RULEMAKING ISSUE
(Affirmation)

August 5, 1996 SECY-96-172

FOR: The Commissioners

FROM: James M. Taylor, Executive Director for Operations

SUBJECT: FINAL RULEMAKING - REVISION TO 10 CFR PART 20, CONSTRAINT FOR AIRBORNE RADIOACTIVE EFFLUENTS TO THE ENVIRONMENT FROM NRC LICENSEES OTHER THAN POWER REACTORS AND AGREEMENT STATE LICENSEES; AND REVISION OF THE GENERAL STATEMENT OF POLICY AND PROCEDURES FOR NRC ENFORCEMENT ACTIONS

PURPOSE:

To request Commission approval to (1) publish a notice of final rulemaking amending the regulations in 10 CFR Part 20 and (2) publish a revision to the General Statement of Policy and Procedures for NRC Enforcement Actions (Enforcement Policy).

BACKGROUND:

The EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for radionuclides on October 31, 1989. Under 40 CFR Part 61, Subpart I, emissions of radionuclides must be limited so that no member of the public would receive an effective dose equivalent greater than 10 mrem (0.1 mSv) per year. In 1990, Congress enacted amendments to the Clean Air Act (CAA) informing EPA that NRC and Agreement State licensed facilities need not be subject to specific radionuclide limits under the CAA if the EPA Administrator determines that the NRC regulatory program provides an ample margin of safety to protect public health. EPA's proposed rescission of 40 CFR Part 61, Subpart I, was published on December 1, 1992 (57 FR 56877).

Based on the results of surveys undertaken by EPA, EPA made an initial determination that the NRC program does provide an ample margin of safety (57 FR 56880). However, EPA expressed concern regarding the adequacy of current measures to assure that future emissions will not exceed levels that

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provide an ample margin of safety, and did not rescind 40 CFR Part 61, Subpart I. Consequently, NRC and Agreement State licensees are currently subject to dual regulation of air emissions of radionuclides. On September 28, 1995, EPA published a notice reopening the comment period on the rescission of Subpart I (60 FR 50161).

On November 15, 1995, the Commission directed the staff to publish a proposed rule amending 10 CFR Part 20, that would establish a constraint of 10 mrem (0.1 mSv) per year total effective dose equivalent (TEDE) for dose to members of the public from airborne radioactive effluents from NRC licensed facilities other than power reactors. A proposed rule was published in the Federal Register on December 13, 1995 (60 FR 63984), amending 10 CFR Part 20 to include a constraint on air emissions.

The proposed rule specified that to implement the "as low as is reasonably achievable" (ALARA) requirements of Part 20, licensees other than power reactors would be required to report to NRC, air emissions that by calculation or measurement, could result in a dose to a member of the public in excess of 10 mrem (0.1 mSv) in any year. In addition, the licensee would be required to implement corrective actions that NRC agrees are adequate to ensure against future air emissions leading to doses in excess of the constraint.

DISCUSSION:

Fifty-seven comment letters were received addressing the proposed rule and/or draft Regulatory Guide DG-8016. Among the 57 letters, 24 were from licensees, 7 from professional organizations, 5 from States, 16 from members of the public, and 5 from environmental organizations.

In general, those commenters who believed that the proposed constraint was too restrictive, too burdensome, and unnecessary were licensees, members of the public, and professional societies. However, the proposed rule did receive substantial support from the Nuclear Energy Institute (NEI) in the sense that the rule was preferred to dual regulation. The commenters who believed that the proposed constraint was too lax, inadequate to protect the health of the public, and not adequately enforceable were representatives of environmental groups. Two of the three States commenting on the proposed rule did not see a benefit in transferring responsibility to NRC. One State was concerned that the cost to States for implementing compatible rules would not be justified by any benefit. The other felt that the proposed constraint was less protective than Subpart I. Another State did not object to the rule, but expressed concern that naturally occurring materials were not covered by the rule. Many commenters believed that EPA should be able to rescind on the basis of existing evidence.

The final rule is basically unchanged from the proposed rule and requires licensees, other than nuclear power reactors, to constrain doses to members of the public to less than 10 mrem (0.1 mSv) per year. This requirement will be codified as a means for implementing the ALARA requirements in § 20.1101(b) for air emissions. Any exceedance of the constraint would require prompt corrective actions and a report to the NRC. The staff believes that the existing NRC programs are adequate to support rescission of Subpart I and that

a constraint rule for air emissions is not needed. However, in the interest of eliminating dual regulation, the staff recommendation is to go forward with the constraint rule.

