ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[FRL–6229–4]

RIN 2060–AF04

National Emission Standard for Hazardous Air Pollutants; National Emission Standards for Radon Emissions From Phosphogypsum Stacks

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating revisions to the National Emission Standard for Hazardous Air Pollutants (NESHAP) that sets limits on radon emissions from phosphogypsum stacks, codified as subpart R of 40 CFR part 61. The Agency is taking today's action in response to a petition for reconsideration from The Fertilizer Institute (TFI), which critiqued the risk assessment EPA performed in support of the version of subpart R promulgated in 1992. Today's action raises the limit on the quantity of phosphogypsum that may be used for indoor research and development from 700 to 7,000 pounds, eliminates current sampling requirements for phosphogypsum used in indoor research and development, and clarifies sampling procedures for phosphogypsum removed from stacks for other purposes.

DATES: These regulations are effective April 5, 1999. Petitions for judicial review of this final action must be filed no later than April 5, 1999.

ADDRESSES: Copies of the two documents entitled ''Risk Assessment for Research and Development Uses of Phosphogypsum'' and ''Statistical Procedures for Certifying Phosphogypsum for Entry into Commerce'' may be obtained by writing to this address. A summary of comments received on the proposed rule accompanied by the Agency's responses may be obtained by requesting the response to comment document entitled ''Comments and Response to Comments—NESHAPS; National Emission Standards of for Radon Emissions from Phosphogypsum Stacks on Amendments to Subpart R.''

FOR FURTHER INFORMATION CONTACT: Pat Tilson; telephone number (202) 564–9762; address: Radiation Protection Division, Mail Code 6602J, U.S. Environmental Protection Agency, Washington, DC 20460; email address: tilson.pat@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket

Docket No. A–79–11 contains the public record supporting the final rule revising 40 CFR Part 61, Subpart R, which EPA issued in 1992 (57 FR 23305, June 3, 1992). It also contains the August 3, 1992, TFI petition, and the EPA response partially granting and partially denying the TFI petition (59 FR 14040, March 24, 1994). Docket No. A–94–57 contains certain documents which led to the May 8, 1996, proposal and this final rulemaking. These dockets are available for public inspection between the hours of 8 a.m. and 5 p.m., Monday through Friday, in room M1500 of Waterside Mall, 401 M Street, SW, Washington, DC 20460. A reasonable fee may be charged for copies of documents.

Introduction

Purpose of Today's Action and Summary of Changes to Subpart R

The Agency is promulgating revisions to those portions of Subpart R of 40 CFR part 61 which concern: (1) the distribution and use of the substance, phosphogypsum, for indoor research and development purposes; (2) the sampling and measurement of radium-226 in phosphogypsum; and (3) use of phosphogypsum for outdoor agricultural purposes. The Environmental Protection Agency is taking today's action in response to issues raised in a petition for reconsideration from The Fertilizer Institute which questioned aspects of the risk assessment EPA performed in support of the rulemaking that revised Subpart R in 1992. The risk assessment was an evaluation of the risk to persons who perform research and development activities in a laboratory using phosphogypsum. Phosphogypsum—a byproduct of the wet-acid process of producing phosphoric acid from phosphate rock—contains naturally occurring radiation emitted by uranium-238 and its decay products such as radium-226 and radon-222. Exposure to the radiation emitted by these and other radionuclides in phosphogypsum can increase an individual's probability of developing cancer. If present in quantities above certain limits, the radionuclides in phosphogypsum could cause unacceptable risks of incurring fatal cancer.

Specifically, today's action revises § 61.205 to conform to the technical findings EPA made when it re-evaluated the risk assessment used to promulgate Subpart R in 1992. *See* 57 FR 23305, June 3, 1992. EPA found that the risk assessment contained errors in the calculation of the quantity of the radioactive gas, radon-222, that would be present in a laboratory in which phosphogypsum was used for indoor research and development purposes. Today's action revises the limit set by Subpart R on the amount of phosphogypsum that may be used in indoor research and development from 700 pounds upward to 7,000 pounds. In addition, today's action provides clarification on how to determine compliance with the new, 7,000-pound limit, such as whether this limit should be applied on a facility-by-facility or on an experiment-by-experiment basis.

