIOSH held three public meetings in June 1996 to discuss these issues. All comments provided in response to the notice were considered in developing the rulemaking priorities.

II. Public Comment on Priority Issues

Thirty-two commenters responded to the document including: eleven respirator manufacturers, seven private sector testing and certification laboratories, five safety professionals, two public utilities, two trade or manufacturers' associations, one Federal agency, one National Laboratory, one fire department, one professional society, and one respirator accessory manufacturer.

III. Ranking Criteria for Technical Modules

NIOSH requested input on what determinants should be used as the criteria to rank the priority of each module, in addition to recommendations for module subject areas. The determinants for ranking listed in the notice were; consideration of the number of persons (workers) affected, the seriousness of hazards or problems that would be addressed, the extent to which changes would improve protection, opportunity for cost savings (reducing costs for manufacturers and purchasers of respirators) and the expediency by which a change could be implemented (e.g., the existence of adoptable consensus standards).

NIOSH specifically sought comments on the following issues for prioritizing the development of modules: the criteria to prioritize each module, existing national or international standards that could be adopted to replace current NIOSH certification requirements, and public health effects of any recommended changes.

A. Discussion of Comments Received

Commenters generally agreed with the determinants listed in the notice. Two commenters stated that allowing flexibility of design and innovative approaches to design and use, as well as encouraging new product development should be included in the priority ranking criteria.

B. Conclusions

NIOSH believes that the ability to use innovative approaches and flexibility in design results in new product development. Performance standards allow manufacturers to use innovative approaches and flexibility in design, resulting in new products to address hazards. NIOSH intends to develop performance-based technical criteria to the extent possible in its rulemaking

activities. Therefore, although neither of these suggestions were included as determinants in the priority ranking criteria, NIOSH expects both will result from the rulemaking activities.

The ranking criteria used to develop the module priority order was: the number of workers affected, the seriousness of hazards or problems that would be addressed, the extent to which changes would improve protection, the expediency by which a change can be implemented (e.g., the existence of adoptable consensus standards), and opportunity for cost savings (reducing costs for manufacturers and purchasers of respirators).

IV. Technical Module Priority

NIOSH requested input to develop a complete, ranked list of priorities for rulemaking, including justification for the ranking. NIOSH specifically sought comments on the following issues for module development ranking: changes needed to current respirator certification requirements in the modules identified in the notice, subject areas for improving current certification requirements not identified in the notice, suggested module rankings, with ranking criteria and data or reasoning, industries and workers affected by potential changes, technical feasibility of suggested changes, economic impact to respirator manufacturers, purchasers, and users, and other factors related to the priority ranking.

A. Discussion of Comments Received

NIOSH has developed a ranked list of priorities for rulemaking, including justification for the ranking based on the comments received. Areas recommended for modification by commenters were grouped into feasible modules, then ranked according to the priority ranking criteria. The ranking justifications, based on the available supporting information, are included with the listing of the identified modules in IV.B. Conclusions.

The purpose of this notice is to inform the respirator community of regulatory priorities to allow research and planning to be coordinated with the development of new standards. NIOSH research and development efforts will be directed primarily at the highest priority areas identified in this notice. NIOSH also encourages others in the respirator community to conduct research in the identified module areas.

Research results and planning information for the regulatory priorities identified in this notice should be submitted to the NIOSH docket when they become available. The information will then be in a forum for public

review and comment. The information received in the NIOSH docket will establish a database to help develop future regulatory proposals.

Most of the determinants in the ranking criteria are based up the agency's current understanding of the capabilities of the manufacturing community as well as the science upon which the product development is based. Chief among these is the expediency by which a change can be implemented. NIOSH has attempted to estimate the research needed for each identified module in this priority-ranking process. It must be recognized that module development will be based on the successful completion of research in most of the identified module areas. Therefore, the rulemaking order of the identified modules may vary slightly from the priority order identified in this notice.

B. Conclusions

The following module list identifies the priority assessment for development of technical improvements based on the information provided by commenters:

1. Powered Air Purifying Respirator (PAPR)

Areas for potential modification in this module are: Establishment of N, R, and P series filters; Use of active low flow or low pressure warning devices; and Addition of new duration ratings.

The regulations require the PAPR battery to have a service time sufficient to maintain a stated air flow throughout 4 hours of operation during a silica dust loading test with particulate filters.

One commenter stated that the current requirements result in units that are too heavy and burdensome for most applications. Another commenter specifically suggested that modifications should be made to allow a light weight hood type PAPR for the health-care industry.

One commenter recommended the requirement of low flow and negative pressure warning devices to assure workers are protected from overbreathing the PAPR air supply. This commenter also recommended the establishment of a pressure demand PAPR. Two other commenters suggested the use of these devices and breathing-assist devices to establish positive pressure and negative pressure classes of PAPR's. These commenters indicated that PAPR duration may be able to be defined by an active alarm from a low pressure or low flow sensor, signaling an end of the battery's service life.

