40 CFR part 61
National Emission Standards
for Hazardous Air Pollutants

EPA-402-R-96-022

RESPONSE TO COMMENTS

NESHAPS RULEMAKING ON NUCLEAR

REGULATORY COMMISSION AND AGREEMENT STATE LICENSEES

OTHER THAN NUCLEAR POWER REACTORS

December 1996
U.S. Environmental Protection Agency
Office of Radiaiton and Indoor Air
Washington, DC 20460

Response to Comments Document

40 CFR Part 61, Subpart I

(NRC-Licensees Other Than Commercial Nuclear Power Reactors)

This Response to Comments Document responds to comments received relating to the Agency's rescission of 40 CFR Part 61 Subpart I as applied to facilities other than commercial nuclear power reactors and not addressed in the preamble to the final rule. EPA received written comments from 14 commenters including individuals, environmental groups, States and industry representatives in response to EPA's proposal to rescind 40 CFR Part 61 Subpart I for NRC licensees other than commercial nuclear power reactors. See 57 FR 56877 (December 1, 1992). EPA subsequently published a notice reopening the comment period for this rulemaking. See 60 FR 50161 (September 28, 1995). This Notice reaffirmed EPA's 1992 proposal to rescind Subpart I, described the expected proposed revisions to the NRC program which would support EPA's rescission, and invited additional comment on five questions relating to the sufficiency of the revisions to the NRC program to support the finding required by CAA Section 112(d)(9). EPA received written comments from 34 commenters including several individuals, environmental groups, States and industry in response to the Notice. In addition, EPA also received comments from individuals, environmental groups and industry representatives during public hearings conducted on January 14, 1993 and February 29, 1996.

Given events which occurred between EPA and NRC after the 1992 proposal, including NRC's proposed constraint rule, EPA believes that the more recent comments submitted by a party in response to the 1995 Notice, should be accorded more weight than comments previously submitted by that same party in 1992, where there is inconsistency between the comments.

In addition, EPA's review of the comments has been limited to the question of whether EPA should rescind Subpart I for NRC licensees other than commercial nuclear power reactors. This rulemaking was not intended to reconsider and did not address whether EPA should have promulgated Subpart I in 1989 or the appropriateness of EPA's 10 mrem/yr dose standard. EPA therefore rejected as irrelevant to this rulemaking, comments addressed to the validity or appropriateness of the promulgation of Subpart I.

1. General

In response to the 1992 proposal and 1995 Notice, 25 commenters supported rescission and 23 commenters opposed rescission. The Agency has reviewed all comments received in this rulemaking carefully.

2. 1995 Request for Comments

This section of the Response to Comments Document addresses the comments received in response to the five questions that the Agency posed in the Federal Register notice (60 FR 50161, September 28, 1995) announcing the reopening of the comment period on its proposed rescission of 40 CFR 61, Subpart I as it

applies to NRC licensed facilities other than commercial power reactors.

2.1 *Question 1: If NRC adopts the proposed ALARA constraint level rule, will the resultant NRC regulatory program assure that routine radionuclide emissions from NRC licensees other than nuclear power reactors result in doses which are consistently and predictably no greater than 10 mrem/year?*

Comment: Numerous commenters, both for and against rescission, note that it is difficult to comment on the effectiveness of a proposed regulation, and caution the EPA to reserve its final decision until the NRC has promulgated its final ALARA constraint rule.

Response: The Agency believes that the draft ALARA constraint rule and the background provided by the Agency in the *Federal Register* notice allow for informed public comment on which EPA can base its decision. As the Agency stated in the *Federal Register* notice announcing the reopening of the comment period, "EPA intends to take final action concerning its proposal to rescind subpart I for NRC and Agreement State licensees other than nuclear power reactors on or after the date that NRC takes final action on the ALARA 'constraint level' rule." 60 FR at 50165 (September 28, 1995). Further, as stated in the September notice, the Agency did not take final action until NRC completed the 'constraint rule'.

Comment: Commenters supporting the Agency's proposal to rescind agree that adoption of an ALARA constraint level rule will provide additional assurance that the same level of protection provided by implementation of Subpart I will be consistently and predictably achieved. While favoring rescission, many of these commenters object to the imposition of such a rule as unnecessary. Citing the Agency's Targeted and Random Survey results, and noting that those levels were achieved prior to the NRC's lowering its exposure limit to 100 mrem/yr and imposing ALARA as a mandatory part of every licensee's radiation protection program, they believe that a constraint rule will only result in additional compliance burdens without affecting the already acceptable levels of emissions.

Commenters opposed to the Agency's proposal to rescind do not agree that adoption of the ALARA constraint level will result in the NRC's regulatory program assuring that doses are consistently and predictably below 10 mrem/yr. Those commenters believe that since actual measurements of dose are not required, the NRC will continue a perceived lax regulatory approach which they believe relies on self-reporting and inadequate inspections and enforcement. The NRC's initiatives to move to more risk-based and performance-based regulations heighten the commenters' concerns about the long-term effectiveness of the NRC's program. These commenters are also concerned that NRC

recently increased its cost limit to $2,000 per person rem avoided.

Response: The Agency does not find the concerns raised by those opposed to rescission to be compelling. In developing Subpart I, the Agency was cognizant that a large fraction of the facilities covered by the NESHAP do not employ continuous effluent or environmental monitoring, and it determined that release fractions and effluent control adjustment factors could be developed and applied for use in compliance assessment. The Agency also finds that levels of emissions and doses caused by these facilities, as documented in its Targeted and Random surveys, do not lead to the conclusion that the NRC improperly relies on self-reporting in deference to an effective inspection and enforcement program.