In addition, the Agency is removing the requirement to sample and measure the radium-226 in phosphogypsum that is used for indoor research and development activities because Subpart R does not contain a corresponding limit on the concentration of radium-226 in phosphogypsum when it is used for these activities. Sampling of radium-226 concentrations must still be performed when phosphogypsum is used for outdoor agricultural purposes, as set forth in § 61.204, and when application is made to EPA for approval to use phosphogypsum for other purposes pursuant to § 61.206. Today's action makes minor changes to §§ 61.204 and 61.205 to draw the distinction more sharply between the uses of phosphogypsum which are covered by the respective sections.

In addition, the Agency is revising section 61.207 to establish the level of statistical uncertainty that is allowed in measurements of radium-226 in phosphogypsum. These measurements are performed in connection with outdoor agricultural uses of phosphogypsum and those other uses of phosphogypsum that the Agency approves on a case-by-case basis.

History of the NESHAP for Phosphogypsum and TFI's Petition for Reconsideration

EPA first promulgated the NESHAP for phosphogypsum stacks on December 15, 1989. At that time, the standard required that all phosphogypsum be disposed of in stacks. Phosphogypsum stacks are large, on-site disposal piles composed of the excess phosphogypsum formed during the wet-acid process. Unlike subsequent versions of Subpart R, the 1989 standard did not permit alternate uses of phosphogypsum such as for indoor research and development.

EPA subsequently received several petitions requesting that it reconsider setting standards that would permit alternatives to disposal of phosphogypsum in stacks. Petitioners argued that EPA had not considered the

implications of these alternatives when it set the 1989 rule. EPA agreed to convene a rulemaking to evaluate the attendant risks of these alternatives to disposal and establish standards under which these alternatives might be permissible. *See* 55 FR 13480, April 10, 1990. EPA promulgated revisions to Subpart R after analyzing the associated risks of alternate uses and evaluating the comments received on the proposed rule. *See* 57 FR 23305, June 3, 1992. The revised Subpart R permitted uses of phosphogypsum that fall into three categories: (1) Outdoor agricultural uses, for example as a conditioner for soils containing high quantities of salt or low quantities of calcium and other nutrients; (2) indoor research and development activities, for example to study the production of road-base and building materials using phosphogypsum; and (3) other alternate uses that are approved by EPA on a case-by-case basis.

Subsequently, TFI sought judicial review of the 1992 rule in The Fertilizer Institute v. Environmental Protection Agency, No. 92–1320 (D.C. Cir.). TFI also filed a petition with EPA on August 3, 1992, requesting EPA to reconsider the 1992 rule pursuant to section 307(d)(7)(B). A second suit was brought against the Agency by ManaSota-88 in ManaSota-88 v. Browner, No. 92–1330 (D.C. Circuit). EPA entered settlement discussions with TFI and ManaSota-88, and agreed jointly to move the D.C. Circuit Court of Appeals to stay judicial review of the 1992 rule. The Court granted the motion. As part of that agreement, EPA agreed to make a final decision whether to grant or deny TFI's petition for reconsideration. EPA decided to partially deny and partially grant the petition after careful review of all the objections to the 1992 rule set forth in the petition for reconsideration. *See* 59 FR 14040, March 24, 1994. The principal purpose of the present rulemaking is to effectuate the decision by EPA to partially grant the TFI petition.

Statutory Basis and the Benzene Policy

EPA initially promulgated the NESHAP for phosphogypsum stacks on December 15, 1989 pursuant to Section 112 of the Clean Air Act (CAA). In 1990, Section 112 was amended by the Clean Air Act Amendments of 1990. Section 112(q)(2) of the CAA, as amended, specifically provides that Section 112 of the CAA shall remain in effect for, *inter alia*, radionuclide emissions from phosphogypsum stacks.

Under the CAA, as in effect prior to enactment of the Clean Air Act Amendments of 1990, the Agency, in establishing risk-based standards, must follow the method specified in the ''Vinyl Chloride decision.'' *Natural Resources Defense Council* v. *EPA*, 824 F.2d 1146 (D.C. Cir. 1987). The Vinyl Chloride decision requires that these Section 112 standards be established in two steps. In the first step, the Agency determines a ''safe'' or ''acceptable'' level of risk by considering only health-related factors. Next, the Agency may make the standard more protective considering costs and technological feasibility. The resulting standard must protect public health with an ample margin of safety.

