



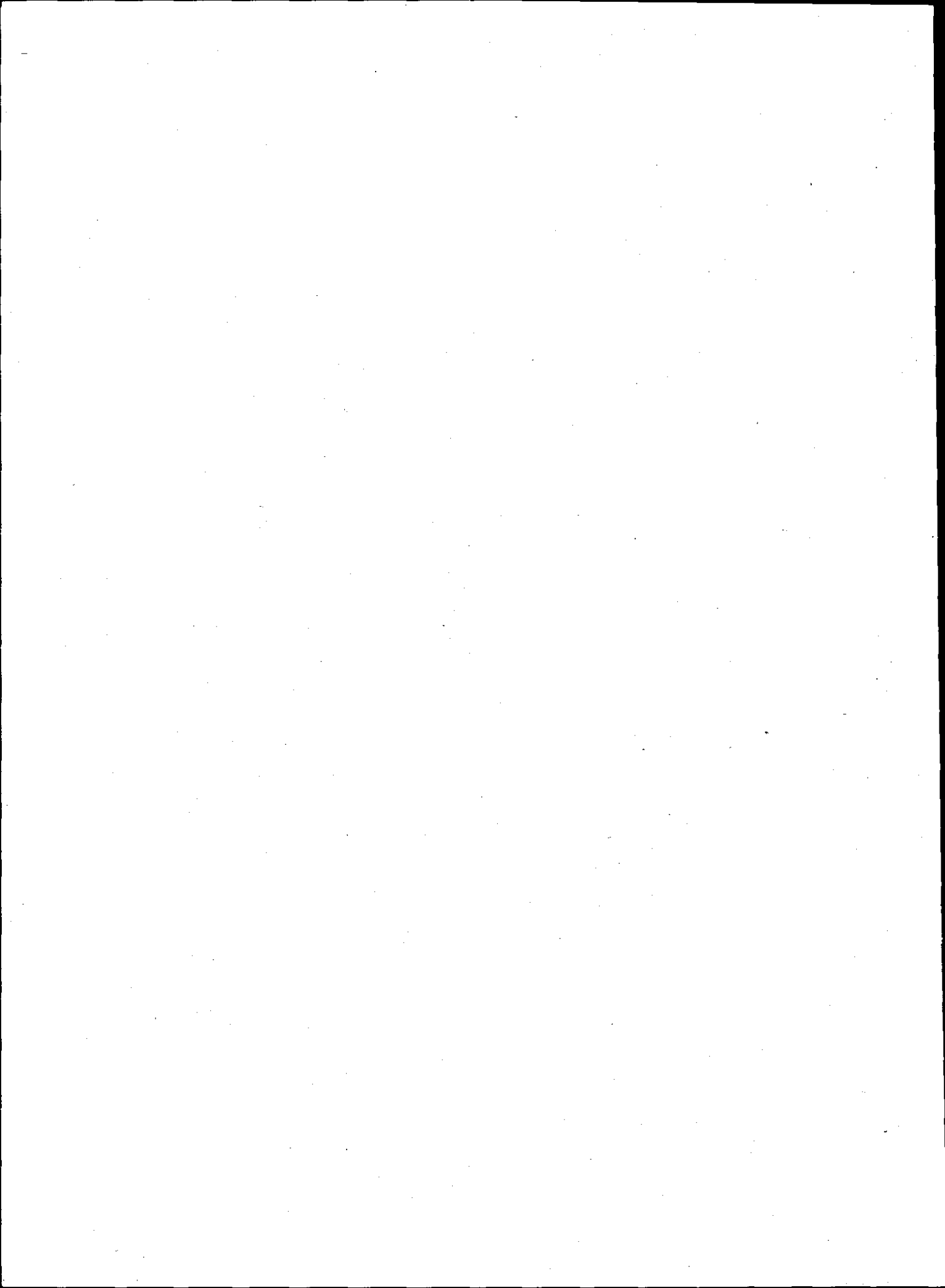
40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

EPA 402-R-98-007

Comments and Response to Comments

NESHAPS; National Emission Standards for Radon Emissions
From Phosphogypsum Stacks