The Agency also finds the argument that NRC has increased the cost limit per person rem avoided not relevant to this rulemaking. NRC has increased the cost limit person rem avoided from $1,000 to $2,000 and this would potentially lead to more stringent regulation. In addition, NRC has adopted a 10 mrem/yr constraint level which assures that radionuclide emissions by the affected licensees will be consistently and predictably below 10 mrem/yr. If a licensee exceeds the constraint level, NRC can require the licensee to take corrective actions to reduce emissions.

2.2 *Question 2: If NRC adopts the proposed ALARA constraint level rule, will NRC have sufficient authority to require any affected facility with routine radionuclide emissions at a level which results in doses exceeding 10 mrem/yr to reduce its emissions to a level resulting in doses no greater than 10 mrem/yr?*

Comment: Many commenters supporting the proposed rescission believe that the NRC and the Agreement States already have effective programs with ample authority to compel licensees to achieve emission levels that will not result in doses exceeding 10 mrem/yr. Promulgation of an ALARA constraint rule will serve to enhance the existing authority.

Commenters opposed to the proposed rescission do not believe that imposition of an ALARA constraint rule will provide the NRC with an enforceable basis for assuring that doses are maintained at levels below 10 mrem/yr. Guidance and ALARA are not enforceable limits, and therefore cannot provide the same level of protection as the Agency's NESHAP.

Response: NRC's promulgation of the constraint rule, while not a limit per se, requires licensees to notify NRC if the licensee exceeds 10 mrem/yr tede and implement adequate corrective actions to ensure that doses do not exceed 10 mrem/yr tede. EPA has determined that the constraint rule together with the recently finalized Agreement State policies and procedures for adequacy and compatibility

ensure that emissions of radionuclides will be consistently and predictably below the Subpart I limit.

2.3 *Question 3: If NRC makes the proposed ALARA constraint rule a matter of Division Level 2 compatibility, will this assure that each individual Agreement State establishes an ALARA constraint level for its licensees which is not greater than 10 mrem/yr, and requires its licensees to report and correct exceedances of that level?*

Comment: Commenters favoring rescission contend that Division Level 2 compatibility will provide the necessary assurance.

Commenters opposed to rescission contend that Division Level 2 compatibility will not provide the same level of assurance as Division Level 1, which requires "strict" compatibility. Several officials of State programs question whether or not Division Level 2 compatibility would allow them to adopt requirements more strict than those imposed by the NRC.

Response: The Agency believes that Division Level 2 compatibility, or an equivalent level of compatibility, will assure that emissions from facilities licensed by the Agreement States will be maintained at NRC's constraint level of 10 mrem/yr tede or at a more stringent level. Adoption of Division Level 2 compatibility, which requires each Agreement State to incorporate provisions into its programs at least as stringent as those in the NRC's rule,

does provide States the opportunity to incorporate even stricter standards.

2.4 Question 4: Are the NRC policies establishing criteria to evaluate the adequacy and compatibility of Agreement State programs, and adopting procedures to permit suspension or termination of Agreement State programs, sufficient to enable the NRC to take necessary action if it determines that an Agreement State program is inadequate or incompatible?

Comment: Commenters favoring rescission believe that the NRC has always had the necessary authority to revoke Agreement State status upon a showing of cause, and contend that the NRC's policy statement will enhance all parties' understanding of the Agreement State program. Several note that the "problems" identified with the Agreement State program have been issues of information flow rather than issues affecting the protection of the public health and safety.

Commenters opposed to rescission contend the NRC has never shown any commitment to evaluating the adequacy of Agreement State programs and has never suspended or revoked Agreement State status. Given the cutbacks in the NRC's program, they believe that a weak Agreement State program would be tolerated by the NRC.

Response: The Agency finds that the NRC authority does provide for suspension or termination of Agreement State status upon a finding that the state program is inadequate or incompatible with the NRC's requirements. Adoption by the NRC of the policy statements and procedures concerning adequacy and compatibility provide the required assurance that inadequate or incompatible agreement state programs will be corrected or revoked, thus assuring protection of public health and safety. See also letter from Martin Malsch, NRC Deputy General Counsel to Ramona Trovato, Director of EPA's Office of Radiation and Indoor Air, November 19, 1996, Docket Entry A-92-50, IV-G-8.

2.5 Question 5: Do these four actions [addressed in questions 1-4 above], in addition to other actions taken by NRC combine to provide an ample margin of safety to protect public health?

Comment: Commenters supporting rescission believe that the NRC's program has consistently provided an ample margin of safety to protect public health, and cite the EPA's Targeted and Random surveys as proof. They believe the four actions will only serve to enhance the degree of assurance that the ample margin of safety is maintained in the future.

Opponents of rescission do not believe that the NRC's program, with or without the four actions, provides the requisite ample margin of safety because: (1) NRC's regulations allow doses of 100 mrem/yr, and provide for

exceptions to allow doses as high as 500 mrem/yr; (2) guidance and ALARA are not enforceable regulations; (3) NRC's mandate is not focused on protecting public health; and (4) NRC has never revoked any Agreement State status. A few commenters also believe that NRC's "dismal" record of protecting the public (e.g., TMI-2, Radiation Sterilizers, Inc., *Time* magazine cover story from March 4, 1996) and its ill-conceived regulatory initiatives (e.g., BRC, elimination of requirements marginal to safety) provide ample proof that it does not intend to hamper licensees by making them operate in a manner that protects the public. One commenter also believes that in making any "ample margin" determination under CAA section 112(d)(9), EPA should base such a determination on the most recent information on low-dose exposure.

Response: The legislative history of Section 112(d)(9) provides guidance as to what is meant by "an ample margin of safety" and what process the Administrator is to follow in making that determination in a rulemaking conducted under section 112(d)(9). The Conference Report accompanying S. 1630 - the Clean Air Act Amendments points out that the "ample margin of safety" finding under section 112(d)(9) is the same "ample margin of safety" requirement that was contained in Section 112 of the CAA prior to its amendment in 1990.