Presently, the filter choices for use with PAPR's has been limited to only high efficiency particulate air (HEPA)

filters with the implementation of part 84. Commenters indicated that additional choices are necessary.

Four commenters stated that the regulations should be modified to include the same filter classes for PAPR's as are provided for non-powered filter respirators under 42 CFR 84. PAPR filter testing was included in the proposed 42 CFR 84 (59 FR 26850), but was not included in the final rule because additional research is needed to make the proposed tests more feasible and consistent with the part 84 filter tests.

Seven commenters indicated that PAPR requirements should be the top priority for technical revision of the regulations. The possibility of increased worker protection with lighter, cheaper units was represented by most of these commenters.

Estimates of more than 500,000 PAPR users in chemical, health care, pharmaceutical, agriculture and welding were provided by a commenter.

2. Airline Respirator

Areas for potential modification in this module are: Single airline for pneumatic devices and breathing air; Airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits); Metabolic simulator tests; Air flow/pressure rate requirements; and Air flow measuring and warning devices.

Presently, 42 CFR part 84 does not contain a respirator classification that allows a single airline to the person for pneumatic devices and breathing air. NIOSH has recommended against this practice due to concerns over potential contamination of the air supply, and the high potential for negative impacts on respirator performance. In the absence of a dedicated breathing-air system, there is an increased risk of a contaminated air supply and negative impacts on respirator performance due to: backflow of contaminants from the pneumatic device line to the respirator air supply, low air flow and pressure to the respirator from a severed pneumatic-tool line, and excessive air flow and pressure from a blocked pneumatic-tool line.

Four commenters asserted that the breathing air could be filtered to Grade D specifications at the person wearing the respirator (e.g. on the belt). They stated that technology is available to ensure that an air filtering system incorporated into a respirator design would provide Grade D breathing air at the wearer, and this design should be certified by NIOSH. One of the commenters indicated that by providing safeguards against robbing air from the respirator, or feedback from pneumatic

tools, a criteria could be developed for supplied air respirators (SAR) that allow a single airline for tools and breathing air. The use of air flow or pressure devices were suggested to provide needed assurances and warning of appropriate user air supply. Three of the commenters indicated that appropriate European standards that NIOSH could adopt exist for such a respirator class.

Presently, there is a standardized set of exercises and work rate criteria used in the evaluation of SAR's. The use of a metabolic simulator for testing was recommended by two commenters to help eliminate the variability associated with human testing. According to several commenters, the criteria for certifying SAR's could be upgraded by modifying the class criteria to reflect differing work rates with minimum flow rates and pressure differential from atmosphere. This would result in new, additional classifications for SAR's. One commenter recommended the use of air flow volume measuring and low flow warning devices. Three commenters suggested that a positive pressure class be defined. Another commenter suggested that a positive pressure within the facepiece should be required at the tested work rate.

Two commenters stated that a criteria is needed for NIOSH-acceptance of airline suits for respiratory protection. These commenters asserted that airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits) have been used for respiratory protection against hazardous and toxic substances for twenty years under a Department of Energy acceptance program. In addition to respiratory protection, one of the commenters stated that the suits provide benefits such as total body protection and relief of heat stress. A Los Alamos National Laboratory evaluation protocol (LA-10156-MS) was recommended for as an acceptable criteria by both commenters.

Estimates of 50,000 auto body shops with over 100,000 workers, with additional unnumbered workers in other industries were given by one commenter as potential users of single airline respirators.

Several commenters stated that workers were improperly protected because the NIOSH-certified supplied air respirators were not conducive to use because they require two airlines to separate pneumatic device air from breathing air. Estimates were given that less than 5% of U.S., more than 95% of British, and more than 90% of European auto painters use proper respirators. Cost savings and greater user acceptance were projected based on the possible

elimination of the installation and maintenance of a second airline.

3. Self Contained Breathing Apparatus (SCBA)

Areas for potential change in this module are: maximum weight limit, with accessory definition; Upgrade of cylinder air specifications; Incorporation of NFPA requirements; Non-facepiece SCBA; Metabolic simulator tests; Air flow/pressure rate requirements.

Presently, 42 CFR part 84 limits the weight of a completely assembled and fully charged SCBA apparatus to 35 pounds for most units. A maximum weight of 40 pounds is allowed only where the weight decreases by more than 25 percent of its initial charge weight during its rated service life or where an apparatus employs a cooling system. NIOSH does not include the weight of accessories in the total weight of a respirator.

Four commenters suggested that the maximum weight limit of an SCBA apparatus should be permitted to exceed 35 pounds where other fire fighter protective clothing or equipment is incorporated with the SCBA. One of them recommended a definition for accessories is needed to better define those items not included in the weight calculation. These commenters stated that this change could result in more comfort, greater protection, and a lower overall ensemble weight for fire fighters.