EPA implemented the Vinyl Chloride decision in 1989 with the promulgation of the NESHAP for benzene. This rulemaking established the ''Benzene Policy'' by which EPA sets standards under Section 112 of the Clean Air Act, as in effect prior to enactment of the Clean Air Act Amendments of 1990. *See* 54 FR 38044 (September 14, 1989). The Benzene Policy sets forth the specific criteria EPA uses when determining the safe level of risk set by NESHAPs. Any amendments or revisions to the existing NESHAP for phosphogypsum would have to meet these criteria for the Agency to consider it adequately protective of public health with an ample margin of safety. Included among these criteria is the requirement that NESHAPs protect the individual receiving the highest lifetime risk to a level of 1 in 10,000.

Description of the Final Rule

Today's action affects those portions of Subpart R which cover the use of phosphogypsum in indoor research and development found at § 61.205 and the procedures for sampling and measurement of radium-226 in phosphogypsum found at § 61.207. In addition, today's rulemaking revises § 61.204 to clarify that agricultural uses that occur in an indoor laboratory must comply with § 61.205, while outdoor agricultural uses of phosphogypsum must comply with § 61.204.

The New 7,000 Pound Limit on Indoor Research and Development Uses

Today's action raises the limit set by § 61.205(b)(2) on the amount of phosphogypsum that may be used in indoor research and development from 700 pounds to 7,000 pounds. The Agency is revising the limit to conform to the technical findings it made when it re-evaluated the risk assessment used to promulgate Subpart R in 1992. Specifically, EPA found that the risk assessment contained errors in the calculation of the quantity of the radioactive gas, radon-222, that would be present in a laboratory in which phosphogypsum was being used for research and development purposes. EPA has revised three of the key assumptions used in these calculations. A complete discussion of the changed parameters and the effect of these changes on the presence of radon-222 are contained in the document, ''Risk Assessment of Research and Development Uses of Phosphogypsum.'' First, EPA revised the assumption made regarding the number of drums of phosphogypsum that would be opened at any one time and from which radon-222 could therefore escape to the ambient air in the laboratory. During the 1992 rulemaking, EPA's risk assessment assumed that five such drums would be open. EPA changed this assumption to reflect that at most only one single drum would be open under actual conditions in laboratories. Public comments on the notice of proposed rulemaking noted that laboratories typically use phosphogypsum a few pounds at a time, making it unnecessary to have several drums open simultaneously.

Second, EPA changed the assumption regarding how much of the radon-222 that is present in the phosphogypsum actually emanates into the ambient air of the laboratory. When setting the 1992 rule, EPA had assumed that all the radon-222 generated by the radium-226 in phosphogypsum would be released. EPA's new risk assessment reconsiders such factors as the rate at which air is ventilated from a laboratory, the size of the laboratory and the effect of moisture on the rate of emanation of radon-222 from the phosphogypsum.

Third, EPA revised the assumption on the number of hours a researcher spends in the laboratory from 4,000 hours down to 1,000 hours per year. The value of 4,000 hours that was used in the 1992 rulemaking exceeded by 100 percent the typical occupational year of 2,000 hours. The value of 1,000 hours was judged to be a more realistic estimate.

By making these three changes and re-calculating the risk, EPA found that the use of 7,000 pounds of phosphogypsum for indoor research and development purposes would cause a risk that was just slightly higher than 1 in 100,000. It was apparent that revising the regulation so as to permit 7,000 pounds of phosphogypsum would still meet the presumptively safe risk level of 1 in 10,000 that EPA established with the Benzene Policy.