EPA has already made a determination in promulgating Subpart I that compliance with the 10 mrem/yr dose standard protects the public health with an ample margin of safety. For the purposes of present rulemaking, EPA has used the 10 mrem/yr standard found to provide an ample margin of safety as the benchmark by which it evaluates the NRC regulatory program and the Court of Appeals for the D.C. Circuit has recently approved this practice in unpublished opinion. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996). EPA's study of NRC licensees not engaged in nuclear power generation, determined that the overwhelming majority were below the 10 mrem/yr limit suggesting that the NRC program was currently affording protection with an ample margin of safety.

As stated in the *Federal Register* notice, the Agency has determined that the promulgation of a constraint rule and adoption of the policy statements and procedures on adequacy and compatibility of Agreement State programs, provide the additional assurances needed to make the finding required by Section 112(d)(9) that the NRC's program pursuant to the Atomic Energy Act will provide an ample margin of safety to protect the public health in the future. The constraint level, while not a limit, is a value above which certain actions are required. Contrary to the opinions expressed by many commenters opposing rescission, Section 112(d)(9) does not require the Agency to find that

the NRC regulatory program is identical to EPA's NESHAP program. Rather, the Agency must determine that the NRC and EPA regulatory programs are functionally equivalent. Given the NRC's actions with respect to the constraint rule and the policy statement concerning adequacy and compatibility, together with EPA's study and experience implementing Subpart I, EPA has determined that the NRC's regulatory program provides an enforceable basis for assuring doses caused by air emissions of radionuclides from NRC and Agreement State licensed facilities will be consistently and predictably below 10 mrem/yr. Thus, the EPA believes that the NRC regulatory program will protect the public to the same level as would be afforded by continued implementation of Subpart I.

3. Adequacy of NRC Program - Incinerator Operations

Comment: Some commenters argue that NRC is lax in implementing its regulatory program and thus, does not protect the public health with an ample margin of safety. Specifically, one commenter argues that NRC does not adequately regulate the nuclear operations at the University of Michigan and hence the EPA should not rescind Subpart I. The following arguments were presented in support of the view that the NRC is not properly regulating the incinerator operations, as well as other categories of licensees.

3.1 NRC Concentration Limit

Comment: The NRC does not use a dose limit. Instead they use a concentration limit, and this makes it difficult for the public to determine the degree of risk they are being exposed to.

Response: This comment was also received in response to EPA's 1992 proposal. EPA considers this issue to be irrelevant, since NRC has adopted a 10 mrem/yr tede constraint level. Further, EPA allows the use of concentration tables under Subpart I for determining compliance with that Subpart.

3.2 NRC 100 mrem/yr Limit

Comment: The NRC's limit of 100 mrem/yr is 10 times that of EPA's limit of 10 mrem/yr.

Response: This comment was received in response to EPA's 1992 proposal. EPA considers the issue raised to be irrelevant because NRC has adopted a 10 mrem/yr tede constraint level. Also, NRC's earlier 500 mrem/yr limit in combination with ALARA, has been found in EPA's study to achieve the functional equivalency of the Subpart I limit.

3.3 NRC Relationship with Industry

Comment: The NRC is trying to relax its regulations at the urging of industry and at the expense of the public.

Response: EPA disagrees with the comment because NRC has adopted a 10 mrem/yr tede constraint rule. In addition, effective January 1, 1994, the NRC regulations governing

facilities like the University of Michigan were made more stringent in that the maximum allowable dose in an unrestricted area was lowered from 500 to 100 mrem/yr. The fact that some permissible concentrations have increased does not reflect a lessening of protection. Rather, it reflects the change in radiation protection to a methodology that better reflects the risks resulting from a given exposure.

3.4 EPA Survey Results Flawed

Comment: The designated survey results are flawed in that the EPA picked only the wealthiest and brightest facilities; i.e., those most likely to comply with the limits. The random survey is flawed because the respondents knew that the EPA was conducting the survey.

Response: In the designated survey, the EPA did not pick only the "wealthiest and brightest facilities". Rather, the Agency spent a great deal of effort to identify those facilities that were likely to emit the largest quantities of radioactivity, thereby resulting in the highest radiation dose.

The letter sent to the random survey respondents contained the following sentence: "You should also be aware that Section 113 [of the Clean Air Act] provides for possible criminal sanctions for anyone who knowingly makes any false statement, representation, or certification in a report required by EPA." The Agency has no reason to

believe that any of the respondents supplied false information.

3.5 EPA Survey Relies on Self-Reporting

Comment: It is not realistic to rely on self-reporting. The University ran the COMPLY code and got a dose of 0.3 mrem/yr. The Michigan Department of Natural Resources got a COMPLY dose of 10.6 mrem/yr, with 9.7 mrem/yr due to radioiodine.

Response: Both the EPA and the NRC regulations provide for criminal penalties in the event of false information being supplied by a licensee. Periodic inspections of facilities and records assure that licensees are in compliance. The differing COMPLY results are discussed in item 3.5.1 below.

3.5.1 Specific Example

Comment: Several COMPLY studies made by the Michigan Department of Natural Resources (DNR) and included as an attachment to testimony suggest that the radiation dose from the University of Michigan incinerator exceeded the Subpart I limits of 10 mrem/yr for all radionuclides and 3 mrem/yr for radioiodine. In addition, commenters cited another study that had an estimated thyroid dose of 66 mrem from radioiodine, which they state is far higher than the 3 mrem/yr limit. They also state that the University of Michigan's COMPLY run gave a dose of 0.3 mrem/yr, far lower than the other studies.

Response: The Agency has run the COMPLY code using the same 1989 emissions data, building and stack parameters, and distance to the resident as in the DNR COMPLY runs supplied by the commenter. The result is a dose in the worst sector of 0.5 mrem/yr from all radionuclides and 0.3 from radioiodine. There are two reasons for this dose being approximately a factor of 20 lower than the DNR results cited by the commenter.