November 1998
U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, D.C. 20460



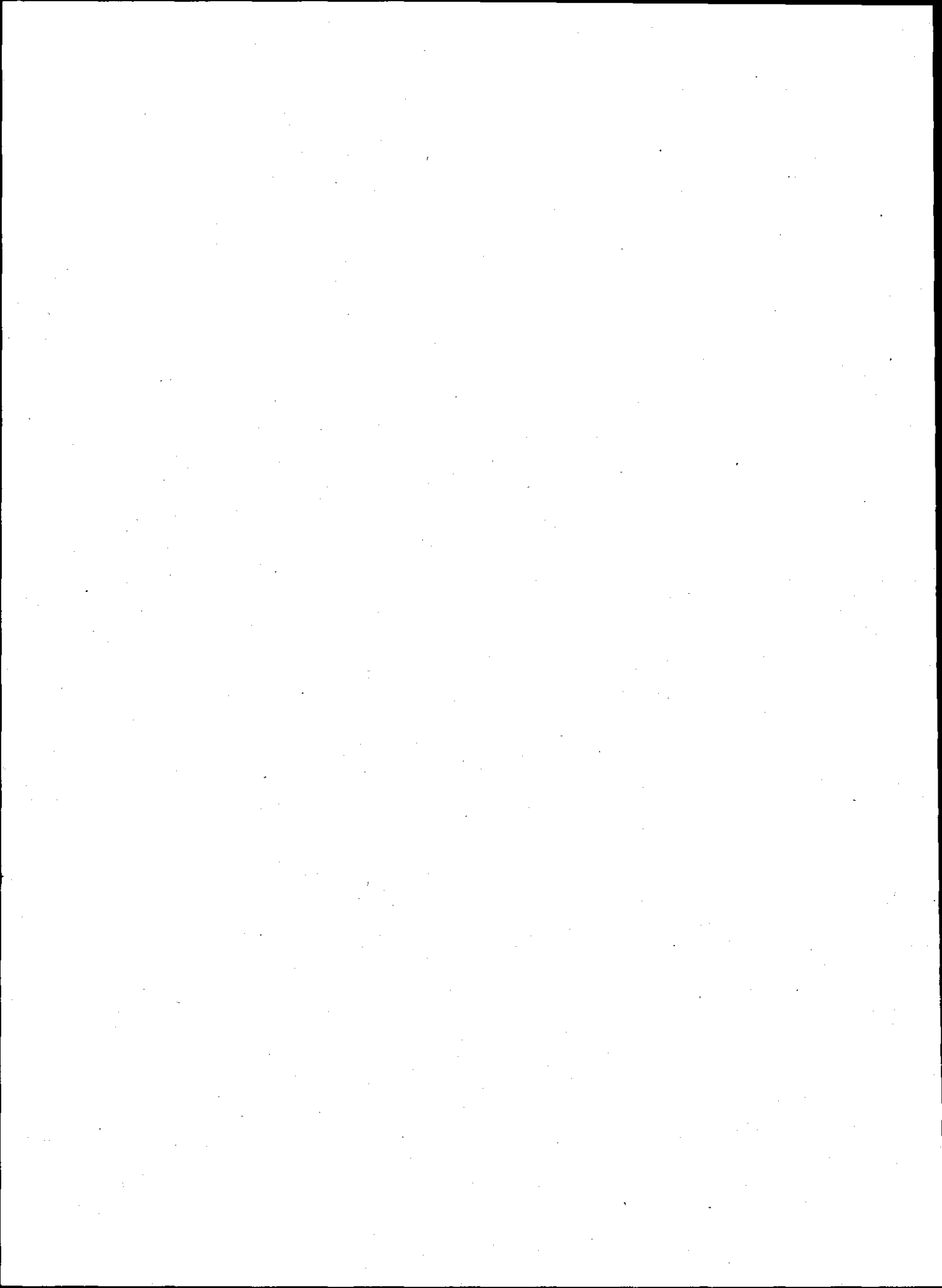
PREFACE

The Environmental Protection Agency (EPA) is promulgating revisions to 40 CFR Part 61, Subpart R, National Emission Standards for Radon Emissions from Phosphogypsum Stacks. This Background Information Document (BID)—Comments and Response to Comments has been prepared in support of the final rulemaking. It contains an introduction, general comments on EPA's approach, laboratory research and development, including sampling and certification, use outside a laboratory setting, and sampling statistics.

Copies of this BID, in whole or in part, are available to all interested persons. For additional information, contact Eleanor Thornton-Jones at (202) 564-9773 or write to:

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An EPA contractor, S. Cohen & Associates, Inc., McLean, VA, provided significant technical support in the preparation of this BID.

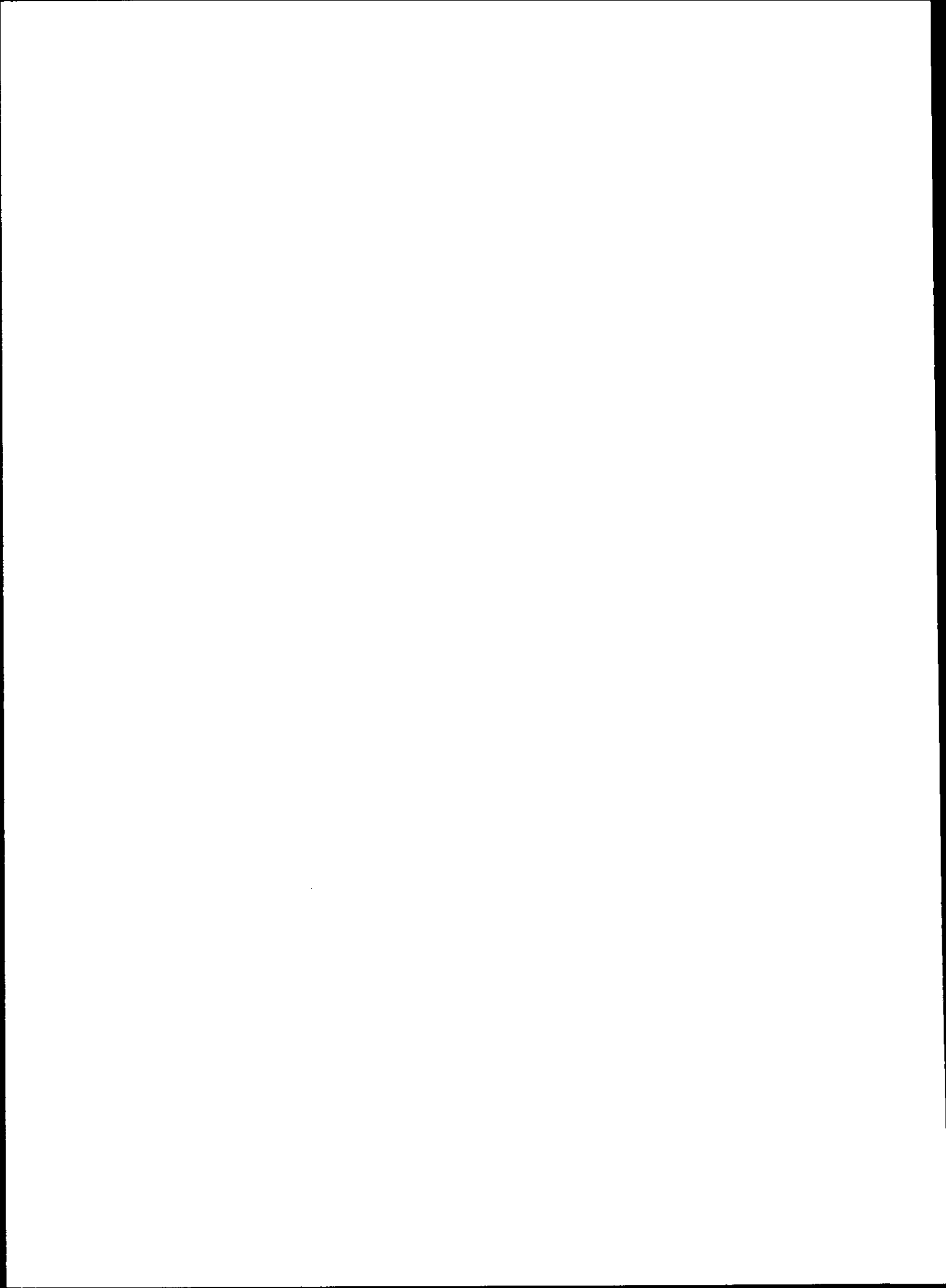


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Response to Comments on Amendments to Subpart R

INTRODUCTION

The Environmental Protection Agency (EPA) is promulgating revisions to those portions of its National Emission Standards for Hazardous Pollutants (NESHAPs) that address radon-222 emissions from phosphogypsum stacks, 40 CFR part 61, Subpart R (Subpart R) 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. EPA is taking this action in response to issues raised in a petition for reconsideration from The Fertilizer Institute (TFI) 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.