In resolving public comments, a few minor changes were made to the final rule. The proposed rule included a requirement to report demographic information on exposed members of the public. The final rule was revised to specify that demographic information is only required for occupationally exposed individuals, because the information is not needed by NRC except for occupationally exposed workers. Some commenters expressed concerns that the NRC rule applied to onsite airborne emissions. To more closely parallel the existing requirements of Subpart I, the final rule has been revised to clarify that the constraint is intended to apply only to airborne radioactive effluents to the environment.

In addition, the staff is recommending that the Enforcement Policy be amended to add an example at Severity Level IV of a violation where the licensee had information to indicate that it had exceeded the ALARA dose constraint in 10 CFR 20.1101(d), but failed to report the exceedance or failed to take the required corrective actions.

It is intended that both the NRC final rule and the EPA rescission will be published concurrently to avoid any unnecessary burden on licensees as a result of dual regulation. EPA has informed the staff that the EPA rescission rule will not be issued until the NRC informs the EPA that the Commission's procedures for suspending or terminating deficient Agreement State programs are finalized. The EDO provided the procedures for suspension and termination of Agreement State programs to the Commission on April 25, 1996.

A draft regulatory guide was issued for public comment concurrent with the proposed rule. The guide has been revised to address comments received, as well as comments on the rule itself where appropriate. The final regulatory guide will be available to licensees on the effective date of the rule.

RESOURCES:

The Office of Nuclear Materials Safety and Safeguards anticipates an expenditure of 3.5 FTE for the first year, and 2.1 FTE per year thereafter, for the development of licensing guidance, inspector training, revisions to the inspection module, review of any licensee reports, routine and reactive inspections. Although the current NMSS Budget does not contain resources to implement this rulemaking, the 3.5 FTE are expected to be available for reprogramming from those allocated for the medical Quality Management Temporary Inspection Module, and possibly from modifications to the medical program. The Offices of Nuclear Regulatory Research and Nuclear Reactor Regulation anticipate minimal expenditure requirements to finalize the rule, the regulatory guide, and to revise test reactor licensing and inspection guidance. These resources will be derived from routine operating budgets.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

RECOMMENDATION:

That the Commission:

1. Approve publication of the final rule.

2. Certify that the final rule will not have a negative economic impact on a substantial number of small entities, in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   Note:

   a. The final rule (Enclosure 1) will be published in the Federal Register;

   b. The revision to the Enforcement Policy (Enclosure 2) will be published in the Federal Register;

   c. A Regulatory Analysis has been prepared and will be made available in the Public Document Room (Enclosure 3);

   d. The staff has determined that, under the Small Business Regulatory Enforcement Fairness Act of 1996, this is not a major rule because licensees affected by this rule are currently subject to the more burdensome requirements of 40 CFR 61, Subpart I, that it replaces. Appropriate notification will be made (Enclosure 4);

   e. An environmental assessment and finding of no significant impact has been prepared and will be made available in the Public Document Room (Enclosure 5);

   f. In accordance with the Regulatory Flexibility Act, a regulatory flexibility analysis has been prepared. The analysis is not a separate document but is part of the Federal Register notice. The analysis indicates that the economic impact on licensees and small entities will not be significant. The analysis will be made available in the Public Document Room. A copy will be sent to the Chief Counsel for Advocacy of the Small Business Administration.

   g. The final rule contains new information collection requirements and, therefore, is subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The staff is preparing a Federal Register notice for submittal to OMB before publication of the final rule;

   h. A public announcement will be issued (Enclosure 6);

i. The appropriate Congressional committees will be informed (Enclosure 7); and

j. Copies of the Federal Register notice of final rulemaking will be distributed to all licensees. The notice will be sent to other interested parties upon request.

James M. Taylor
Executive Director
for Operations

Enclosures: As stated (7)

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB August 20, 1996.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT August 13, 1996, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an Open Meeting during the Week of August 26, 1996. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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ENCLOSURE 1

FEDERAL REGISTER NOTICE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF31

Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to establish a constraint of 10 mrem (0.1 mSv) per year total effective dose equivalent (TEDE) for dose to members of the public from air emissions of radionuclides from NRC licensed facilities other than power reactors. This action is necessary to: (1) provide assurance to the Environmental Protection Agency (EPA) that future emissions from NRC licensees will not exceed dose levels that will provide an ample margin of safety; and (2) to provide EPA a basis upon which to rescind its Clean Air Act (CAA) regulations as defined in 40 CFR Part 61 for NRC licensed facilities (other than power reactors) and Agreement State licensees, thereby relieving these licensees from unnecessary dual regulations.