The first reason is that the DNR runs used the COMPLY default annual average wind speed and frequency. The Agency used a wind rose (which accounts for the actual annual average frequency and speed with which the wind blows toward a given sector). This reduced the estimated doses by about a factor of five to 2.2 for all radionuclides and 2.0 mrem/yr for iodine. This is because the actual frequency the wind blows toward the maximum sector is 0.11 versus the default value of 0.25 and the actual wind speed is 4.2 meters/sec versus the default value of 2.0 meters/sec.

The second reason is that in the DNR COMPLY runs all the person's food (vegetables, milk, and meat) was assumed to be raised at home. The Agency put the farms supplying dairy and meat products one mile away (approximately the distance to the city limits; cattle and other farm animals cannot be raised within the city limits of Ann Arbor). Having the cattle one mile away but with all the produce raised at home reduced the doses by about another factor of

four to 0.5 for all radionuclides and 0.3 mrem/yr for iodine.

The Agency notes that both the use of a wind rose, and placing farms in realistic locations are allowed by the compliance procedures.

The Agency does not know what assumptions and parameters were made to obtain the 66 mrem/yr thyroid dose in the other study. However, note that a 66 mrem/yr thyroid dose corresponds to an effective dose equivalent (ede) of 2.0 mrem/yr (the weighing factor is 0.03), so that it would still be within the limit of 3 mrem/yr ede for radioiodine. The Agency does not know the reason for the difference between the 0.5 mrem/yr from its COMPLY run and the University's 0.3 mrem/yr. The difference is not significant, however, and could be caused, for example, by the maximum sector versus the actual sector.

3.6 Basis for 40 CFR Part 61, Subpart I Standard

3.6.1 "Standard Male"

Comment: The EPA standards are based on the "standard male". Why were population groups like women and children not considered?

Response: This comment relates to the assumptions used in the 1989 rulemaking. As such it is not relevant to the limited scope of this rulemaking. Notwithstanding the above, for the sake of clarity EPA makes the following observation:

The risk is that from a lifetime exposure to 10 mrem/yr. Because the exposure, dose and risk are calculated for the whole lifetime, the child's risk is inherent. Additionally, the dose range resulting from age dependence appears to be small for lifetime exposures. See "Radionuclides: Background Information Document for Final Rules", EPA 520/1-84-022-1. The "standard man" is the nomenclature used by the International Commission on Radiation Protection (ICRP). It does not presume a sex; rather, factors like body weight and metabolism are standard.

3.6.2 Multiple Sources Not Considered

Comment: Why does the EPA not consider multiple sources? For example, there may be a hospital, a university, and a radiopharmaceutical company all in the same town.

Response: This comment relates to the assumptions used in the 1989 rulemaking. As such it is not relevant to the limited scope of this rescission rulemaking. Notwithstanding the above, for the sake of clarity EPA makes the following observation:

> Because the dose drops off with approximately the square of the distance between the source and receptor, the effects of other, more distant sources on persons located close to one source, are usually trivial.

3.7 CAA Section 112(d)(9) Ample Margin Determination

Comment: The determination of safe and acceptable should be made under the guidelines of the *Vinyl Chloride* decision; that is, only health factors should be considered, not cost. Does the NRC's ALARA principle (as low as reasonably achievable) violate the *Vinyl Chloride* guidelines by taking into account costs and benefits?

Response: Section 112(d)(9) authorizes EPA to decline to regulate radionuclide emissions from NRC licensees under the CAA, provided the Agency determines that NRC's regulatory program protects the public health with an ample margin of safety. The legislative history of Section 112(d)(9) provides additional guidance as to what is meant by "an ample margin of safety" and what process the Administrator is to follow in making that determination in a rulemaking conducted under Section 112(d)(9). The Conference Report accompanying S. 1630 points out that the "ample margin of safety" finding under Section 112(d)(9) is the same "ample margin of safety" requirement that was contained in Section 112 of the CAA prior to its amendment in 1990.

In 1989 EPA promulgated NESHAPs for radionuclides utilizing the two step *Vinyl Chloride* analysis. In the first step EPA determined an acceptable level of risk based only on health factors and then in the second step the Agency considered health, cost and other factors to determine the "ample margin of safety". EPA has already

made a determination in promulgating Subpart I that compliance with the 10 mrem/yr dose standard protects the public health with an ample margin of safety. See 54 FR 51654 (December 15, 1989). EPA conducted a risk assessment in promulgating Subpart I in 1989. EPA is not revisiting either the risk analysis or decision methodology that supported the promulgation of Subpart I; rather, EPA is only considering whether NRC's regulatory program will result in meeting the 10 mrem/yr dose standard established in Subpart I as being the level that provides an ample margin of safety thereby rendering Subpart I unnecessarily duplicative. EPA has determined that NRC's regulatory program, including the 10 mrem/yr constraint rule, will protect the public to the same level as would continued implementation of Subpart I.

The determination that 10 mrem/yr ede constitutes an ample margin of safety was made in the context of the rulemaking promulgating Subpart I. The appropriate place to raise concerns regarding the adequacy of the standard or seek review of the appropriate methodology was in the context of that rulemaking and not in this rescission rulemaking. For purposes of the present rulemaking EPA has used 10 mrem/yr ede, the standard found to provide an ample margin of safety to protect the public health, as the benchmark by which EPA evaluates the NRC regulatory program and in an unpublished opinion the Court of Appeals for the

D.C. Circuit approved this practice. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996).

4. Adequacy of NRC Program General

4.1 EPA Limit Too High

Comment: The EPA limit of 10 mrem/yr is too high. Thus, EPA does not protect public health with an ample margin of safety.