EPA published a notice of proposed rulemaking on May 8, 1996 and solicited comments. See 61 FR 20775, May 8, 1996. A total of 107 general and specific comments were received by the docket and at the subsequent public hearing in Florida from 19 organizations and private citizens. A small number of these comments were procedural in nature, requesting a public hearing, asking that the comment period be extended, and acknowledging the extension of time to submit comments. The request for a public hearing was granted. The vast majority of the comments dealt with policy, legal and technical issues.

Comments are presented here in summary form under four categories that best describe their content:

1. General Comments on EPA's Approach
2. Laboratory Research and Development, including Sampling and Certification
3. Use Outside a Laboratory Setting
4. Sampling Statistics

1. General Comments on EPA's Approach

Comment 1.a: EPA's authority under the Clean Air Act is limited to ambient air. Air inside laboratories does not fall within the Clean Air Act definition of ambient air, so EPA has no authority to regulate the laboratory research and development uses of phosphogypsum. (TFI)

Response: This rulemaking is limited to reconsideration of certain specified issues, including the amount of phosphogypsum that can be removed from stacks for use in research and development and correction of the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses an issue presented by the Subpart R rule promulgated in 1992 which is not among those under reconsideration in this rulemaking. In any case, the commenter misunderstands the structure of the rule. When EPA first promulgated Subpart R in 1989, it required that radon emissions be controlled by placement of all phosphogypsum in a stack or mine. In response to that general prohibition, many parties argued that it would effectively preclude other existing uses of phosphogypsum in activities such as agriculture and research and development. In order for such uses to be permissible, it was then necessary for EPA to make specific exceptions to the general requirement that all phosphogypsum be disposed in stacks or mines, which EPA had determined would protect public health with an ample margin of safety. EPA concluded that it would be inappropriate to amend the 1989 NESHAP to permit any alternative disposition of phosphogypsum if that alternative would present potential health risks from radon emissions greater than those EPA would consider legally permissible as part of disposal. If EPA were not permitted to establish procedures governing distribution of phosphogypsum removed from a stack which would assure that exceptions to the general requirement of disposal in a stack or mine would not themselves result in unacceptable health risks, EPA believes that it would be irresponsible to permit such exceptions. Thus, analysis by EPA of the risks presented by laboratory use of phosphogypsum is necessary to decide under what circumstances EPA can make an exception to the general requirement that phosphogypsum be disposed of in a stack or mine, not because it is the intent of EPA to establish a NESHAP directly regulating radon emissions to air inside laboratories.

Comment 1.b: While EPA has acknowledged that its original risk assessment contained errors, the agency's response to its current risk assessment proposes that researchers demonstrate that using more than 700 pounds of phosphogypsum in a laboratory project would be "helpful." This approach is completely counter to the NESHAPs methodology set out in the *Vinyl Chloride* decision. It is not the responsibility of the regulated community to show that an erroneous limitation is a burden, but it is EPA's responsibility to determine an amount of phosphogypsum that is presumptively safe to use in research and development and then determine whether, considering all other factors, that quantity protects human health with an ample margin of safety. There is no basis for EPA to reduce the amount of phosphogypsum to be used in laboratory research and development below that which is presumptively safe. (TFI)

Response: This comment misconstrues the *Vinyl Chloride* decision. Under the methodology required by that decision, once EPA has determined the level of emissions which is presumptively

safe, EPA must then establish an additional margin of safety. In this second step, EPA is required to consider factors such as the economic feasibility of greater control. If there were no practical utility associated with the ability to use more than a specified amount of phosphogypsum in a laboratory setting, then it would be appropriate for EPA to establish a limitation which reflected this conclusion.

However, based on the record in this rulemaking, EPA has concluded that the ability to use greater quantities of phosphogypsum in a laboratory setting does have practical utility. Since the corrected risk analysis demonstrates that the use of 7,000 pounds of phosphogypsum for indoor research and development presents a lifetime risk to the maximally exposed individual which EPA has deemed presumptively safe under the applicable quantitative criteria, EPA has decided to revise Subpart R to permit such use.

Comment 1.c: EPA must consider the quantity and value of phosphogypsum in evaluating its stance on phosphogypsum research, since that research is consistent with reuse and recycling approaches to waste management. The work of the phosphate industry, FIPR, and LSU has led to many possible uses. EPA has not shown either the understanding the industry expected or provided necessary support through the regulatory process, by eliminating all research uses, then by placing very stringent limitations on research and development based on a risk assessment that the Agency acknowledges included significant errors. TFI supports the proposed modifications to the 1992 rule, but EPA should reevaluate its entire approach to phosphogypsum research and development to encourage sound research and development on reuse while still protecting human health and the environment. (TFI)

Response: EPA has determined that its approach, allowing laboratory research and development projects using limited quantities of phosphogypsum, is safe, with an ample margin of safety. This research and development has the potential for finding ways to promote reuse and recycling of phosphogypsum. In increasing the limit on the amount of phosphogypsum that can be used in research and development, the Agency is seeking to assure that the proper balance is reached between the benefits of such research and development and the risks posed by the use of phosphogypsum. In this way, EPA is promoting research and development on reuse and recycling of phosphogypsum.

Comment 1.d: EPA's proposed limitation of 7,000 pounds of phosphogypsum per laboratory is better than the former limit of 700 pounds per experiment, but the higher limit appears to be as much for EPA's enforcement convenience as for research flexibility. Enforcement convenience is not a sufficient basis for establishing regulatory limits. EPA should determine a limit per research and development project that is presumptively safe and request comments on various regulatory approaches. (TFI, IMC-Agrico)

Response: The Agency's decision to allow the use of 7,000 pounds of phosphogypsum for research and development is based on a revised risk assessment; not on enforcement convenience.

Comment 1.e: The limited and controlled nature of all three types of phosphogypsum research and development (bench scale work in labs, "pot" scale work in greenhouses, and field studies) make substantive command and control regulation unnecessary. Procedural requirements, including notice of the radionuclide content of phosphogypsum involved in particular projects, and, if necessary, deed restrictions and other notice requirements to control access to field research and development sites are sufficient to protect human health - of both researchers and the general public - with an ample margin of safety. (TFI)

Response: The Agency's policy is to establish limits on the amount of phosphogypsum that can be used in a laboratory, and to allow researchers the freedom to conduct their work within that constraint. The reporting of the radium-226 content of phosphogypsum used in research and development is no longer required. Outdoor research and development is not permitted under Section 61.205. Researchers who wish to undertake field studies utilizing phosphogypsum in a manner not permitted under Section 61.204 may apply for permission to undertake such studies under Section 61.206. Applicants under Section 61.206 are free to propose any restrictions that they believe will assure that the risk from a proposed alternative use is kept within acceptable levels.