By separate notice in the Federal Register, the Commission is modifying its "General Statement of Policy and Procedures for NRC Enforcement Actions"

(Enforcement Policy), to address the new regulation, and to provide an example Severity Level IV violation of the constraint. This change will also be reflected when the Enforcement Policy is reprinted in its entirety in the next revision of NUREG-1600.

EFFECTIVE DATE: This rule will become effective 30 days after publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Charleen T. Raddatz, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6215.

SUPPLEMENTARY INFORMATION:

Background

The EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for radionuclides on October 31, 1989. Under 40 CFR Part 61, Subpart I, emissions of radionuclides must be limited so that no member of the public would receive an effective dose equivalent greater than 10 mrem (0.1 mSv) per year[1]. Subpart I of 40 CFR Part 61 was promulgated to implement the CAA and limit doses to members of the public from air emissions of radionuclides (other than Radon-222) from all NRC licensees other than licensees possessing only sealed sources, high-level waste repositories, and

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1 Subpart I expresses dose in effective dose equivalent (EDE). NRC expresses dose in total effective dose equivalent (TEDE). These terms are essentially equivalent.

uranium mill tailings piles that have been disposed of in accordance with 40 CFR Part 192. Radon-222 emissions from tailings were covered by 40 CFR Part 61, Subparts T (addressing non-operational uranium mill tailings piles) and W (addressing operating mill tailings piles). EPA rescinded Subpart T for NRC licensees after Appendix A to 10 CFR Part 40 was amended by the Commission to conform to changes EPA issued to 40 CFR Part 192. Subpart W still applies to NRC licensees. Because Radon-222 is adequately addressed in 10 CFR Part 40, Appendix A, and other provisions of 10 CFR Part 20, it is not covered in this final rulemaking.

In 1990, Congress enacted amendments to the CAA. Section 112(d)(9) of these amendments to the CAA (the Simpson amendment) states:

> No standard for radionuclide emissions from any category or subcategory of facilities licensed by the Nuclear Regulatory Commission (or an Agreement State) is required to be promulgated under this section if the Administrator determines, by rule, and after consultation with the Nuclear Regulatory Commission, that the regulatory program established by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act for such category or subcategory provides an ample margin of safety to protect public health.

Upon issuance, the effectiveness of Subpart I for all NRC licensees was immediately stayed by EPA pending further evaluation. During the stay period, EPA conducted two studies of the air emissions from NRC and Agreement State materials licensees. The first was a survey of 367 randomly selected nuclear materials licensees. EPA determined that the highest estimated dose to a

member of the public from air emissions from these facilities was 8 mrem (0.08 mSv) per year, based on very conservative modeling. In addition, 98 percent of the facilities surveyed were found to have doses to members of the public resulting from air emissions less than 1 mrem (0.01 mSv) per year. The second study evaluated doses from air emissions at 45 additional facilities that were selected because of their potential for air emissions resulting in significant public exposures. EPA found that 75 percent of these licensees had air emissions resulting in an estimated maximum public dose less than 1 mrem (0.01 mSv) per year. For the licensees evaluated, none exceeded 10 mrem (0.1 mSv) per year.

In its initial proposal to rescind Subpart I for NRC licensees other than power reactors, EPA stated that:

> Based on the results of the survey undertaken by EPA and the commitments made by NRC in the MOU, EPA has made an initial determination that the NRC program under the Atomic Energy Act provides an ample margin of safety to protect public health (57 FR 56880; December 1, 1992).

However, EPA continued to express concern regarding the adequacy of the measures to assure that future emissions from NRC licensees will not exceed levels that will provide an ample margin of safety. The stay on Subpart I expired on November 15, 1992, and Subpart I became effective on November 16, 1992. Subsequently, in July of 1993, the EPA Administrator determined that there was insufficient basis at that time to rescind Subpart I. Consequently, NRC and Agreement State licensed facilities were subject to dual regulation of airborne effluents of radionuclides under both the AEA and the CAA, including

regulatory oversight by EPA (or authorized State) and NRC (or Agreement State).