Response: This question is outside the scope of the present regulatory proceedings since the Agency is not revisiting the basis for the standard established in the 1989 rulemaking. The commenter's assertion that the EPA limit of 10 mrem/yr is too high to protect the public health with an ample margin of safety is not relevant to the issue of whether or not Subpart I should be rescinded. However, the Agency does direct the commenter's attention to the language of Section 112 of the Clean Air Act which grants the Administrator the authority to establish emission limits at the level which he or she determines will protect the public health and safety with an ample margin.

4.2 NRC Limit Greater Than EPA's Limit

Comment: The NRC's limits are much greater than the EPA limit of 10 mrem/yr, and the ALARA procedures rely on hidden negotiations between the facility and the regulators to establish actual emission levels. The NRC uses a different

approach than the EPA's approach of formal rulemaking coupled with open verification of compliance.

Response: EPA rejects this comment in light of NRC's recent promulgation of a 10 mrem/yr constraint rule applicable to materials licensees. Additionally, EPA does not believe the NRC approach prior to the promulgation of the constraint rule was ineffective. The effect of the NRC's limits and ALARA procedure was to limit the dose to less than 10 mrem/yr as evidenced by the results from both EPA's Random and Targeted surveys, as well as EPA's implementation of Subpart I.

4.3 Memorandum of Understanding and Penalties for Non-Compliance

Comment: Several commenters to the 1992 proposal commented on the Memorandum of Understanding (MOU) between EPA and NRC. Commenters were concerned that the 10 mrem/yr goal of ALARA was not protective of public health. Those commenters believed that 10 mrem/yr should be the limit and ALARA should reduce the dose below that. Some commenters believe that the MOU does not provide for rigorous emissions testing. Commenters argue that the MOU does not define penalties for non-compliance. They believe that penalties for non-compliance are more strict under the Clean Air Act than they are under NRC's imprecise, negotiated, undefined penalty procedures.

Response: EPA is not responding to the comments concerning the MOU because the Agency believes such comments were

addressed by NRC's promulgation of a constraint rule. The constraint rule requires a licensee which estimates or measures a dose to the nearest resident from air emissions greater than 10 mrem/yr, to report the dose to NRC in writing within 30 days. The report must also describe the corrective steps the licensee has taken or proposes to take to ensure that the 10 mrem/yr constraint is not exceeded again. A notice of violation will be issued if a licensee fails to report exceeding the constraint. In addition, provisions for penalties are contained in the NRC regulations governing licensees. In general, the penalty for a violation is in proportion to the severity of the violation. The Commission does provide for the licensee to dispute the facts and/or provide evidence of mitigating circumstances, and considers these in its final determination of the penalty. These decisions are a matter of public record.

4.4 EPA Failure to Justify Proposal to Rescind

Comment: The EPA has failed to justify the proposed rescission for the following reasons:

4.4.1 EPA Statistical Analysis of Survey Results

Comment: The EPA's statistical analysis refutes the Agency's contention that all facilities presently comply with the NESHAP limits.

Response: The Agency disagrees. None of the doses caused by the facilities that the Agency has evaluated is greater

than the limits established by the NESHAP. The statistical analysis, which is based on the deliberately conservative assessments of the facilities included in the random survey, indicates that it is probable that some small number of facilities would be found to exceed the standard using the same conservative assumptions to evaluate the doses they cause.

Comment: The COMPLY computer model used to calculate compliance with Subpart I conservatively overestimates doses, particularly where the source and the receptor are in the same building. A more realistic dose calculation and statistical extrapolation to the entire population would show that no facility causes a dose that exceeds 10 mrem/yr.

Response: EPA believes that the commenter does not understand the purpose of EPA's survey. Apparently the commenter believes that the survey was intended to calculate the actual dose. However, the purpose of the survey is to determine doses in accordance with the Agency's framework for compliance under Subpart I, i.e., COMPLY computer code.

4.4.2 EPA Survey

Comment: The EPA's assessment of the facilities does not account for possible errors in the inputs used to estimate doses. Given the number of facilities estimated to have emissions that result in doses approaching the NESHAPs limits, the EPA's failure to assure that all estimates are

accurate simply underscores the conclusion that numerous facilities are causing unacceptable doses.

Response: The Agency agrees that at facilities where estimated doses approach the standard, great care must be exercised to assure that the impacts are not underestimated. However, the Agency does not agree that it has failed to exercise this care. Analysts who performed the assessments scrutinized the values assigned to input parameters prior to running the COMPLY code, and the code itself has been designed to flag parameter values that are outside expected ranges. Finally, an independent quality assurance check was made of each evaluation. In instances of uncertainty, the Agency's policy is to assign the more conservative value (i.e., the higher dose) to assure that the resulting estimate does not underestimate dose.

Comment: The conclusions that the EPA has reached concerning the current levels of exposure rely on data generated primarily by licensees, and the EPA cannot rely on licensees to provide unbiased data. Neither can the EPA rely on the MOU that establishes a goal of 10 mrem/yr ede, as licensees will simple reclassify the maximally exposed individuals as radiation workers to meet the goal. The EPA must recognize that Dr. Gofman's work demonstrates that low doses of radiation are not protective of public health. Finally, the EPA should revise its risk assessment to reflect the findings of Dr. Gofman.

Response: The letter sent to the random survey respondents contained the following sentence: "You should also be aware that Section 113 [of the Clean Air Act] provides for possible criminal sanctions for anyone who knowingly makes any false statement, representations, or certification in a report required by EPA." The Agency has no reason to believe that any of the respondents supplied false information.

The Agency does not find the argument that persons will simply be reclassified to circumvent the regulations compelling.

With respect to Dr. Gofman's findings, the Agency has reviewed his work, and does not find that his positions are proven by the evidence. The Agency constantly reviews the bases for its radiation risk assessments, and has made appropriate revisions as new data and/or analyses become available.