Comment 1.f: EPA should not change the existing NESHAP to allow any increase in the quantity of phosphogypsum available for research and development uses or allow more than one project per site. There is considerable evidence that the linear non-threshold relationship is the best tool to predict the risks of radiation exposure at low doses, despite the position taken by some members of the Health Physics Society. It is more difficult to control and monitor 7,000 than 700 pounds of phosphogypsum; expanded use will increase cancers in laboratory personnel. EPA should increase, rather than decrease, restrictions on the use of phosphogypsum, or at the minimum, maintain the current restrictions, and alternative uses should not be permitted. (Envir. Confederation, Brown, Behrens, ManaSota-88)

Response: EPA has determined that 7,000 pounds in laboratory research and development use to be safe, with an ample margin of safety, so long as this limit is not exceeded for any individual research activity and no one room within the facility contains more than this limit. The Agency does not believe that facilities conducting research and development activities involving phosphogypsum will exercise any less care in storing and handling the larger quantities of material permitted under the revised NESHAP than they did in storing and handling the 700 pounds previously allowed.

Comment 1.g: New studies show that linear no-threshold assumptions are not completely accurate and grossly overestimate cancer risk. The linear no-threshold hypothesis has not been proven; research conducted and evidence obtained over the last decade calls this hypothesis into question. The Health Physics Society's recent position statement on low-level radiation exposure recommends against quantitative estimation of health risk below an individual dose of 5,000 mrem in one year or a lifetime dose of 10,000 mrem in addition to background radiation. The Society holds that risk estimation in this dose range should be strictly qualitative, emphasizing a range of

hypothetical health outcomes within an emphasis on the likely possibility of no adverse effects at all. In addition, the dose rate that has been estimated for a phosphogypsum researcher is much lower than 5,000 mrem/yr. (Simplot, Gidry)

Response: The Agency position is that the assumption of no threshold and a linear response is prudent public policy. In conducting risk assessments, EPA must take into account the limitations and uncertainties in our scientific knowledge about the effects of radiation at all levels of exposure. An annual exposure to 5,000 mrem would pose a risk far in excess of that determined to be safe, with an ample margin of safety, which is a lifetime risk to the maximally exposed individual no greater than 1×10^{-4} .

Comment 1.h: Industry should be required to use a phosphoric process that creates no phosphogypsum or other hazardous byproducts, as indicated by the Phosphoric Acid Dialogue Committee. (ManaSota-88)

Response: This comment is beyond the scope of the issues subject to reconsideration in this rulemaking. In any case, since the risks posed by releases of radionuclides from phosphogypsum can be maintained at levels that protect public health with an ample margin of safety, there is no basis for utilizing a NESHAP to prohibit the production of phosphates by the wet acid process.

2. Laboratory Research and Development, including Sampling and Certification

Comment 2.a: An aggregate limit of 7,000 pounds of phosphogypsum per facility for research purposes is better than the 700 pound limit per experiment, the 7,000 pound limit will still restrict research in removing radium from phosphogypsum. At 30 pCi/g, there are less than 10 micrograms by weight of radium-226 in 700 pounds of phosphogypsum, making separation research difficult. In 7,000 pounds, there are still less than 100 micrograms available. Milligram quantities of radium are needed for effective separation research. The larger limit also will permit experiments that are more realistic in size, providing better data and yielding results about using phosphogypsum that are more accurate. The larger amount per facility would also provide a more homogeneous supply of phosphogypsum, which is important to providing relationships among research and development projects and more flexibility in their development. A larger stockpile would also allow better control of the phosphogypsum by supporting a central controlled access area, rather than individual project storage areas. (FIPR, TFI, Scott, Gidry, Seals)

The proposed 7,000 pound limit for a given facility is preferable to setting a limit for each individual experiment. Even with this limit, the risk would be less than estimated by EPA, as no laboratory will ever have 7,000 pounds of phosphogypsum on hand every day of the year. The average amount would probably not be more than 2,000 pounds. (FIPR)

Response: The limit on the amount of phosphogypsum that can be used in a laboratory was determined to protect those researchers that work with 7,000 pounds of phosphogypsum on a

continuous basis. This 7,000 pound limit applies separately to each individual research and development activity. The final rule protects researchers in those rooms in laboratories in which 7,000 pounds of phosphogypsum is used. No more than 7,000 pounds may be stored, or in use in ongoing experiments, in any room at a research and development facility. A particular facility may 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.

Although it is likely that many laboratories will hold less than 7,000 pounds at any one time, much of the phosphogypsum on hand in a laboratory at a time may be in use in ongoing experiments, rather than stockpiled in barrels awaiting use.

Comment 2.b: There should be no limitation on multiple research and development activities at a single facility or by a particular principal investigator, since the actual time the investigator spends in the laboratory working with phosphogypsum is limited, usually to a maximum of 2 to 3 hours a day, less than 5 days a week, for a maximum of 150 days a year. An increase to 7,000 pounds of phosphogypsum for multiple research projects would therefore be very unlikely to result in unacceptable worker exposure. Given limited storage space in most research laboratories, phosphogypsum would not be stored in the laboratories, but brought in only on an as-needed basis. The nearly universal practice is to store phosphogypsum outside in 5-gallon pails. No more than 2 pails are in active use at any one time. (FIPR, Seals)

Response: The Agency agrees that, within the overall limit of 7,000 pounds per room, no limit on the number of research and development activities at a given facility is necessary.

Comment 2.c: Using 7,000 pounds of phosphogypsum will not appreciably increase the overall risk of working in a laboratory, when one considers other hazards such as chemical, electrical, or fire in that setting. In addition, there should be no limit on multiple research and development activities at any facility or by any investigator. EPA's indoor radon screening criterion of 4 pCi/l would allow about 500,000 pounds of phosphogypsum in a research laboratory, an essentially unlimited amount. Other radiation/carcinogen risks deemed acceptable (from air travel, food, dwelling construction) because they are so small have not been regulated. (Scott, Gidry)

Response: EPA acknowledges that working in a laboratory exposes individuals to a broad spectrum of risks. However, this does not obviate EPA's responsibility for protecting the public health of laboratory workers with an ample margin of safety. The Agency's screening level of 4 pCi/l for indoor radon was established for a different purpose. NESHAPs promulgated under the Clean Air Act Section 112 must achieve a maximum individual lifetime risk not to exceed 1×10^{-4} .