NRC licensees subject to EPA's Subpart I are also subject to NRC dose limits for members of the public contained in 10 CFR Part 20, Subpart D, entitled "Radiation Dose Limits for Individual Members of the Public" (Subpart D). Under Subpart D, licensees shall ensure that doses to members of the public are less than 100 mrem (1.0 mSv) per year from all pathways (including airborne effluents) and all sources associated with the licensee's operation. In addition, under Subpart B, entitled "Radiation Protection Programs," licensees must ensure that doses to members of the public be kept as low as is reasonably achievable (ALARA). Based on the studies conducted by EPA and licensee reporting of doses to members of the public from airborne effluents to EPA, it is evident that less than 10 mrem(0.1 mSv) per year to the maximally exposed member of the public from airborne radioactive effluents to the environment is reasonably achievable.

NRC power reactor licensees subject to 10 CFR 50.34a must keep doses to members of the public from airborne effluents consistent with the numerical guidelines in Appendix I to 10 CFR Part 50. These licensees have reported estimated doses to members of the public from air emissions well below the Subpart I value for many years. Based on the combination of a continuing regulatory basis for reduced air emissions and documented proof of the effectiveness of the NRC program for these licensees, EPA rescinded Subpart I for power reactors licensed by NRC (60 FR 37196; September 5, 1995).

Amendments

The amendments proposed on December 13, 1995 (60 FR 63984), and finalized in this rule establish a constraint of 10 mrem (0.1 mSv) per year TEDE to members of the public from airborne radioactive effluents to the environment from NRC-licensed facilities, other than power reactors, as a part of its program to maintain doses ALARA. These amendments codify numerical values for NRC's application of ALARA guidelines for radioactive air emissions from its licensees, other than power reactors. For power reactors, ALARA guidelines have already been established within 10 CFR Part 50 and existing facility licensing conditions. These final amendments ensure that air emissions are maintained at very low levels and, taking into consideration the elimination of dual regulation, at some reduced cost to licensees. This action brings consistency between the EPA's dose standard and the NRC's ALARA application, and is expected to be the final step in providing EPA with the basis to rescind Subpart I as it applies to NRC-licensed facilities other than power reactors. NRC has been working cooperatively with EPA to achieve rescission of EPA's standards in 40 CFR Part 61, Subpart I, under Section 112(d)(9) of the CAA. EPA published a proposed rescission of 40 CFR Part 61, Subpart I, on December 1, 1992 (57 FR 56877). On September 28, 1995, EPA published a notice in the Federal Register reopening the comment period on rescission of Subpart I (60 FR 50161). The objective of this effort is to eliminate duplicative regulations that provide no incremental benefit in terms of public and environmental protection.

The regulatory framework that NRC is providing as a basis for rescission of EPA's Subpart I consists of the requirement in 10 CFR Part 20 to limit doses to members of the public to 100 mrem (1.0 mSv) per year, and the

requirement to constrain doses to members of the public from airborne effluents of radioactive materials to the environment from a single licensed operation to 10 mrem (0.1 mSv) per year.

Currently, under § 20.1501 licensees are required to make or cause to be made surveys that may be necessary to comply with the regulations in 10 CFR Part 20. This data would be made available to inspectors upon request. If the licensee estimates or measures a dose to the nearest resident from air emissions greater than 10 mrem (0.1 mSv) per year, the licensee would be required to report the dose to NRC in writing within 30 days, which would include the circumstances that led to the greater than 10 mrem (0.1 mSv) per year dose, a description of the corrective steps the licensee had taken or proposed to take to ensure that the constraint is not again exceeded, a timetable for implementing the corrective steps, and the expected results. Records of the results of measurements and calculations needed to evaluate the release of radioactive effluents to the environment will still be required pursuant to 10 CFR 20.2103(b)(4).

Exceeding this constraint will not result in a Notice of Violation (NOV) as would be the case if a limit needed for adequate protection of public health and safety were exceeded. In the case of the constraint rule, an NOV will be issued only if and when (1) a licensee fails to report an actual or estimated dose from airborne effluent releases from a facility that has exceeded the constraint value; or (2) if a licensee fails to institute agreed upon corrective measures intended to prevent further airborne effluents in excess of those which would result in doses exceeding the constraint level.

The rule applies to airborne effluents of radioactive materials to the environment, other than Radon-222 and daughters, from all NRC licensees except power reactors. Power reactors are exempt from this rule because they are already required, under 10 CFR 50.34a, to identify design objectives and the means to be employed for keeping doses to members of the public from air effluents ALARA in their license application. Appendix I to 10 CFR Part 50 contains the numerical guidelines to meet this requirement.