Comment: The EPA's study of NRC licensed sites and the conclusion that the facilities are below the NESHAP limit is unconvincing. No direct measurements were made by the EPA, it relies entirely on data provided by the licensees, and no effort was made in the BID to evaluate whether or not the sample size was sufficient for drawing valid statistical inferences.

Response: The EPA has already determined in the 1989 NESHAP rulemaking that measuring emissions is not necessary in order to determine compliance with the limits. Therefore, it does not believe that relying on data provided by the licensees was inappropriate, particularly as the letter sent to the random survey respondents contained the following sentence: "You should also be aware that Section 113 [of the Clean Air Act] provides for possible criminal, sanctions for anyone who knowingly makes any false EPA." The Agency has no reason to believe that any of the respondents supplied false information.

The discussion in the BID noes not dwell upon the question of whether or not the size of the random sample is sufficient to drawing valid statistical inferences for the simple reason that the sample size was determined a priori on the basis of the size needed to provide 95% confidence that the largest value represented the 99th percentile of the surveyed facilities.

4.4.3 ALARA Is a Future Requirement

Comment: The EPA has relied, in part, on the fact that the NRC will impose ALARA on all its licensees by 1994. Relying on a requirement that is not currently effective as a basis for rescinding the NESHAP is improper.

Response: The comment was received in response to the 1992 proposal, as such it is no longer appropriate. In its 1991 revisions to 10 CFR part 20, NRC codified the ALARA

principle which had previously been guidance. Those revisions have been effective since 1994.

4.4.4 ALARA Does Not Support Rescission

Comment: Even when the NRC's ALARA requirement goes into effect, it cannot be found to support rescission. The NRC's ALARA requirement explicitly places a cost-benefit limitation on control measures that a facility must implement, which is in direct conflict with the strictures of the court under *NRDC vs. EPA* 824 F.2d 1146 (D.C. Cir. 1987) (en banc) that "safe" be determined irrespective of cost considerations. There is no enforceable basis in the NRC's regulations to guarantee that emissions do not result in doses exceeding 10 mrem/yr.

Response: The issue is now irrelevant, since NRC promulgated a constraint level rule requiring NRC licensed facilities other than nuclear power reactors to constrain emissions of radionuclides to the environment to 10 mrem/yr. EPA has determined that the constraint rule provides the assurances needed to make the finding required by CAA Section 112(d)(9). EPA has determined that the NRC's regulatory program provides an enforceable basis for assuring doses caused by air emissions of radionuclides from NRC and Agreement State licensed facilities are consistently and predictably below 10 mrem/yr.

4.4.5 Ample Margin Determination

Comment: The EPA has failed to fulfill the second step of the process for establishing the "ample margin of safety" from these facilities. Nothing in the rulemaking record indicates that the EPA considered requiring additional emissions reductions beyond those associated with the 10 mrem/yr standard. As the discussion of the M.D. Anderson Medical Center and the Washington University Medical Center indicates, reducing iodine releases by installation of charcoal filters can be accomplished. Yet, the EPA did not address whether or not facilities such as the NIH or Johns Hopkins should employ such systems. Without performing such an analysis, the EPA is in no position to determine whether or not the NRC's program provides the requisite level of protection.

Response: The determination that 10 mrem/yr ede constitutes an ample margin of safety was made in the context of the rulemaking promulgating Subpart I. The appropriate place to raise concerns regarding the adequacy of the standard or seek review of the appropriate methodology was in the context of that rulemaking and not in this rescission rulemaking. For purposes of the present rulemaking EPA has used 10 mrem/yr ede, the standard found to provide an ample margin of safety to protect the public health, as the benchmark by which EPA evaluates the NRC regulatory program and in an unpublished opinion the Court of Appeals for the

D.C. Circuit approved this practice. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996).

Comment: NRC is not a competent regulatory body. In support of this premise, a commenter in 1992 noted NRC's oversight of Nucrar Metals, Inc., where air emissions data are not required to be submitted is an example of the NRC's laxity. Commenters in 1995 noted the potential for high emissions at low-level waste sites, the UCLA reactor and some other facilities discussed in the BID. These commenters believe that Subpart I is required to assure the public that the licensees are in compliance with the standards.

Response: EPA conducted an exhaustive study which found that the overwhelming number of NRC licensees subject to Subpart I were below the standard. The Agency has no reason to believe these results have changed. COMPLY is available to the public and no member of the public has provided data suggesting that the 10 mrem/yr limit has been exceeded.

Comment: EPA's implementation shows that a few licensees reported emissions above EPA's standard, therefore EPA's conclusion that virtually all facilities were below the limit and that those few above would be in compliance with adjustments to the COMPLY code, is not a sound basis on which to rescind.

Response: EPA's survey predicted that 14 facilities would exceed the standard. The method of prediction was deliberately designed to be conservative, i.e. designed to over estimate the number of facilities that would exceed the standard. EPA believes that its experience implementing Subpart I demonstrates the validity of EPA's prediction. Those facilities that are out of compliance are not brought into compliance by adjustments in the COMPLY code. In most cases, it was found that these facilities were, in fact, in compliance, but that they had made procedural errors in using COMPLY, or had incorrectly compiled the data entered in COMPLY. Facilities found to be out of compliance must undertake measures to lower their emissions sufficiently to come into compliance. EPA believes that the few facilities exceeding 10 mrem/yr out of the 6,000 licensees tends to confirm the Agency's conclusions. Additionally, no facility reported exceeding EPA's standard for calendar year 1995. Thus, the Agency believes it is appropriate to rescind Subpart I.

4.4.6 EPA Benchmark

Comment: The EPA's selection of "1 in 10,000" as the benchmark for safety has been challenged on the grounds that it fails to satisfy the court's demand that the level chosen must be considered "safe" regardless of cost. Until that litigation is resolved, the EPA cannot logically determine whether or not the NRC's program is adequate.