Presently, there is a standardized set of exercises and work rate criteria used in the evaluation of air supplied respirators. According to several commenters, the criteria for certifying SCBA's could be upgraded by modifying the class criteria to reflect differing work rates with minimum flow rates and pressure differential from atmosphere. This would result in new, additional classifications specifically for SCBA's. One commenter recommended the use of air flow volume measuring and low flow warning devices. Three commenters suggested that a positive pressure class be defined. Another commenter suggested that a positive pressure within the facepiece should be required at the tested work rate. One commenter suggested that the requirements for open circuit apparatus should be separated from the requirements for closed circuit apparatus.

The use of a metabolic simulator for testing was recommended by two commenters to help eliminate the variability associated with human testing.

Incorporation of standards consistent with life support efficacy portions of the

NFPA requirements were recommended to upgrade the current standards. Three commenters stated that some NFPA 1981–1992 requirements should be included in the NIOSH requirements. Higher air flow rates and lens abrasion resistance were provided as examples. One of these commenters recommended the incorporation of NFPA 1981–1992 for fire fighter SCBA, with some of the requirements applicable to all SCBA. This commenter also stated that the dew point and particulate level requirements of NFPA 1500–1992 should be required for SCBA cylinder air.

One commenter requested provisions be developed for NIOSH to approve SCBA without a facepiece. This commenter asserted that the National Aeronautics and Space Administration (NASA) has used non-facepiece, suit SCBA since the early 1960's without any serious problems. This commenter stated that similar suits are being developed for decontamination and decommissioning of Department of Energy sites and other chemical waste sites. The commenter recommended a revision to the regulations to allow NIOSH certification of this class of respirator.

One commenter suggested that NIOSH should accept alternatives to Department of Transportation (DOT) and Compressed Gas Association (CGA) cylinder requirements. This commenter asserted that a cylinder could be incorporated as an integral part of the SCBA design without a standardized CGA cylinder thread, which is design restrictive. The commenter also recommended that cylinder acceptances of other certifying agencies throughout the world be recognized as equivalent to the United State's DOT requirements. No user population size or overall user type estimates were provided by commenters for SCBA. However, NIOSH is aware of estimates of the number of fire fighters in the U.S. While not representing users of all SCBA, fire fighters are believed to be a significant portion of the SCBA user population.

According to the National Fire Protection Association's (NFPA) 1995 Fire Department Profile, there are 1,098,850 fire fighters (260,850 career and 838,000 volunteer) in the United States. According to the National Volunteer Fire Council, a non-profit membership association representing the interests of the volunteer fire, emergency medical, and rescue services, there are 1.5 million volunteer firefighters who staff more than 28,000 fire departments throughout the United States. The International Association of Fire Fighters (IAFF) represents over 225,000 professional fire fighters and

emergency medical personnel in the United States and Canada. In 1992, NIOSH estimated 400,000 firefighter SCBA's were in use by some 200,000 full time and 1,000,000 volunteer and non-municipal firefighters in the U.S.

4. Gas and Vapor Respirator

Areas for potential modification in this module are: Certification to a wider variety of specific substances and addition of service life categories.

Presently, NIOSH certifies gas and vapor (chemical cartridges included) respirators only to provide protection against only sixteen specific substances. Gas mask canisters and chemical cartridges may be classified for protection against the general category of organic vapors. Gas mask canisters may also be classified for protection against the general category of acid gases. Their use against substances with poor warning properties has not been recommended.

One commenter stated that there is a need for a new class of respirators for protection against the accidental release or terroristic use of chemical agents. This commenter asserted that local law enforcement, first response teams, and local and state agencies are seeking and need NIOSH-certified respirators in responding to these events. The use of existing facilities that test and evaluate equipment against chemical warfare agents for the military was proposed as an alternative to new NIOSH facilities.

The current standards in 42 CFR 84 provide for a canister or cartridge absorption capacity test criteria based on the respirator type. Two commenters indicated that NIOSH-certified canisters and cartridges are heavy and bulky because of too severe service life requirements. They asserted that various service times (or sorbent capacities) could be appropriately used, based on the conditions of use. They recommended modifying the certification standards to include other service time possibilities and absorption capacities under additional test parameters. One of these commenters recommended the regulations be modified to allow for certification of three cartridge capacity sizes by using three challenge levels of exposure for certification, similar to the European standards.

No precise user population estimates were cited by commenters. Users were identified only as unnumbered workers such as law enforcement personnel and first response teams with accidental release of chemical agents and chemical warfare agents.

V. Notification of Revised Priority Assessment

A. Comment Request

NIOSH will readily notify respirator manufacturers directly about changes to the regulatory priorities established in this notice. NIOSH specifically sought comments on how respirator purchasers and users should be notified of revised priorities.