Response to Comments

Fifty-seven individuals and organizations provided written comments on the proposed rule and Draft Regulatory Guide DG-8016. Among the 57 commenters, 24 were licensees, seven were professional organizations, five were States, 16 were members of the public, and five were environmental organizations. Because many letters commenting on the Draft Regulatory Guide DG-8016 also included comments on the rule, these comments were also considered in developing the final rule.

Issue 1--Proposed Rule Approach

Comments: A total of thirty-one individuals and organizations commented on the basis for the rule. Five commenters agreed with the approach and need for the constraint. Four commented that the rule should not be finalized and that EPA's Subpart I should remain in effect. Twenty-two commenters stated that existing NRC programs provided an ample margin of safety and that the constraint was not needed. However, of these, seven agreed that the constraint was preferable to dual regulation or Subpart I alone.

Those commenting that existing NRC programs are adequate to protect the public cited the two EPA studies on doses from air emissions. Two-thirds of these commenters were opposed to going forward with the constraint because they believed it was not needed and that licensee and regulator costs could not be justified given the expectation that risk to public health and safety would not be reduced. These commenters encouraged NRC to continue working with EPA to provide sufficient basis for rescission of Subpart I without the imposition of an equally unnecessary regulation. A few commenters stated that the risk was considerably less than estimated because excessively conservative calculational methods were used by EPA. A few commenters compared the 10 mrem (0.1 mSv) per year constraint to variability in background or doses from commercial air traffic as evidence that the dose and the risk is trivial. Seven commenters cited burden reduction and single-agency oversight as the reasons for agreeing that the constraint was preferable to dual regulation or EPA's Subpart I alone.

Commenters opposed to the constraint as a less protective standard, stated that the constraint was based upon a voluntary program (ALARA) and, as such, was not adequate to protect the public. One commenter stated that NRC does not perform confirmatory measurements and therefore, NRC jurisdiction was not adequate.

Response: NRC and EPA have been working to develop a basis upon which dual regulation could be eliminated. EPA has stated that there are two necessary components to any finding that NRC's program is sufficient to protect the health and safety of the public. The first is evidence that doses from air emissions are below 10 mrem (0.1 mSv) per year to a member of the public. This has been demonstrated through the two studies by EPA and by

licensee reporting of actual air emissions. The second component is a program to ensure that doses remain at this level. In the absence of rulemaking requiring licensees to maintain doses to levels of no more than 10 mrem (0.1 mSv) per year, EPA would not rescind Subpart I and dual regulation would continue.

The Federal Radiation Council (FRC) was formed in 1959, to provide recommendations to the President for Federal policy regarding radiation matters that affect health. In May 1960, FRC set forth basic principles for protection of both workers and the public. The council was abolished in 1970 when its functions were transferred to the EPA Administrator. In 1981, EPA published proposed recommendations for new Federal guidance for occupational exposure. In 1987, President Reagan approved recommendations by the EPA Administrator for new "Radiation Protection Guidance to Federal agencies for Occupational Exposure." EPA has not yet issued recommendations on limits for the public. A working group comprised of representatives from affected Federal agencies and experts on radiological health matters has been developing these recommendations for several years and expects to provide them during the next year.

In 1977, the International Council on Radiological Protection (ICRP) issued its Report No. 26 "Recommendations of the International Council on Radiological Protection" in 1977. These recommendations concluded that the average doses to members of the public should not exceed 100 mrem (1.0 mSv) per year with a limit of 500 mrem (5.0 mSv) per year to any individual.

The National Council on Radiation Protection and Measurements (NCRP) is required by Congress to recommend limits for exposure to ionizing radiation. In June 1987, NCRP issued its Report No. 91, "Recommendations on Limits for

Exposure to Ionizing Radiation." This report contains recommendations on exposure limits for both occupationally exposed individuals and individual members of the public. The report recommended that doses to individual members of the public be limited to 100 mrem (1.0 mSv) per year averaged over a lifetime, not to exceed 500 mrem (5.0 mSv) in 1 year.

In 1991, NRC revised 10 CFR Part 20 "Standards for Protection Against Radiation." This revision included new limits for individual members of the public. Though both the ICRP and the NCRP recommended limits of 500 mrem (5.0 mSv) in any one year, the NRC established a limit of 100 mrem (1.0 mSv) per year because it was impractical to control dose in terms of lifetime average without keeping track of individual exposures. In addition, 10 CFR Part 20 requires that licensees use procedures and engineering controls to maintain doses ALARA.

Both the NRC and EPA regulatory programs are designed to achieve protection of the public with an ample margin of safety. The approaches of the two agencies differ. NRC limits TEDE, requires that doses are maintained ALARA, and maintains an active inspection program. EPA limits dose from individual pathways of exposure and individual radionuclides to ensure that the total dose does not exceed recommended levels. Both programs achieve similar levels of protection.