Response: The Agency disagrees with both contentions. With respect to the issue of the appropriate benchmark, the determination that 10 mrem/yr ede constitutes an ample margin of safety was made in the context of the rulemaking promulgating Subpart I. The appropriate place to raise concerns regarding the adequacy of the standard or seek review of the appropriate methodology was in the context of that rulemaking and not in this rescission rulemaking. For purposes of the present rulemaking EPA has used 10 mrem/yr ede, the standard found to provide an ample margin of safety to protect the public health, as the benchmark by which EPA evaluates the NRC regulatory program and in an unpublished opinion the Court of Appeals for the D.C. Circuit approved this practice. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996).

With respect to determining whether NRC's program is adequate, CAA section 112(d)(9) provides the authority for EPA to rescind Subpart I. Congress was clear that EPA's regulatory program, in this case Subpart I, provides the benchmark against which the Agency determines whether the NRC program protects the public with an ample margin of safety. EPA is rescinding Subpart I because the Agency has determined that the NRC regulatory program protects the public health with an ample margin of safety.

Comment: The EPA's "dose standards" are illegal under Section 112. Since they will not survive judicial review,

the EPA cannot rely on the NRC's dose standards to provide equivalent protection.

Response: Again, the determination that 10 mrem/yr ede constitutes an ample margin of safety was made in the context of the rulemaking promulgating Subpart I. The appropriate place to raise concerns regarding the adequacy of the standard or seek review of the appropriate methodology was in the context of that rulemaking and not in this rescission rulemaking.

Comment: The limit on air emissions of radionuclides should be reduced to 5 mrem/yr.

Response: This question is outside the scope of the present regulatory proceedings since the Agency is not revisiting the basis for the standard set in the 1989 rulemaking. EPA believes that it is apparent from the language of Section 112(d)(9) that where the EPA has already specifically determined what level of emissions must be achieved to provide an "ample margin of safety" that level is the benchmark by which EPA must evaluate the adequacy of the NRC program. EPA specifically found when it promulgated Subpart I in 1989, that 10 mrem/yr would provide the requisite "ample margin of safety" to protect the public health. The Court of Appeals for the D.C. Circuit recently approved this interpretation in an unpublished opinion. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996).

5. EPA's Background Information Document

5.1 Source Terms

Comment: The Background Information Document (BID) should make allowance for the source terms used to evaluate the dose from the various facilities having been based upon information supplied by the facilities in the surveys and not on emission monitoring that is known to be accurate and precise.

Response: If the contention is that some of the respondents in the survey supplied false information, then the Agency notes that the letter requesting the information under Section 114 of the Clean Air Act points out that there are criminal sanctions for those knowingly supplying false information. The Agency has no reason to believe that any respondents supplied false information.

If the contention is that all facilities should have emissions monitoring, the Agency notes that only a small portion of the licensees are able to monitor their emissions. Most of the facilities (e.g., hospitals) do not have definite emission points. In developing Subpart I, the Agency expended considerable time and effort to develop release fractions and emission control reduction factors for estimating airborne emissions.

5.2 Procedures

Comment: The EPA did not follow its own procedures in calculating the dose from the Johns Hopkins incinerator;

that is, assume 100 percent release when the temperature is above 100 C.

Response: The assumption of 100 percent release at elevated temperatures is the pre-approved EPA method for estimating the source term. In establishing 100 percent as the pre-approved release fraction, the Agency was constrained by the need to establish a value that would encompass the physical properties of all radionuclides used by NRC licensed facilities, even though most radionuclides are not volatile at 100 C. In evaluating likely doses from the John Hopkins incinerator, the EPA relied on measurement data obtained from other facilities to estimate the likely release fractions. This methodology is fully appropriate for the EPA purposes. Had the facility itself used such a methodology, it would have required the prior approval of the EPA.

5.3 Estimate of Number of Facilities Expected to Exceed NESHAP

Comment: Two commenters disagree with the statement in the BID that "...EPA expects that 16 facilities out of approximately 6,000 cause doses in excess of the NESHAP standard." These commenters are confident that had the EPA surveyed all of the facilities, they would have found that none have doses greater than the standard.

Response: The estimate in the BID was 14, not 16, facilities above the standard. The Agency agrees, however, that the estimate of 14 is based upon a statistical

extrapolation and does not represent a certainty that there are 14.

5.4 Radiation Dose at the Fence Line

Comment: The BID should include estimates of the radiation dose at the fence line. In the future persons could move closer than the current closest resident, school, or business.

Response: This question is outside the scope of the present regulatory proceedings since the Agency is not revisiting the basis for the standard established in the 1989 rulemaking. Notwithstanding the above, for the sake of clarity EPA makes the following observation:

> the estimate of the radiation dose to the closest resident, school, or business was an attempt to determine the dose to any member of the public as specified by Subpart I. Subpart I does not require fence line doses, only doses at currently-occupied locations. If someone should move closer, then he or she would then constitute the closest resident, school, or business.

5.5 NRC Inspection and Enforcement Procedures

Comment: The BID should describe in detail the NRC inspection and enforcement procedure.

Response: See Appendix A of the Draft and Final Background Information Documents. Copies are included in the docket

for this rulemaking (A-92-50, II-B-1, V-B-1). See also NRC's Enforcement Policy (A-92-50, IV-B-5).

5.6 Recommended Changes to the BID

Comment: The NRC supports EPA's decision to rescind Subpart I for NRC and Agreement State licensed facilities. The Commission did provide extensive specific comments on the 1992 (draft) BID seeking minor corrections or clarifications.

Response: These comments have been closely reviewed and appropriate changes made to the final BID.

6. Prevention of Future Increases in Emissions

Comment: In the 1992 proposal, EPA cites two regulations governing radionuclide emissions: 40 CFR 190 and 10 CFR 20. Neither of these rules, either singly or in combination, is sufficient to prevent future increases in radionuclide emissions.