EPA requested public comment on what practical advantages a higher limit of 7,000 pounds would provide in the Notice of Proposed Rulemaking (61 FR 20775, May 8, 1996). The comments received by the Agency indicated that

the higher limit would permit larger scale experiments yielding results which can be applied more accurately to real uses of phosphogypsum. Comments also stated that the higher limit would permit a facility to keep phosphogypsum in one large, 7,000-pound storage area rather than in several smaller separate storage areas associated with each individual experiment or activity. (For more on how to apply the 7,000-pound limit, see discussion below on how regulated parties should determine if individual laboratories and experiments are in compliance.) Further comments stated that the health risk corresponding to 7,000 pounds of phosphogypsum was acceptable, especially given the view that EPA's conservative choice of parameter values (e.g., hours spent inside a laboratory) led to over-estimates of the risk to persons doing research. Other comments expressed concern, however, that doses to persons performing radium extraction might be higher than in routine handling in other indoor research and development. EPA's revised risk assessment nonetheless shows that even handling the large amounts of phosphogypsum required for extracting radium would not cause risks in excess of the 1 in 10,000 level set by the Benzene Policy, provided that the 7,000-pound limit was not exceeded. Based on the public comments received and the findings of EPA's revised risk assessment, EPA is amending the limit on the amount of phosphogypsum to 7,000 pounds. For further discussion of the revised risk assessment, see the document, ''Risk Assessment of Research and Development Uses of Phosphogypsum.''

How to Determine Compliance With the 7,000-Pound Limit

Today's action revises § 61.205(b)(2) to clarify how compliance is determined with the 7,000 pound limit. Both TFI's petition and many public comments on the notice of proposed rulemaking (61 FR 20775, May 8, 1996) expressed confusion over whether this limit applies to one room (i.e., a ''laboratory''), an entire building, etc. In other words, is the correct method for determining compliance to add up the total pounds of phosphogypsum in use, everywhere for all experiments and rooms in a facility, and testing this total against the 7,000-pound limit? Or should compliance be determined by separately comparing the phosphogypsum used in each experiment and/or room to the 7,000-pound limit?

The Agency first evaluated the health risk implied by each of the above two methods of determining compliance. The risk assessment examined whether a person working in a facility that had several ongoing projects of 7,000 pounds would experience greater risk than a person working in a facility having only one such project. The risk breaks down to the sum of two types of radiation risks: (1) the risk from direct gamma radiation; and (2) the risk from inhaled radon which is generated by the presence of radium-226. With respect to gamma radiation, the risk assessment assumes that the researcher is exposed to 10 drums (7,000 pounds) in the same room for 1,000 hours, at a distance of one meter. A researcher might receive additional gamma radiation if any other experiments were taking place elsewhere in the building. EPA's risk assessment considered this latter possibility. The effect of gamma radiation from these additional rooms would, however, be substantially decreased the further away a person is located from the source. Hence, EPA's risk assessment found that the researcher would for the most part only be affected by the gamma radiation from the drums in the room he is standing in. The risk due to gamma radiation would effectively remain unchanged with either way of determining compliance with the 7,000-pound limit.

The second component of risk, the inhalation of radon-222, would not increase if additional experiments took place in nearby rooms within the same building. This results from the fact that the air in rooms where separate experiments occur would effectively remain isolated; the radon-222 in one room would not migrate to other rooms and increase the radon-222 concentration found within the other rooms. The combined risk from gamma radiation and inhaled radon-222 effectively would be the same whether the limit applied separately to the different projects within a facility or if it limited the total phosphogypsum from all research activities within a research complex to 7,000 pounds. A more in-depth discussion is contained in ''Risk Assessment for Research and Development Uses of Phosphogypsum.''

Based on the findings of the risk assessment and public comments received on the notice of proposed rulemaking, EPA revised § 61.205(b)(2) of Subpart R so that the 7,000-pound limit applies separately to each individual research and development activity. In addition, no more than 7,000 pounds may be stored in any room at a research and development facility. Thus, a particular facility may purchase or possess more than 7,000 pounds of phosphogypsum for use in multiple research activities, so long as it does not exceed this limit for any individual research activity and no one room within the facility contains more than this limit.