B. Discussion of Results

Commenters suggested various mechanisms for notifying respirator purchasers and users of revised priorities. One commenter suggested the use of a Respirator Users' Notice. Three commenters suggested the use of the NIOSH internet Web site. Three commenters recommended the information be published in safety industry newspapers, magazines, and newsletters like the BNA "Occupational Safety and Health Reporter". Two commenters suggested the use of another **Federal Register** notice. One commenter each suggested that the respirator manufacturers, sales and marketing managers, and major users groups like the American Industrial Hygiene Association (AIHA), Chemical Manufacturers Association (CMA), National Association of Manufacturers (NAM), and American Iron and Steel Institute (AISI) be used to notify respirator purchasers and users.

C. Conclusions

NIOSH has established the priorities for rulemaking based on the comments received to the May 16, 1996 request. However, these priorities may change as new needs are identified or unforeseen delays are encountered with research efforts. New modules may be needed to respond to emerging hazards and developing technology.

Commenters failed to reveal any new mechanisms for NIOSH use to better disseminate rulemaking priority updates. NIOSH has used respirator-related mailing lists (including the Users Notice List and Respirator Manufacturers List), the NIOSH internet Web site, the Government Printing Office electronic bulletin board, press releases, and the NIOSH toll-free information number to disseminate **Federal Register** notices.

Publication of the information in safety industry newspapers, magazines, and newsletters is dependent on the publishers' expectations of reader interest. Dissemination of the information by the respirator manufacturers, sales and marketing managers, and major users groups depends on their willingness and ability

to relay the information to their clientele. NIOSH respirator-related mailing lists have historically been generated as a result of public comments or a request for respirator-related publications. World-Wide Web and electronic bulletin board listings rely on the reader to go to the site to find the information.

NIOSH will continue to disseminate **Federal Register** notices as in the past, while continuing to seek better notification methods.

VI. Administrative and Quality Assurance Issues

A. Private Sector Testing Laboratories

Specifically, NIOSH sought comments on the following issues for the potential use of private sector testing laboratories for the certification process:

- Capability of private sector testing laboratories to conduct the respirator testing currently performed by NIOSH.
- Qualification requirements of private laboratories if they were to perform certification and product audit testing under NIOSH guidance.
- Assignment of a manufacturer's respirators to testing laboratories by NIOSH or manufacturer choice among approved laboratories.
- Monitoring of private sector laboratories to assure quality service would be continued if they were to perform certification and product audit testing under NIOSH guidance.

1. Discussion of Comments Received

Many of the commenters endorsed, with reservation, the idea of empowering private sector testing laboratories to conduct the NIOSH certification testing. Concerns about NIOSH's ability to empower these laboratories were raised by most of the commenters. These concerns centered around (1) the existence of lab capability in the private sector, (2) impartiality and credibility of testing and (3) documentation of the NIOSH testing procedures and reproducibility of results.

Five commenters questioned the existence of testing laboratory capability in the private sector. Nine commenters supported the belief that private sector testing laboratories are capable of performing the NIOSH testing. Several of these commenters indicated that the testing ability and capacity currently exists with certification of self contained breathing apparatus to NFPA requirements. They further stated that added capacity would be quickly obtained for other respirators once the market was there.

Five commenters stated that the documentation of the NIOSH testing

procedures need to be improved before other testing authorities should be authorized to conduct the certification testing. These commenters expressed concern that test results would not be reproducible among a number of testing facilities. That is, test results could vary from laboratory to laboratory without an inter-laboratory validation program.

Concerns were raised by several commenters that impartiality and credibility would be lost with the testing portion of the certification process removed from NIOSH control. One commenter was concerned that any laboratory not have any vested interest in the certification of products or with manufacturers. A few commenters indicated increased NIOSH staff would be more productive than using private sector laboratories. These commenters felt that NIOSH resources would be consumed with oversight of accredited laboratories.

Another commenter stated that the survivability of private sector testing laboratories depends on their ability to demonstrate impartiality and credibility in their test results. Several other commenters indicated that use of already established accreditation or certification programs would require little or no additional NIOSH oversight.

Four commenters indicated that the European experience with privatization and U.S. certification authorities such as the NFPA and Safety Equipment Institute (SEI) have been good. Experiences with favorable turnaround times and costs were reported.

Commenters recommended that NIOSH adopt an existing system, rather than create a new one. Three commenters recommended accreditation by the American National Standards Institute (ANSI) to ANSI Z34.1. This standard was judged inappropriate for lab privatization by another because it is a complete program that includes design, QA and product testing requirements for the certification of manufacturers' products by the authorized entity. This is similar to the current NIOSH process. ISO Guide 25, a tool to assess and accept a laboratory's calibration and QA procedures for accurate and consistent results, was recommended by four commenters. Two more commenters suggested that NIOSH should become ISO certified as well.

2. Conclusions

NIOSH agrees with those commenters who stated that the use of private sector testing laboratories could expedite the approval process and the availability of the latest and safest technology. This will be accomplished only if the use of

these laboratories increases the resources available to conduct the tests. NIOSH shares the concern expressed by some commenters that an insufficient business base may exist to assure the increased resources, quality level and cost would be acceptable.