Response: This comment was received in response to EPA's 1992 proposal. The issue raised is now irrelevant since NRC has adopted a 10 mrem/yr constraint level rule. Furthermore, EPA has concluded that the constraint level rule supports the requisite determination for rescission under CAA Section 112(d)(9). The final promulgation of the constraint level rule assures that radionuclide emissions by the affected licensees will be consistently and predictably below a level which would result in doses exceeding 10 mrem/yr, and that NRC can require an individual licensee who

exceeds the 10 mrem/yr level to take corrective actions to reduce emissions.

7. Establishment of a Medical Advisory Board

Comment: Two commenters proposed the establishment of a medical advisory board within the EPA.

Response: The EPA does not believe that the establishment of such an advisory board is necessary at this time.

8. Impact of Rescission on 40 CFR Part 61 Subpart H

Comment: Rescission of Subpart I could lead to the rescission of Subpart H.

Response: The Agency fails to appreciate the basis for this concern. Promulgation of Subpart H was, in part, premised on the understanding that the DOE was self-regulated. In addition, EPA does not have the statutory authority to rescind regulations which apply to DOE facilities under Section 112(d)(9) of the CAA.

Comment: One commenter requests that gaseous diffusion plants be included under Subpart I rather than Subpart H.

Response: This request is outside the scope of the present regulatory proceeding since the Agency is not revisiting the standards established in the 1989 rulemaking. Irrespective of the above, for the sake of clarity EPA makes the following observation:

> the Agency notes that the Energy Policy Act of 1992 (42 U.S.C. Sections 1201-1608) provides for the formation of the United

States Enrichment Corporation (USEC), for purposes of transforming the Federal uranium enrichment program into a commercial venture. The USEC will be a wholly owned Government corporation and an agency of the United States, subject to all Federal environmental laws. The Energy Policy Act further provides that the USEC will lease but not take ownership of the Paducah and Portsmouth Gaseous Diffusion plants. 40 CFR Part 61, Subpart H applies to "any facility owned or operated by the Department of Energy..." 40 CFR section 61.90. Thus, the Agency believes both plants remain subject to Subpart H, since the Department of Energy will retain ownership of these plants.

9. Major Sources

Comment: It is not clear whether facilities that emit radionuclides will be considered major sources that require operating permits. Until the EPA establishes the definition of major source for radionuclides (required by Title V of the CAA and 40 CFR Part 70) it is premature for EPA to rescind Subpart I.

Response: The comment is not clear and is beyond the scope of the present rulemaking. While the Agency has contemplated promulgating a definition of major source for

radionuclides under the CAA by a separate rulemaking, it has not done so. The Agency disagrees with the assertion that such a definition is required by Title V of the CAA or the Part 70 regulations.

10. 1990 CAA Amendments Require EPA/Surgeon General Report

Comment: In the 1990 amendments to the CAA, Congress required the EPA and the Surgeon General to report by 1996 on their findings on health effects and risks of emissions and background concentrations of hazardous air pollutants (radionuclides are considered hazardous). Therefore, the Agency's rescission of Subpart I is premature.

Response: The Agency does not find the commenter's assertion compelling. While it is true that the CAA as amended in 1990 requires EPA "to investigate and report, after consultation with the Surgeon General and after opportunity for public comment, to Congress on remaining risk," those provisions apply to technology based standards promulgated under revised CAA Section 112(d). See CAA Section 112(f). Thus, it is not appropriate for the Agency to consider the report in the rescission of Subpart I since the radionuclide NESHAPs were expressly "saved" as health-based standards. CAA Section 112(q). EPA is rescinding Subpart I because the Agency has determined pursuant to Section 112(d)(9) of the CAA as amended, that the NRC regulatory program, including a 10 mrem/yr constraint level, protects the public health with an ample margin of safety.

11. Radioactive Waste

Comment: A few commenters are concerned with transporting radioactive waste by rail and truck because it could lead to accidents and no training or funds are being provided to emergency personnel. Some commenters are also concerned about the siting of radioactive waste disposal facilities.

Response: The Agency understands that transport and disposal of radioactive waste are concerns. However, the concerns as related to rescission of Subpart I are neither clear nor compelling. Additionally, EPA believes that the comments are beyond the scope of the present rulemaking. Subpart I, limits radionuclide emissions from NRC licensed facilities (stationary sources) to the ambient air to that amount which would cause any member of the public to receive in any year an effective dose equivalent no greater than 10 mrem. EPA is rescinding Subpart I because the Agency has determined that the NRC program, which includes the 10 mrem/yr constraint level, protects the public health with an ample margin of safety.

With respect to accidents which occur during the transport of radioactive waste by rail or truck, the Agency notes that during the transport of radioactive waste by rail or truck, Department of Transportation (DOT) radioactive material packaging and transportation regulations diminishes the probability of an airborne release of radioactive material exceeding the 10 mrem/yr level. DOT does provide

training for emergency personnel with the publication and distribution of the North American Emergency Response Guidebook. It is unlikely that a rail or truck accident involving radioactive waste would result in an airborne release of radioactive material.

12. Chernobyl Data

Comment: Given the recent data from Belarus indicating an increase in thyroid cancer in children resulting from radiodine releases by the Chernobyl accident, EPA should not rescind Subpart I and should possibly consider lowering the dose limit.

Response: This comment is beyond the scope of the present rulemaking, since the Agency is not revisiting the standard established in the 1989 rulemaking. The limit in Subpart I was established pursuant to an EPA policy for Section 112 pollutants first announced in the benzene NESHAP (54 FR 38044, September 14, 1989), utilizing the two-step process outlined in the vinyl chloride decision. *Natural Resources Defense Council v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987). In addition, the Agency believes it is premature to respond or react to the Chernobyl data at this time. EPA would not act until such time as the data has undergone the international review process.