Difference in Applicability Between Sections 61.204 and 61.205

EPA is revising § 61.205(b)(5) to clarify that research and development activities authorized by this section must occur indoors in a controlled laboratory setting that the public cannot enter freely, except on an infrequent basis for tours of the facility. In addition, EPA is revising the title of § 61.205 to indicate that this section applies to indoor research and development. EPA is making these revisions in response to both TFI's petition and public comments. These parties expressed uncertainty as to which section of Subpart R would apply to agricultural uses of phosphogypsum that are conducted for the purpose of research and development. To this end, EPA has added clarifying language to § 61.205(b)(5) of the final rule that specifies that *outdoor* agricultural research and development must comply with § 61.204, on *outdoor agricultural uses.* As a compliment to this new language, EPA has added language to § 61.204 to specify that agricultural research and development that occurs indoors, in a laboratory, must comply with § 61.205, on *indoor research and development in a laboratory.*

To summarize, outdoor uses of phosphogypsum must comply with either § 61.204, ''Distribution and use of phosphogypsum for outdoor agricultural purposes'' or § 61.206, ''Distribution and use of phosphogypsum for other purposes.'' Section 21.206 allows EPA to authorize, on a case-by-case basis, indoor and outdoor uses not covered or authorized by §§ 61.204 and 61.205. Phosphogypsum that remains in outdoor stacks must comply with the numerical limits of § 61.202.

Situations in Which Sampling of Radium-226 is Required

Today's action removes the portions of §§ 61.205(a) and 61.207(a) requiring sampling of phosphogypsum that is to be used for indoor research and development activities. TFI's petition and many public comments on the notice of proposed rulemaking noted that Subpart R does not establish any limit on the concentration of radium-226 in phosphogypsum used pursuant to § 61.205, only on the number of pounds that are used. Hence, these parties noted that the existing requirement on sampling would merely add hundreds of dollars of cost without

increasing the assurance that public health is being protected with an ample margin of safety.

By removing this requirement, EPA will not change the level of protection afforded to persons who perform indoor research and development. The risk assessment EPA performed on indoor research and development assumed that the phosphogypsum would have a very high concentration of radium-226 (equal to 26 pCi/g) and set a pound limit appropriate to this assumption. This high level of radium-226 represents the radium concentration found in the most radioactive phosphogypsum stacks, which are in Florida. The 7,000-pound limit controls the radiological cancer risk because it has the effect of limiting the total quantity of radium-226 that is present.

Sampling of radium-226 concentrations must nonetheless still be performed when phosphogypsum is used for outdoor agricultural purposes, as set forth in § 61.204, and when application is made to EPA under § 61.206 for approval of phosphogypsum use for other purposes.

Procedures for Sampling and Measurement of Radium-226

The Agency is substantially revising § 61.207, on sampling and measurement of phosphogypsum, to clarify what levels of statistical uncertainty are allowable in measurements of radium-226 in phosphogypsum. The 1992 rule established the requirement for measurement and sampling of phosphogypsum used for outdoor agricultural uses under § 61.204 and for ''other uses'' under § 61.206. TFI's petition and the public comments on the notice of proposed rulemaking noted that the 1992 rule did not specify the allowable uncertainties. Today's action provides clarification on the statistical method that must be followed to establish this statistical uncertainty.

The following discussion relies on several statistical terms. *Critical value* means the percentile value, α, of a probability distribution above or below which only α per cent of the probability lies. Thus there is a .05 probability that a normally distributed variable will have a value above the upper 5% critical value, which is calculated by summing the product of 1.64 times the standard deviation of the distribution to the mean of the distribution. When testing an hypothesis, α is the level of significance, and determines the critical value.

Hypothesis testing means a procedure for the statistical determination of the validity of an hypothesis. A test statistic, such as the standard normal variable, is calculated for the purpose of discriminating between a null hypothesis and an alternative.

Level of significance means the probability, α of rejecting the null hypothesis in a test of an hypothesis.

Sampling distribution means a probability distribution assumed by a statistic such as the sample mean, calculated from a sample drawn from a population.

Under this final rule, the procedure for certifying an area of a phosphogypsum stack for entry into commerce requires the collection of samples of phosphogypsum and the measurement of their radium-226 content. The samples must be collected from regularly spaced locations across the area of the stack being considered for entry into commerce. After the radium-226 concentration in each sample is measured, the mean and standard deviation of the collected samples must be calculated.

A decision rule, based on the sampling distribution for the sample mean, must be used to determine if the phosphogypsum is acceptable for entry into commerce. This rule requires the determination of the critical value for a 5% level of significance in the upper, or right hand, tail of the sampling distribution. The critical value is the 95th percentile of the sampling distribution.