Private sector testing laboratories can be utilized in the certification of respirators, provided that adequate procedures and safeguards are in place. No existing testing laboratory accreditation or certification programs have standards and procedures that accredit or certify laboratories to perform the NIOSH tests. The procedures and standards to accredit or certify testing laboratories to conduct the NIOSH tests need to be developed before a laboratory could be accredited. Clear, objective test requirements and protocols that provide test results reproducible between laboratories also need to be finalized and made available before most NIOSH tests can be used by private testing laboratories.

NIOSH has determined that there are private sector testing laboratories with the capability to perform the NIOSH tests. However, NIOSH is concerned that there is insufficient testing capacity to meet the demand for testing. NIOSH has seen no evidence that this capacity is present, especially considering the comments that refined procedures are needed to allow others to conduct the NIOSH tests. Efforts to develop testing laboratory certification and auditing criteria will consume some NIOSH resources to establish the program.

NIOSH is continuing to explore options for the potential use of private sector testing laboratories for the certification process. However, the infrastructure to define and support the use of these laboratories remains to be established. NIOSH intends to propose an Administrative module to address the use of private sector testing laboratories for the certification process after the infrastructure needs are better determined.

B. Private Sector Quality Auditors

Specifically, NIOSH sought comments on the following issues for the potential use of private sector quality auditors for the certification process:

- Qualification requirements (e.g., certification by ANSI-Registrar Accreditation Board, United Kingdom Accreditation Service, International Auditor and Training Certification Association, etc.) of independent quality auditors if they were to perform manufacturing site audits under NIOSH guidance.
- Assurances of integrity for a program using private quality auditors.

- Frequency of audits needed to assure that only quality products are distributed.

- Auditing of manufacturing sites prior to the issuance of a NIOSH certification.

1. Discussion of Comments Received

No commenters opposed the use of private sector quality auditors for the certification process. Three commenters endorsed the use of the International Organization of Standardization certification standards (ISO) for evaluation of the manufacturers' quality assurance systems. Two of these commenters pointed out that, specifically, ISO 9001 should be adopted because it documents the design and development process, unlike ISO-9002.

The ISO standards were perceived by several commenters as sufficient to ensure the integrity of the program. One commenter stated that the ISO system requires auditors to be certified by authorities such as Underwriters Laboratories. A commenter stated that NIOSH must develop the criteria for an acceptable quality assurance plan for use by an ISO auditor. Two commenters believed that ISO 9001 audits could be used instead of NIOSH audits because the ISO audit would ensure the quality assurance plan is met. These same commenters thought that the ISO semiannual or annual frequency of audit was appropriate.

Two commenters pointed out that ISO 9000 requires site audits prior to registration. Therefore, if a manufacturer has been ISO-certified, they stated no NIOSH pre-certification audit would be needed. If the manufacturer has not been ISO-certified or is a new manufacturer, they stated that a NIOSH pre-certification audit would be appropriate.

2. Conclusions

Qualified quality auditors may be used to perform site audits for verification that the manufacturers' quality systems are being followed and are appropriate. Empowering qualified auditors would expand the audit portion of the certification program to levels consistent with most contemporary certification authority requirements. NIOSH has been developing audit guidelines that could enable a qualified auditor to evaluate compliance with the salient points of a manufacturer's quality assurance plan.

NIOSH is evaluating the appropriateness of the ISO 9000 series standards with NIOSH-added requirements specific to respirators, or equivalent, to evaluate a manufacturer's

quality system. NIOSH is also considering requirements for certification of auditors, and the oversight needed to ensure that audit quality is comparable to that which has been provided by NIOSH employees. Audits conducted by independent auditors would be used to complement NIOSH audits. The requirement for a pre-certification audit is also under evaluation. NIOSH intends to address the use of private sector quality auditors for the certification process in an Administrative/Quality Assurance module to be proposed in the near future.

C. Fee Schedule

Specifically, NIOSH sought comments on the following issues for updating the fee schedule to reflect the actual costs to maintain the program:

- Certification fee structure and calculation to recoup the cost of the certification process.
- NIOSH fee collection for manufacturing site and product audits.
- NIOSH fee collection for respirator complaint investigations.

1. Discussion of Comments Received

Eight commenters supported fair fee charges that accurately reflect the services received. These commenters stated that fees should be fair and equitable to NIOSH and the manufacturers. One of these commenters noted that excessive fees would be a deterrent to improving products, while another stated a willingness to pay more for faster approval. Two commenters recommended that collected fees be retained in the certification program to make it self-sustaining.

Five commenters did not think that NIOSH should recoup all costs of the program. One of these commenters felt there should not be charges for site and product audits. The other four argued against fees for product complaint investigations. One of them suggested there could be challenge procedures where the loser pays the investigative costs for a complaint. Another stated that the manufacturer should not be responsible for most complaints, because they are minor or frivolous. Another commenter believed that fees would be unfair because the manufacturer may not necessarily be at fault. The fifth commenter felt that NIOSH should bear the cost of complaint investigations because they are a NIOSH responsibility. Three of these commenters did indicate, however, that a fee may be appropriate if the basis for the complaint is

determined to be the manufacturer's fault.