Comment 2.d: Radium extraction experiments with more than 700 pounds of phosphogypsum could cause higher exposures than simple handling and storage. There is no information about the exposures from radium extraction in the record. (ManaSota-88)

Response: The Agency does not believe that research into radium extraction would result in significantly different exposure pathways causing higher risk than those evaluated in its risk assessments for other research and development uses of phosphogypsum. In fact, much research would likely involve wet chemistry, which will significantly reduce radon-222 emissions compared to other handling activities.

Comment 2.e: Three respondents stated that the requirement for an owner/operator of a phosphogypsum stack to sample the phosphogypsum to be released for research and development uses should be removed. It is not needed, as there is no limitation on the radium content of phosphogypsum used for research and development, and in any case, researchers will determine the radium content. Eliminating the certification requirement would result in most research and development facilities maintaining a lower phosphogypsum inventory, since it would be easier to replace the phosphogypsum consumed in research activities. Two other respondents stated the opposite: that the requirement for stack owners/operators to analyze the radium content of the phosphogypsum they release should not be eliminated, due to the potential risk of cancer and the potential mixing of phosphogypsum from different stacks for research and development. The cost to analyze phosphogypsum has been cited as about \$200 per 55-gallon drum, which is insignificant. (FIPR, TFI, Florida Phosphate Council; ManaSota-88, Sheppard)

Response: The Agency supports research and development that may derive benefits from the utilization of phosphogypsum, so long as this research can be carried out safely. The risk analysis demonstrates that the risk from storing and using 7,000 pounds of phosphogypsum in a laboratory is safe, with an ample margin of safety. EPA has not sought to limit laboratory use of phosphogypsum with higher radium levels, and the EPA risk assessment assumes that phosphogypsum used in a laboratory setting will contain higher activity levels. Therefore, the current requirement that the radium-226 content in the phosphogypsum used in research and development be measured serves no useful purpose and has been removed from the rule.

Comment 2.f: While a greenhouse may be regarded as a laboratory for legal and policy purposes, raising the issue of EPA's authority to regulate the air inside the greenhouse, the fact that air exchanges in greenhouses are substantially higher than those in laboratories located in permanent structures and the fact that researchers generally spend much less time in greenhouses than at bench-scale work in laboratories both significantly reduce potential exposures for researchers. In addition, the assumption of two air changes per hour in a laboratory using 7,000 pounds of 26 pCi/g phosphogypsum is likely to be incorrect by a factor of 400 to 500 percent, given the OSHA recommendation of 4 to 12 air changes per hour, and a 1995 study that shows that the typical number of air changes in laboratories is at the high end in the range of 1 to 10 air changes per hour. Based on the OSHA recommendation alone, EPA's assumption of two changes per hour is low by at least 100 percent. (TFI, Gidry, Simplot)

Response: The Agency recognizes that greenhouses may have more air changes per hour than laboratories and that researchers may spend fewer hours in greenhouses. However, the Agency is promulgating a rule that applies to all indoor research and development activities involving

phosphogypsum. It is Agency policy to select parametric values that are reasonable in evaluating risk.

Comment 2.g: The risk analysis allowing the use of 7,000 pounds of phosphogypsum is based on a ventilation rate of two air changes per hour to remove radon and a gamma exposure based on an average level of shielding and proximity of a researcher to the phosphogypsum. These two types of exposure can be varied to allow more phosphogypsum to be used, since the level of radioactivity in the phosphogypsum should determine the ventilation rate and the shield thickness required. For example, using the equation given in the risk assessment for the steady-state radon concentration of radon in laboratory air, the area of exposed phosphogypsum allowed in a laboratory can be calculated for a given ventilation rate and radium concentration. A greater ventilation rate would be needed for phosphogypsum containing more radium or for a greater exposed area. A similar analysis holds for gamma exposure and the amount of shielding needed. The regulation should indicate the maximum radon concentration and the maximum gamma emission, rather than a specific amount and concentration. (Simplot)

Response: The proposed regulatory approach described in Comment 2.g. would be considerably more difficult and burdensome to implement than the rule promulgated by the Agency in 1992, and being revised today. In addition to requiring data on the radium-226 content of the phosphogypsum, it would require detailed evaluation of ventilation rates, shielding, and exposure geometries. By contrast, the limitation on the quantity within a facility simply requires the facility to limit its inventory.

Comment 2.h: EPA's analysis overestimates the risk to phosphogypsum researchers because it was not conducted in accordance with the recommendation of the ICRP that potential doses be multiplied by their probability of occurrence. All of EPA's exposure assumptions are treated as though they will occur. Distribution data can be used to estimate the probability of occurrence for the parameters assumed. (Gidry)

Response: The Agency is familiar with the recommendations of the ICRP and other advisory groups. However, EPA's NESHAPs, such as Subpart R, are based on the exposure to the maximally exposed individual, in conformance with the provisions of the *Vinyl Chloride* decision, using the framework of the Benzene NESHAP. In doing this, the EPA ensures that the NESHAPs protect the health of even the most exposed individual regardless of the likelihood of that individual's becoming exposed.

Comment 2.i: EPA's multi-laboratory geometry, used for exposure calculations in the risk assessment, is highly improbable, and assumes no credit for shielding from walls or floors. This risk assessment is highly conservative, and EPA finds the risk to be acceptable, so more realistic conditions should provide an even greater "ample margin of safety." (Chambers)

Response: The Agency believes that its risk analysis meets the needs of estimating the maximum individual risk in a multi-laboratory setting.

Comment 2.j: In 1992, EPA determined that the presumptively safe level is a maximum individual risk of 1×10^{-4} . It also removed the blanket prohibition on research and development activities. The Agency concluded that those conditions would protect public health with an ample margin of safety. Thus, EPA has already found that where the risk from phosphogypsum research and development is less than 1×10^{-4} , there is an ample margin of safety. The only thing that changed between 1992 and 1996 is that EPA found its risk assessment was flawed and severely understated the amount of phosphogypsum associated with that presumptively safe risk level. EPA should therefore increase the limit of phosphogypsum that can be used in research and development, consistent with the corrected risk assessment findings. (TFI)

Response: EPA agrees and has done so with this rulemaking.