The decision rule has three outcomes. If the critical value is less than or equal to 10 pico-curies per gram (pCi/g), phosphogypsum from this area of the stack can be entered into commerce. (By definition, one curie of a given radionuclide experiences 37 billion nuclear decays per second. A pico-curie (pCi) is one trillionth of one curie.) If the mean of the collected samples is greater than or equal to10 pCi/g, phosphogypsum from this area of the stack cannot be entered into commerce. If the sample mean is less than 10 pCi/g and the critical value is greater than 10 pCi/g, the phosphogypsum cannot be entered into commerce unless further testing is undertaken. The sample size must be increased, and the sample mean and standard deviation recalculated. The increased sample size reduces the standard deviation of the sampling distribution of the mean, thereby, reducing the interval between the mean of the sampling distribution and the critical value. This increases the ability of the decision rule to distinguish between the mean of the sample and the 10 pCi/g concentration limit, thereby improving the chance that the radium-226 concentration can be shown to be less than 10 pCi/g.

The reason for determining the critical value for the upper, or right hand, tail of the sampling distribution is the concern that the radium-226 concentration in the phosphogypsum not be greater than 10 pCi/g.

If a larger sample size is needed to demonstrate that the sample mean is less than 10 pCi/g, the number of additional samples required increases rapidly as the mean approaches 10 pCi/g, and can be quite large in cases where the sample mean is only slightly less than 10 pCi/g. In such cases the additional cost of certification may become a factor in the decision to continue with the attempt to enter the phosphogypsum from this area of the stack into commerce.

Any required additional samples must also be taken from regularly spaced locations across the area of the phosphogypsum stack being considered for entry into commerce. Once the required number of additional samples have been collected, the radium-226 concentrations in each additional sample must be measured. The mean and standard deviation of the radium-226 concentrations for the entire set of sample concentrations (including those previously measured) must be recalculated and a new sampling distribution established. The critical value for a 5% level of significance in the upper tail is established once again. The decision rule must then be revisited. As before, phosphogypsum from this area of the stack can be entered into commerce only if the critical value is less than or equal to 10 pCi/g.

Although acceptance for entry into commerce is the objective of increasing the sample size and establishing the new sampling distribution and critical value, and is the expected outcome of the reconsideration, it is possible the recalculated critical value will not be less than or equal 10 pCi/g. This is because random variation in the new sample concentrations, which can result from nonuniformity in the distribution of radium-226 in the phosphogypsum and the random nature of radioactive decay, may cause an increased sample mean or standard deviation. Either or both of these increases can change the critical value so that it is not less than 10 pCi/g. If this is the case, either the sample size must be increased once again, and a new sampling distribution and critical value determined, or the attempt to certify that area of the stack for entry into commerce must be abandoned.

Judicial Review

This rulemaking action promulgates revisions of a national standard issued under Clean Air Act Section 112, 42 U.S.C. 7412. Any petition for judicial review of this action must be filed no later than April 5, 1999 in the United States Court of Appeals for the District of Columbia Circuit. Under Section 307(d)(7)(B) of the Clean Air Act, only those objections to this rule which were raised with reasonable specificity during the period for public comment or at the public hearing may be raised as part of such judicial review.

Regulatory Analyses

Regulatory Flexibility Act

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this rule under section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b). EPA has further determined that this final rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. Today's rule will have a positive economic impact on the great majority of entities regulated by subpart R, including small businesses. Specifically, this rule will allow greater quantities of phosphogypsum to be used and reduce costs of demonstrating compliance by removing certain regulatory requirements. No new restrictions, exclusions or limitations are being added. As such, this rule will lessen the regulatory burden on regulated entities, including small entities, which existed prior to today's action.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Today's final action contains no Federal mandates (under the regulatory provisions of Title II of UMRA) for State, local or tribal governments or the private sector.

Paperwork Reduction Act

There are no information collection requirements in this final rule.

Review Under Executive Order 12866

Under Executive Order 12866, 58 FR 51736 (October 4, 1993), EPA must determine whether a regulation is ''significant'' and therefore subject to review by the Office of Management and Budget. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

EPA has determined that this action does not meet any of the criteria enumerated above, and therefore does not constitute a ''significant regulatory action'' under the terms of the Order.

Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by E.O. 12866, and because it does not involve decisions on environmental health or safety risks that may disproportionately affect children.

Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

The National Technology Transfer and Advancement Act 2 of 1995 (NTTAA)

The National Technology Transfer and Advancement Act of 1995 (NTTAA), Section 12(d) of Pub L. No. 104–113, is designed to encourage the

adoption of standards developed by ''voluntary consensus bodies'' in regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs agencies to provide Congress, through OMB, explanations when a decision is made not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

The Congressional Review Act (CRA)

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective April 5, 1999.

List of Subjects in 40 CFR Part 61

Environmental protection, Air pollution control, Phosphogypsum, Radon, Radium.

Dated: January 27, 1999.

Carol Browner,

Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency amends 40 CFR part 61 as follows:

PART 61—[AMENDED]

1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 7401, 7412, 7413, 7416, 7601 and 7602.

Subpart R—National Emission Standards for Radon Emissions From Phosphogypsum Stacks

2. Amend § 61.204 by revising the section title, introductory text, paragraph (c), paragraph (d), and adding paragraph (e) to read as follows:

§ 61.204 Distribution and use of phosphogypsum for outdoor agricultural purposes.

Phosphogypsum may be lawfully removed from a stack and distributed in commerce for use in outdoor agricultural research and development and agricultural field use if each of the following requirements is satisfied:

* * * * *

(c) All phosphogypsum distributed in commerce for use pursuant to this section by the owner or operator of a phosphogypsum stack shall be accompanied by a certification document which conforms to the requirements of § 61.208(a).

(d) Each distributor, retailer, or reseller who distributes phosphogypsum for use pursuant to this section shall prepare certification documents which conform to the requirements of § 61.208(b).

(e) Use of phosphogypsum for indoor research and development in a laboratory must comply with § 61.205.

3. Amend § 61.205 by revising the section title and paragraphs (a) and (b) to read as follows:

§ 61.205 Distribution and use of phosphogypsum for indoor research and development.

(a) Phosphogypsum may be lawfully removed from a stack and distributed in commerce for use in indoor research and development activities, provided that it is accompanied at all times by certification documents which conform to the requirements of § 61.208. In addition, before distributing phosphogypsum to any person for use in indoor research and development activities, the owner or operator of a phosphogypsum stack shall obtain from that person written confirmation that the research facility will comply with all of the limitations set forth in § 61.206(b).

(b) Any person who purchases and uses phosphogypsum for indoor research and development purposes shall comply with all of the following limitations. Any use of phosphogypsum for indoor research and development purposes not consistent with the limitations set forth in this section shall be construed as unauthorized distribution of phosphogypsum.

(1) Each quantity of phosphogypsum purchased by a facility for a particular research and development activity shall be accompanied by certification documents which conform to the requirements of § 61.208.

(2) No facility shall purchase or possess more than 7,000 pounds of phosphogypsum for a particular indoor research and development activity. The total quantity of all phosphogypsum at a facility, as determined by summing the individual quantities purchased or possessed for each individual research and development activity conducted by that facility, may exceed 7,000 pounds, provided that no single room in which research and development activities are conducted shall contain more than 7,000 pounds.

(3) Containers of phosphogypsum used in indoor research and development activities shall be labeled with the following warning: Caution: Phosphogypsum Contains Elevated Levels of Naturally Occurring Radioactivity.

(4) For each indoor research and development activity in which phosphogypsum is used, the facility shall maintain records which conform to the requirements of § 61.209(c).

(5) Indoor research and development activities must be performed in a controlled laboratory setting which the general public cannot enter except on an infrequent basis for tours of the facility. Uses of phosphogypsum for outdoor agricultural research and development and agricultural field use must comply with § 61.204.

* * * * *

4. Section 61.207 is revised to read as follows:

§ 61.207 Radium-226 sampling and measurement procedures.

(a) Before removing phosphogypsum from a stack for distribution in commerce pursuant to § 61.204, or § 61.206, the owner or operator of a phosphogypsum stack shall measure the average radium-226 concentration at the location in the stack from which phosphogypsum will be removed. Measurements shall be performed for each such location prior to the initial distribution in commerce of phosphogypsum removed from that location and at least once during each calendar year while distribution of phosphogypsum removed from the location continues.