Five commenters specifically endorsed a NIOSH fee to recoup the total cost for audits. One of these commenters stated that this would not be an additional expense for NIOSH or ISO-certified manufacturers if NIOSH accepted the results of ISO audits. Conversely, this commenter believed that NIOSH should conduct audits and charge fees to recoup their cost for manufacturers not ISO-certified. Another of these commenters suggested that the original fees that NIOSH charges for issuing a certification should include the costs of site and product audits.

One commenter stated that the fees should relate to all the tasks performed in the certification process. Another stated that the fee structure should include fees for each discrete, identifiable part of the process. A third commenter supported flat fees as the preferred fee structure. This commenter also stated that NIOSH should charge an hourly rate based on staff time and supply costs if flat rates can't be calculated. Two commenters suggested an annual maintenance fee based on the number of units produced or sales. One of these commenters further stated that an annual fee should be collected per model.

Two commenters suggested that fees should be reviewed and recalculated annually. Another commenter stated that the fees should be computed based on actual costs, and published for comment.

Several commenters recommended that collected fees be retained in the certification program to make it self-sustaining.

One commenter requested the establishment of fee accounts for withdrawal of fees when due.

2. Conclusions

The fees and fee structure for activities conducted in the certification program are currently based on the fee schedule contained in 42 CFR part 84. This fee schedule has not been updated since 1972. The costs of conducting a certification program have risen over the years, but these increased costs have not been reflected in certification charges. The fees charged for NIOSH services do not recover the costs to maintain the program.

NIOSH intends to update the current fee structure to offset the expenses and administrative costs of the program. NIOSH intends to update the current fee structure in an Administrative/Quality Assurance module to be proposed in the near future. For future updates in the

fees, NIOSH may consider other fee structures to better cover the program costs.

D. Component Part Certification

Specifically, NIOSH sought comments on the following issues for evaluation and certification of respirator component parts:

- Authorization of manufacturers other than the original respirator manufacturer for replacement parts.
- Effectiveness of replacement parts, if alternate suppliers for replacement parts were allowed.
- Component-specific requirements of replacement parts, if alternate suppliers for replacement parts were allowed.
- Certification of respirator components in addition to, or instead of, complete respirators.
- Other certifying agencies or standards organizations that allow suppliers other than the original manufacturer to provide replacement parts for certified units.
- Monitoring of alternate suppliers, if suppliers other than the original manufacturer were permitted to provide replacement parts.
- Monitoring of replacement parts, if suppliers other than the original manufacturer were permitted to provide them.
- Interchangeability of parts by design specifications, if alternate suppliers for replacement parts were allowed.

1. Discussion of Comments Received

Three commenters endorsed the concept of component certification for the manufacture and sale of replacement parts by persons other than the respirator manufacturer. Two of these commenters stated that other standards or certifying organizations, including NFPA, allow third party replacement parts. One commenter stated that lower prices for respirators and disposable parts would result from standards that facilitate interchangeability of some parts. Two commenters stated that the replacement parts should be certified just as complete respirators, documenting equivalent form, fit and function of the original respirator. Component-specific requirements should be able to be covered in the general certification scheme, according to one commenter.

Most commenters did not favor the concept of component certification for the manufacture and sale of replacement parts by persons other than the respirator manufacturer. Nine commenters objected to allowing replacement parts from a manufacturer

other than the respirator's original manufacturer. Respirator design restrictions to allow interchangeability of parts, copyright infringements and liability concerns were expressed as reasons for opposition.

Two commenters indicated that replacement parts by others should be permitted only if the manufacturer is in agreement. Four commenters voiced concerns of product liability of replacement parts by others. One commenter stated that the acceptable use of third party parts would encourage copyright infringements.

Six commenters believed there would be no way to verify original specifications are met with other manufacturers' parts. Therefore, they asserted, the certification program could not assure respirator system performance. Two commenters supported certification of complete respirators only. Two commenters stated that other standards, including SEI certification, Japanese, Korean, and Australian loosely-EN-based standards do not allow interchangeability of components.

Four commenters pointed out that interchangeability in Europe is allowed only for certain components. Two of these commenters asserted that the conformity required for interchangeability in Europe creates design restrictions. One commenter believed that developing component-based requirements would be horrendous. Another commenter reported the European experience to be that users don't utilize the option to obtain replacement parts from third parties. One commenter pointed to significant administrative expenses with testing and certification of replacement parts as another rationale for not adopting this concept.

Five commenters stated that NIOSH would need to monitor third party parts and suppliers the same as respirator manufacturers. Three commenters stated that allowing replacement parts by other than the respirator manufacturer would require testing to assure overall compliance of assembled respirator.