Comment 2.k: EPA's assumption that a researcher spends 1,000 hours per year (about 4 hours per working day) at an average distance of 1 meter from a drum of phosphogypsum is too conservative. A researcher typically spends only a few hours per week at a distance of 1 meter and the remainder of the approximately 20 hours per week at a much greater distance. The assumed phosphogypsum-contaminated air dust concentration of 100 micrograms per cubic meter is also unreasonably conservative, as this degree of concentration could only occur (if it occurs at all) when the phosphogypsum was being sampled or otherwise disturbed. (TFI)

Response: The Agency's choice of exposure parameters and scenarios is consistent with its policy to set standards which protect the health of the maximally exposed individual.

Comment 2.l: The assumption that researchers using phosphogypsum are exposed for only 10 years is not supported by the record. Exposure times may be much longer. (ManaSota-88)

Response: The Agency agrees that no typical exposure period can be determined from the available information and that some workers might incur exposures over a period longer than 10 years. However, the Agency believes that using an exposure time of 10 years is reasonable, given the values assigned to other exposure parameters (hours per day, distance from the source, etc.) that affect the risk estimate.

Comment 2.m: Any radon build-up in a closed drum typically occurs within the first two weeks, with longer storage having no significant effect since radon build-up is limited by equilibrium. Radon will be distributed through the pore spaces of the phosphogypsum, rather than build up on top of the phosphogypsum in the barrel. There would probably be only a slight increase in radon over that released from an open drum. There would be no gamma radiation problem because the drum would act as shielding. In addition, EPA's assumption that research and development drums of phosphogypsum are open would allow the water to evaporate, which would foreclose effective research. A closed drum provides significant shielding from gamma radiation. (TFI, Scott, Simplot)

Response: The Agency agrees that equilibrium in an undisturbed drum will be reached within a

few weeks, with the radon distributed in the pore spaces of the phosphogypsum. However, the Agency does not agree that it should ignore the possibility of an open drum over long periods of time simply because some research plans would be impractical if the material were allowed to dry out. Finally, the Agency's estimates of the gamma exposure do take into account the geometry of the storage drum and the shielding that it would provide.

3. Use Outside a Laboratory Setting

Comment 3.a: The statement in Section 61.206(c), that proposed phosphogypsum use or distribution must protect public health to the same degree as disposal in a stack or mine is a test for determining a safe or acceptable level, not for establishing an ample margin of safety, as required under Clean Air Act Section 112. Ample margin is to be determined on a case-by-case basis, considering alternatives to the proposed use or distribution, so the ample margin provided by disposal in stacks or mines cannot be transferred to another use. Placing field research under Section 206, without providing evaluation criteria for field research projects, creates an invalid rule. (ManaSota-88)

Response: This rulemaking is limited to the reconsideration of the amount of phosphogypsum that can be used for research and development and to correct the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses an issue of the 1992 rulemaking itself, which is not under reconsideration here. EPA is now developing a document laying out the procedures for applying for an alternative use application.

Comment 3.b: It is not correct that Section 61.205 provides the exclusive basis for authorized research and development activities, as contended at the hearing. This position would preclude EPA from approving a project where the risk was shown to be much smaller than 1×10^{-4} , clearly not the intended result, as EPA has stated in Section 61.206. Section 61.205 provides the generic prescribed conditions under which EPA has determined that phosphogypsum can be used with an ample margin of safety. Those generic conditions cannot preclude other research and development uses that can also be conducted with an ample margin of safety. (TFI)

Response: Section 61.205 is revised to confirm the intent of EPA that it apply only to indoor laboratory research and development. Outdoor uses of phosphogypsum must comply with either Section 61.204, "Distribution and use of phosphogypsum for outdoor agricultural purposes" or Section 61.206, "Distribution and use of phosphogypsum for other purposes." Section 61.206 allows EPA to authorize, on a case-by-case basis, indoor and outdoor uses not covered or authorized by Sections 61.204 and 61.205. Phosphogypsum that remains in outdoor stacks must comply with the numerical limits of Section 61.202.

Comment 3.c: Unlimited amounts of phosphogypsum can be used for agricultural purposes if the radium content does not exceed 10 pCi/g. The limitation on field research should be the same. Even at a higher radium content, 7,000 pounds of phosphogypsum should be allowed at any one

field site, since a reasonable rate of application would limit the size of controlled test fields to a relatively small number of acres. Controlled field studies contribute very little radon in excess of background levels, and these slightly increased levels are insignificant compared to the indoor standard of 0.02 Working Levels. Stack sampling data indicate no excess risk from radon due to working on or very near a phosphogypsum stack (0.01 WL averaged across all four boundaries of the stack), so there should be no radon danger from field studies, because the phosphogypsum concentration would be reduced by the physical process of land application. Further, deed restrictions or other forms of notice could be used to control later access if significant amounts of phosphogypsum are left in place after a field study is completed. (FIPR, TFI)

Response: The 10 pCi/g restriction on the radium-226 content of phosphogypsum used in agriculture was based on representative application rates and tillage practices in the U.S. This limit applies to agricultural field uses, including those field uses which are for the purpose of agricultural research and development. Research utilizing phosphogypsum containing more than 10 pCi/g can be approved on a case-by-case basis under Section 61.206. The efficacy of deed restrictions or other forms of notice in limiting potential risks can be considered in the context of individual applications which propose them.

Comment 3.d: EPA's proposal to allow unrestricted agricultural application of 10 pCi/g phosphogypsum, based on an annual application over 100 years, could be made even more flexible by allowing similar applications of phosphogypsum with higher radium levels over a shorter time. This should not change the risk significantly, if EPA would set a maximum amount of phosphogypsum (perhaps 400 pounds per acre) that could be applied over the period of an agricultural research and development program. Evaluating requests following this pattern could be approved more quickly and help simplify and reduce paperwork. (FIPR)

Response: EPA agrees that the risk assessment model used in deriving the 10 pCi/g limit for agricultural applications of phosphogypsum under Section 204 could be used to determine alternative radium-226 concentrations, application rates, and time periods of usage for phosphogypsum that would meet an acceptable risk. In cases where there are applications dealing with similar alternative uses, the Agency is prepared to streamline its approval process under Section 206 to reduce the burden on applicants, provided their data demonstrate the projects meet the 1×10^{-4} risk criteria.