(1) A minimum of 30 phosphogypsum samples shall be taken at regularly spaced intervals across the surface of the location on the stack from which the phosphogypsum will be removed. Let n_1 represent the number of samples taken.

(2) Measure the radium-226 concentration of each of the n_1 samples in accordance with the analytical procedures described in 40 CFR part 61, appendix B, Method 114.

(3) Calculate the mean, $\bar{x}_1$, and the standard deviation, s_1, of the n_1 radium-226 concentrations:

$$\bar{x}_1 = \frac{\sum_{i=1}^{n_1} x_i}{n_1},$$

$$s_1 = \sqrt{\frac{\sum_{i=1}^{n_1} (x_i - \bar{x}_1)^2}{n_1 - 1}},$$

Where $\bar{x}_1$ and s_1 are expressed in pCi/g.

(4) Calculate the 95th percentile for the distribution, $\bar{x}^*$, using the following equation:

$$\bar{x}^* = \bar{x}_1 + 1.64\left(\frac{s_1}{\sqrt{n_1}}\right),$$

Where $\bar{x}^*$ is expressed in pCi/g.

(5) If the purpose for removing phosphogypsum from a stack is for distribution to commerce pursuant to § 61.206, the owner or operator of a phosphogypsum stack shall report the mean, standard deviation, 95th percentile and sample size. If the purpose for removing phosphogypsum from a stack is for distribution to commerce pursuant to § 61.204, the additional sampling procedures set forth in paragraphs (b) and (c) of this section shall apply.

(b) Based on the values for $\bar{x}_1$ and $\bar{x}^*$ calculated in paragraphs paragraphs (a)(3) and (4) of this section, determine which of the following conditions will be met:

(1) If $\bar{x}_1 < 10$ pCi/g and $\bar{x}^* \leq 10$ pCi/g; phosphogypsum may be removed from this area of the stack for distribution in commerce pursuant to § 61.204.

(2) If $\bar{x}_1$, < 10 pCi/g and $\bar{x}^* > 10$ pCi/g, the owner or operator may elect to follow the procedures for further sampling set forth in paragraph (c) of this section:

(3) If $\bar{x}_1 \geq 10$ pCi/g; phosphogypsum shall not be removed from this area of the stack for distribution in commerce pursuant to § 61.204.

(c) If the owner or operator elects to conduct further sampling to determine if phosphogypsum can be removed from this area of the stack, the following procedure shall apply. The objective of the following procedure is to demonstrate, with a 95% probability, that the phosphogypsum from this area of the stack has a radium-226 concentration no greater than 10 pCi/g. The procedure is iterative, the sample size may have to be increased more than one time; otherwise the phosphogypsum cannot be removed from this area of the stack for distribution to commerce pursuant to § 61.204.

(1)(i) Solve the following equation for the total number of samples required:

$$n_2 = \left(\frac{1.64 s_1}{10 - \bar{x}_1}\right)^2.$$

(ii) The sample size n_2 shall be rounded upwards to the next whole number. The number of additional samples needed is $n_A = n_2 - n_1$.

(2) Obtain the necessary number of additional samples, n_A, which shall also be taken at regularly spaced intervals across the surface of the location on the stack from which phosphogypsum will be removed.

(3) Measure the radium-226 concentration of each of the n_A additional samples in accordance with the analytical procedures described in 40 CFR part 61, appendix B, Method 114.

(4) Recalculate the mean and standard deviation of the entire set of n_2 radium-226 concentrations by joining this set of n_A concentrations with the n_1 concentrations previously measured. Use the formulas in paragraph (a)(3) of this section, substituting the entire set of n_2 samples in place of the n_1 samples called for in paragraph (a)(3) of this section, thereby determining the mean, $\bar{x}_2$, and standard deviation, s_2, for the entire set of n_2 concentrations.

(5) Repeat the procedure described in paragraph (a)(4) of this section, substituting the recalculated mean, $\bar{x}_2$, for $\bar{x}_1$, the recalculated standard deviation, s_2, for s_1, and total sample size, n_2, for n_1.

(6) Repeat the procedure described in paragraph (b) of this section, substituting the recalculated mean, $\bar{x}_2$ for $\bar{x}_1$.

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