Some of the commenters opposing the concept recognized potential cost and program savings if a limited component certification program were developed. Three suggestions were made for components to be certified for use within the assembly of a single manufacturer's components, to make a complete respirator by the assembly of certified components. The certification for interchangeability of air lines and some air-supplied respirator parts were

also suggested as viable program options by two commenters.

2. Conclusions

The certification standards limit NIOSH to certify only complete respirators. Component parts are not evaluated independently. Any component part, or replacement part, certification program would require the development of component-specific requirements that ensure that the respirator continues to perform effectively.

No commenters raised safety or health concerns to support development of a component parts certification program. Only economic benefits were provided as reasons for support. Commenters raised seemingly valid safety and health, legal and technical concerns opposing component parts certification. Based on the comments received, NIOSH is not developing a component certification program at this time.

E. Product Auditing

Specifically, NIOSH sought comments on the following issues for product auditing of respirators:

- The maximum number of respirators per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH.
- Acquisition of products for audit (i.e., by voucher, reimbursement, random selection by NIOSH at the manufacturer or distributor).
- Reimbursement of NIOSH costs for product audits.

1. Discussion of Comments Received

One commenter stated that there should be no charge for conducting product audits. This commenter stated that auditing costs should be included in the cost of government enforcement activities. Another commenter believed that, with the resources available to the government, the government should pay for all products it acquires. Five commenters indicated that fees should relate to the task, and that the total cost for any audit should be charged. One of these commenters thought that the original fees for a certification should include costs of site and product audits.

One commenter suggested that products for audit should be selected from the manufacturer's warehouse during site audits, as is done in other programs. A second commenter recommended a voucher system be used to acquire audit samples from distributors. This commenter stated that it was important that the manufacturer not be allowed to pre-screen audit samples to assure compliance.

2. Conclusions

NIOSH has historically purchased product audit samples from distributors. Although NIOSH occasionally requests audit samples from the manufacturer's inventory during site audits, products for audit are predominately purchased with appropriated funds. This severely limits the number and type of products that can be audited each year.

NIOSH is considering options to obtain appropriate numbers of product audit samples from manufacturers at no cost to NIOSH. NIOSH intends to address the acquisition of product audit samples in an Administrative/Quality Assurance module to be proposed in the near future.

F. Approval Duration

Specifically, NIOSH sought comments on the following issues for limiting the time duration or number of units for which a respirator certification would be valid:

- Time limits for the NIOSH certification to be valid.
- Conditions for renewing a NIOSH certification, if it were time-limited.
- Recommended time limits for a NIOSH certification and renewal, if it were time-limited.
- Notification requirements for changes in production status and the number of produced units when production is halted.
- Affect on purchasers and users if the certification of their respirator expires.
- Benefits to purchasers and users of an expired certification.
- Benefits to purchasers and users of knowing the number of respirators produced under a certification.

1. Discussion of Comments Received

Generally, comments were divided on the issue of time limits on an approval. Five commenters opposed time limits, while four commenters endorsed the concept.

Suggestions for a renewal process varied. One commenter suggested that annual renewal should be required. Another commenter pointed out that the National Fire Protection Association's standard for firefighter SCBA certification (NFPA 1981) requires recertification every 5 years. Yet another commenter stated that product approvals of this type are generally required to be requalified after a one to five year period. One commenter believed that a complete resubmittal from the manufacturer of the product should be required 9 years after certification, or the authority to manufacture and sell the product as

NIOSH-certified would expire in the tenth year.

Commenters opposed to time or quantity limitations contended that certification expirations would cause undue user confusion and be overly burdensome on the manufacturers, and users would not benefit in knowing the population of specific models. One commenter pointed out that similar European requirements resulted in increased cost and obstructed sales. Several commenters also believed that production and sales levels are confidential to the manufacturer. Other commenters contended that such limitations were not needed because the evolution of products through technological advancements and approval schedule updates will limit the age of approvals that can remain active.

Three commenters suggested that NIOSH could require production change reports from the respirator manufacturers. A fourth commenter suggested that NIOSH could check the production status of approved respirators in conjunction with annual quality audits. Two commenters recommended that approvals be classified as Active, Inactive or Obsolete based on their production status. One of these commenters suggested inclusion of the production status in the NIOSH Certified Equipment List (CEL). Yet another commenter stated that users would be notified of an approval's expiration by removal from the equipment list.

2. Conclusions

NIOSH agrees with commenters who asserted that user notification of the status of NIOSH-certified respirators is important. NIOSH also agrees with commenters who believed that time or quantity limitations on certifications could create an added burden on manufacturers and NIOSH by creating added applications for recertification of products.

NIOSH is aware that manufacturers generally sell components individually that can be used in configurations covered under a number of certifications. Therefore, potentially little data exists to represent the number of respirators sold or in use under a specific approved design.