Comment 3.e: Studies of radium uptake by plants would be severely constrained by a 700-pound limitation, as a laboratory study showed no difference in radium uptake between rice plants grown in a control medium and in phosphogypsum; this should be examined on a larger scale. Data from plants growing on phosphogypsum stacks also often show little or no difference from those grown in a control medium; however, the numbers of samples are too small to properly assess those results. Water hyacinths do show an increased radium uptake when grown in water with phosphogypsum. However, for perspective, a person consuming a typical diet receives a dose of about 1.5 mrem/yr. If consuming milk and meat from cattle grazing on a phosphogypsum test

plot, the annual total additional dose would be 0.15 mrem. For vegetables such as radishes and kale, the additional dose would be about 0.18 mrem/yr. (Scott)

Response: This rulemaking is limited to the reconsideration of the amount of phosphogypsum that can be used for research and development and to correct the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses the 1992 rulemaking itself, which is not under reconsideration here. In any case, the limit on the radium content of phosphogypsum used in agriculture is based on risks associated with subsequent occupancy of treated land, not on any hypothetical dietary exposures. The limit on indoor research and development is being increased to 7,000 pounds with this rulemaking.

Comment 3.f: With no limit on the quantity of phosphogypsum that can be used in field studies (the research and development limit does not apply), any such study must be specifically approved by EPA. This currently requires the applicant to provide a full risk assessment acceptable to the agency. EPA has not provided: 1) guidance on the content of the required risk assessment, 2) a consistent approach and standards for approval of field study requests by regional offices, and 3) a defined time period for EPA review of risk assessments and applications. This situation is unduly burdensome to industry. The individual approval regulatory scheme that applies to phosphogypsum field studies is therefore arbitrary and capricious. If EPA continues to require individual approval for phosphogypsum field studies, it must develop protocols for seeking and granting those approvals, taking into account two main issues. First, the protocols should include a "tiering" process, under which smaller, more limited field studies can be approved on the basis of a screening analysis rather than a complete risk assessment. Second, field studies that are the same or similar to those already approved after a full risk assessment should not have to duplicate that risk assessment: the subsequent studies should be required only to address the relevant differences between the projects. Further, field studies that do not result in permanent installations should not be required to provide a formal risk assessment. (TFI, Seals, Florida Phosphate Council)

Response: This rulemaking is limited to the reconsideration of the amount of phosphogypsum that can be used for research and development and to correct the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses the 1992 rulemaking itself, which is not under reconsideration here. These issues were considered in the 1992 rulemaking and the Agency determined that the use of phosphogypsum in agriculture and for research and development, under the limitations imposed on its use, is safe. The Agency also provided for alternative use of phosphogypsum under the provisions of Section 61.206, where Agency approval is required for its use. Any applicant is required to demonstrate that the alternative use meets EPA's risk requirements before the use can be approved. The Agency shares the commenters' view that wherever possible, the application process and review should be streamlined. Existing models and other precedents will be allowed wherever appropriate to eliminate redundancy and unnecessary steps for applicants and EPA. In response to specific issues raised in this comment: 1) EPA has been and will continue to be

available to offer guidance to applicants and is developing comprehensive written guidance; (2) All alternative use applications are approved at the EPA headquarters level, not at the regional level, which assures that all applicants under Section 61.206 are evaluated in a consistent manner; (3) Given the uniqueness of each application, EPA cannot commit to a predetermined review period. However, as stated above, where there are acceptable precedents, EPA will allow them as part of an application.

Comment 3.g: Public health will not be protected if more field projects are allowed. Using phosphogypsum as roadbed material and for agricultural purposes will contaminate soil, groundwater, air, and vegetation as radium-226 is leached by traffic, flooding, rain, and other weather conditions. Using phosphogypsum as landfill cover and to enhance waste decomposition will contaminate the site for future use and expose landfill workers and the public to excess cancer risk. This use will also contaminate ground and surface waters, as all landfills, lined or unlined, eventually leak. Using phosphogypsum to make reefs in offshore waters is equivalent to dumping; phosphorus will harm aquatic ecosystems, accumulate radionuclides and heavy metals, and eventually enter the food chain through benthic feeders. Future use of land areas would have to be restricted for thousands of years to protect public health. Deed restrictions for using phosphogypsum in projects such as these are meaningless when used to secure an EPA exemption for that use, because the applicant admits that phosphogypsum is harmful by agreeing to a deed restriction. However, any deeds to lands that have been treated with phosphogypsum should still state that fact. (ManaSota-88, Sheppard)

Response: This rulemaking is limited to the reconsideration of the amount of phosphogypsum that can be used for research and development and to correct the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses the 1992 rulemaking itself, which is not under reconsideration here. These issues were considered in the 1992 rulemaking and the Agency determined that the use of phosphogypsum in agriculture and for research and development, under the limitations imposed on its use, is safe, with an ample margin of safety. The Agency also provided for alternative use of phosphogypsum under the provisions of Section 61.206, where Agency approval is required for its use. Any applicant is required to demonstrate that the alternative use meets EPA's risk requirements before the use can be approved.

Comment 3.h: Use of phosphogypsum in roadbeds will contaminate soil, groundwater, air, and vegetation by leaching, flooding, and traffic wear. Monitoring wells adjacent to a road constructed with phosphogypsum have shown elevated radionuclide levels. (ManaSota-88)

Response: This rulemaking is limited to the reconsideration of the amount of phosphogypsum that can be used for research and development and to correct the formula used to demonstrate that phosphogypsum removed from a stack for agricultural purposes meets the 10 pCi/g limit. This comment addresses the 1992 rulemaking itself, which is not under reconsideration here. Any use of phosphogypsum for roadbed use would have to be approved under Section 61.206. Such

use would be approved only if the applicant demonstrates that the requirements of Section 61.206 are satisfied.

4. Sampling Statistics

Comment 4.a: The rules requiring sampling across the area of the stack to be moved into commerce need to be better defined, as the sampling requirements are burdensome and expensive. The proposed requirements leave open several questions, such as:

- do underlying strata have to be sampled?
- will EPA require a new sampling program for each new stratum?
- does each shipment from a stratum have to be analyzed? (Simplot)

Response: No sampling is required for phosphogypsum removed from the stack for use in research and development. For all other cases, the surface of the area from which phosphogypsum is to be removed must be sampled once a year. The underlying strata do not need to be sampled. The same sampling protocol must be used each time the surface of the area from which the phosphogypsum is to be removed is sampled, that is a minimum of 30 samples must be taken each time the area is sampled. Individual shipments do not need to be sampled provided they have been removed from the area of the stack that was sampled and found to be less than 10 pCi/g by the procedures outlined in the rule and described in the document "Statistical Procedures for Certifying Phosphogypsum for Entry into Commerce, as Required by Section 61.207 of 40 CFR Part 61, Subpart R" and provided that this sampling was performed no longer than one year preceding its removal.

Comment 4.b: According to the rule, apparently every stratum of phosphogypsum that might be moved off the site must be sampled, with the number of samples to be determined by how close the phosphogypsum is to the average radium-226 concentration of 10 pCi/g. The error bound of the samples must be no more than 0.05. The explanation section of "Statistical Procedures for Certifying..." assumes that the standard deviation among samples is 8.2 pCi/g. This equation indicates that the closer to 10 pCi/g the radium-226 concentration of the phosphogypsum, the required number of samples and thus the testing expenses increase rapidly, due to the stringent error bound of 0.05. A regulation stating a total exposure limit based on the product of radium concentration and area could solve this sampling problem. Regulations should require the same knowledge of the error distribution of radium concentrations without regard to the actual concentration, to allow the company to design their operation based on that knowledge, again taking concentration and area into account. (Simplot)

Response: The test does not require that every stratum of the phosphogypsum in a stack be sampled. It requires that the surface of the area from which phosphogypsum is to be removed must be sampled annually. A minimum of 30 samples is needed in all cases. The number of samples needed does increase as the true radium-226 concentration approaches 10 pCi/g. This is a characteristic of the statistics underlying hypothesis testing. As stated in the rule, this situation,

where the required sample size may be quite large, may cause the cost of sampling to increase to the point that a stack operator may abandon the attempt to certify this area of the stack for the removal of phosphogypsum. The standard deviation of 8.2 pCi/g used in the Appendix to "Statistical Procedures for Certifying Phosphogypsum for Entry into Commerce, as Required by Section 61.207 of 40 CFR Part 61, Subpart R" was for illustration only, although it was chosen to be representative of values likely to be encountered in these types of tests. It was not intended to represent a true case. Note that both the mean and standard deviation enter into the determination of the critical value, which is needed for certification of an area of a stack for removal of phosphogypsum.

Comment 4.c: Since phosphogypsum has a low radioactivity content and the accuracy of laboratory equipment is not perfect, the way radiation is released (in bursts, not continuously) may lead to overestimating the radium content of a sample of phosphogypsum. EPA should clarify the equations used for determining the radium-226 concentration of a phosphogypsum stack, and revise the methods for determining the sample size and testing needed to demonstrate that the radium concentration is less than 10 pCi/g. However, EPA has assumed that the number of disintegrations from a 10 g portion of a 10 pCi sample is enough to justify the assumed transitions from the mathematically correct binomial distribution to approximate and thus somewhat less accurate Gaussian statistics used in the draft of "Statistical Procedures ...". A binomial distribution is more appropriate for testing purposes, rather than a Gaussian distribution, as it measures both mean and variance, and is the appropriate expression for radioactivity release. A rule should be based on full mathematical rigor. The NESHAP should be revised to permit a statistical analysis based on either a binomial or Gaussian distribution. (TFI, Simplot)

Response: This comment confuses two separate steps that must be undertaken in characterizing the radium-226 content of phosphogypsum. The first step is to determine the radium-226 content of each sample removed from the stack. This requires the use of counting statistics, based on the Poisson distribution. A separate analysis (or count) must be performed on each sample to determine its radium-226 concentration. The required procedures are described in Part 61, Appendix B, Method 114. The techniques described there are standard laboratory procedures for measuring the levels of radioactivity in samples. Once the radium-226 concentrations of each of the samples has been determined, the procedures outlined in the revised Section 61.207 of Subpart R, promulgated with this rulemaking, are used in performing the second step, where the average radium-226 concentration of the phosphogypsum in the area of the stack is determined. The second step does not rely on the procedures of Method 114. Instead the statistics outlined in Section 61.207, and discussed in the document "Statistical Procedures for Certifying Phosphogypsum for Entry into Commerce, as Required by Section 61.207 of 40 CFR Part 61, Subpart R" are appropriate.

For example, in a case where 30 samples of phosphogypsum had been removed from a stack for analysis, the procedures used in Method 114 would be used to determine the radium-226 concentrations in each of the 30 samples. After these 30 concentrations had been determined, the radium-226 concentration in the area of the stack from which phosphogypsum is to be removed

would then be determined following the procedures outlined in Section 61.207 and discussed in the document "Statistical Procedures for Certifying Phosphogypsum for Entry into Commerce, as Required by Section 61.207 of 40 CFR Part 61, Subpart R." The procedures outlined there are based on the normal (or Gaussian) distribution. As discussed in the Appendix of this document, there is good theoretical justification for the use of this distribution

Comment 4.d: For the sampling protocol, EPA should consider a method that would take known characteristics of a particular phosphogypsum source into account and allow the mean value of a certain number of samples to be used as a qualifying limit, since the risk associated with radium content does not vary that much within a few pCi/g of EPA's limit of 10 pCi/g. The closer the radium content is to 10 pCi/g, the more samples are required to determine the actual radium content within EPA's error band, and there will always be a risk of misclassification. (Chambers)

Response: The test that the Agency is requiring for demonstrating that the phosphogypsum which is to be removed from a stack is no greater than 10 pCi/g is based on the standard statistical test of hypotheses. The test is conservative. It is structured in such a way that strong evidence is required in demonstrating that the true concentration is less than 10 pCi/g. In cases where the true mean is less than 10 pCi/g, the closer the true mean is to 10 pCi/g, the more demanding the evidence required (i.e. the larger the sample needed to demonstrate compliance). This is appropriate, because the Agency's concern is the risk posed by the use (or misuse) of phosphogypsum.

Comment 4.f: The value of 0.05 in the proposed rule is the probability that sampling the stratum of phosphogypsum entering commerce shows that it is safe to distribute/transport the phosphogypsum when it is not in fact safe to do so - that is, when the true sampling value exceeds 10 pCi/g. This type of analysis will result in phosphogypsum being rejected for use when it should be accepted. This false rejection rate could be excessively high, depending on the mean radium content of the phosphogypsum. The revised rule should adopt a balance between allowable Type I and Type II errors. (Simplot)

Response: There is always a chance of occurrence a Type I or a Type II error in tests of statistical hypotheses, such as the test required by Section 61.207. The chance of error is inherent in all tests of hypotheses. In structuring these tests, there is a tradeoff in the chances of Type I and Type II errors. Given no change in the sample size, the consequence of reducing the chance of occurrence of a Type I error is to increase the chance of occurrence of a Type II error. Similarly, an attempt to reduce the chance of a Type II error will result in an increase in the chance of a Type I error. An increase in the sample size, with no other changes in the test, is the only way to simultaneously reduce the chance of occurrence of both the Type I and Type II errors. The Agency's choice of a .05 probability of occurrence of a Type I error is predicated on the need to protect the general public from the risk of radiation exposure.