NIOSH has concluded that it would not be appropriate or beneficial to initiate time or quantity limitations on certifications at this time. The purpose of user notification on certifications could be served by receiving production status reports from respirator manufacturers to indicate if the respirator is currently being produced (active), no longer produced but units in

the field are supported with parts (inactive), or no longer in production or supported with replacement parts (obsolete).

The status listing of Active, Inactive, or Obsolete status is included in the NIOSH certified equipment list (CEL). In accordance with received comments, NIOSH is requesting the manufacturers to provide this production status information as soon as it becomes available, to update the CEL. NIOSH intends to address the reporting of production status information in an Administrative/Quality Assurance module to be proposed in the near future.

VII. Priority of Quality Assurance/Administrative Modules

Based on the comments received, NIOSH intends to propose three Administrative/Quality Assurance modules. The intended subjects for these modules are:

A. Corrections and Existing Policies

1. Discussion of Comments Received

One commenter recommended that NIOSH publish technical amendments to 42 CFR part 84 prior to any other modules. Specifically, this commenter requested clarification of the 200 mg. filter loading levels for particulate filters used in pairs.

One commenter suggested that air purifying respirators with end of service life indicators (ESLI) should be certified for polyisocyanate catalyzed paints. Several commenters stated that workers were improperly protected because the adequate NIOSH-certified (supplied-air) respirators were not conducive to use. Estimates of 50,000 auto body shops with over 100,000 workers, with additional unnumbered workers such as law enforcement personnel and first response teams with accidental release of chemical agents and chemical warfare agents were given.

Air-purifying respirators can be certified with ESLI's in accordance with requirements published in the **Federal Register** on July 19, 1984 (49 FR 29270). That notice provided for the approval of air purifying respirators with either effective passive or active ESLI for use against gases and vapors with adequate warning properties or for use against gases and vapors with inadequate warning properties whenever there is a regulatory standard already permitting the use of air purifying respirators.

Two commenters suggested a module to address self contained self rescuers (SCSR) that are used in the mining industry. Both commenters urged development of a duration testing

protocol using a metabolic simulator to replace human subject testing.

2. Conclusions

There are typographical errors in 42 CFR 84 to be corrected. There are also a number of existing program policies that have been developed since 1972 that are not included in the regulations. Policies affecting areas such as ESLI for air purifying respirators and service life plans for SCSR, need to be codified in the regulations as a single source for the respirator approval requirements.

NIOSH will publish a module to make corrections and incorporate all existing certification program policies into 42 CFR 84.

B. Upgrade of Quality Assurance Requirements and Fee Schedule

1. Discussion of Comments Received

As discussed previously in VI.B., no commenter opposed the use of private sector quality auditors in the certification program. Commenters also generally endorsed the use of ISO-9000 or similar quality assurance requirements. NIOSH acceptance of audits conducted by private sector auditors was also generally recommended by commenters.

As discussed previously in VI.C., the majority of commenters supported fees that reflect the costs of the certification program.

As discussed previously in VI.F., a number of commenters supported use of the NIOSH CEL to notify respirator users of the production status of approved respirators.

2. Conclusions

NIOSH intends to publish a module to address the use of independent quality auditors, respirator production status information and updated fees.

C. Use of Independent Testing Laboratories in the Certification Program and Restructured Fee Schedule

1. Discussion of Comments Received

As discussed previously in VI.A., a number of commenters expressed reservations about the ability of NIOSH to use private sector testing laboratories in the certification program. Several concerns, such as the availability of test procedures and the accreditation method, were presented.

As discussed previously in VI.C., some of the comments on fee revision recommended substantial changes to the fees structure. These recommendations included concepts such as: retention of the fees in the certification program; annual maintenance fees; and fees for complaint investigations.

2. Conclusions

NIOSH intends to publish a module to address the use of independent testing laboratories and a restructured fee schedule.

VIII. Continued Comments

As stated previously, NIOSH is requesting additional comments and information on content for the modules identified and prioritized in this notice. Comments for the need to prioritize other module topics are also welcomed. NIOSH will periodically review the information in the docket to assist in determining if a priority reassessment is needed. Comments should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-8450, fax (513) 533-8285. Comments may also be submitted by e-mail to: DMM2@CDC.GOV. E-mail attachments should be formatted as WordPerfect 4.2, 5.0, 5.1/5.2, 6.0/6.1, or ASCII files.

Dated: October 8, 1997.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97-210, RM-9166]

Radio Broadcasting Services; Soldiers Grove, WI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Lyle Robert Evans d/b/a Rural Radio Company proposing the allotment of Channel 290A to Soldiers Grove, Wisconsin, as that community's first local FM broadcast service. There is a site restriction 11.8 kilometers (7.3 miles) northeast of the community at coordinates 43-28-16 and 90-40-21. **DATES:** Comments must be filed on or before November 24, 1997, and reply comments on or before December 9, 1997.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Lyle Robert Evans, d/b/a Rural Radio Company,