NRC agrees that adoption of the constraint in § 20.1101(d) is preferable to dual regulation due to the reduction in burden on licensees as well as State and Federal agencies. Under the provisions of 40 CFR Part 61, licensees with doses to members of the public greater than 1 mrem (0.1 mSv) per year but less than 10 mrem (0.1 mSv) per year must submit reports. However, under 10 CFR 20.1101(d), these licensees will not have to file reports for doses

below the constraint level because doses can be evaluated during routine inspections. Under the final rule, the burden of calculating doses should be reduced for most licensees because the proposed guidance for demonstrating compliance with 10 CFR 20.1101(d) allows significantly more flexibility and simpler methods for calculating doses than the model currently used to demonstrate compliance with 40 CFR Part 61. These new methods for calculating doses should result in fewer reporting and corrective actions, as under EPA's Subpart I.

Licensees are required under § 20.2103 to maintain records of surveys required to demonstrate compliance with the public dose limit. Review of licensee records used to demonstrate compliance with the public dose limit is part of the NRC inspection program. Confirmatory measurements would generally not be useful since most licensees in this category do not have routine ongoing effluent releases.

Finally, concerning those commenters that believe NRC's requirements are less safe than Subpart I, Congress enacted legislation comprehensively amending the Clean Air Act (CAA), which included a section addressing the issue of regulatory duplication between EPA and NRC in 1990. The 1990 CAA amendments permit the EPA Administrator to rescind the CAA standards as they apply to radionuclides, at sites licensed by NRC, and the Agreement States, if he or she finds that the NRC regulatory program provides an ample margin of safety to protect public health.

EPA's analysis of the NRC regulatory program focused on two general issues: (1) whether the implementation of the NRC regulatory program results in sufficiently low doses to protect the health and safety of the public with an ample margin of safety; and (2) whether the NRC program is sufficiently

comprehensive and thorough, and administered in a manner that will continue to protect public health in the future. EPA undertook studies to determine the level of protection provided by the existing regulatory program and found that doses were sufficiently low to protect the health and safety of the public with an ample margin of safety. The implementation of this rule will ensure that doses to members of the public from air effluents will continue to remain below 10 mrem (0.1 mSv) per year and provide evidence to EPA that the current level of protection will continue.

The purpose of this rulemaking is not to reduce doses, because it has already been demonstrated that doses are sufficiently low. The purpose is to ensure that doses are maintained at the low level currently achieved by NRC licensees, eliminate unnecessary dual regulation, and reduce costs associated with the current level of protection, by providing a basis upon which EPA can find that doses will not increase as a result of rescission of Subpart I.

Issue 2 --Promulgation of the Constraint as ALARA

Comments: There were a number of commenters who objected to the ALARA basis for the proposed constraint rule. Some commenters objected on the ground that ALARA is a matter of operating philosophy, good radiation protection practice and licensee judgment, and cannot be translated into an enforceable dose number. Other commenters objected on the basis that ALARA is inherently site specific and cannot be defined generically or that the proposed dose constraint cannot be ALARA but must be a limit because the constraint contemplates some enforcement actions for exceedance even if the licensee has followed all good radiation protection practices. Some

commenters argued that the rule cannot be ALARA because it adds costs with no safety benefit. Other commenters stated that the constraint is inconsistent with a prior NRC decision in 10 CFR Part 20 (56 FR 23360) on the use of "reference levels."

Response: The Commission has retained an ALARA basis for the rule but recognizes that its use of the term in this rule may have led to some confusion. The Commission acknowledges that the ALARA concept in 10 CFR 20.1003 is an operating philosophy which requires good radiation protection practice and the exercise of expert licensee judgement. The ALARA concept is site specific in that some of the factors to be considered may vary from case to case, as the court so found in York Committee for a Safe Environment v. NRC, 527 F. 2d 812 (D.C. Cir. 1975). The Commission has presumed, without deciding, that the ALARA concept in § 20.1003 can be enforced in a particular case so as to require a specific radiation protection practice, but it is clear that the existing regulation does not translate readily into a generic dose number, which, if exceeded, will lead to enforcement action.

The NRC intended the constraint rule to be a somewhat broader concept found in the governing statute, the Atomic Energy Act of 1954, as amended (Act). The Act, as construed by both the Commission (e.g., 10 CFR 50.109) and the courts (Union of Concerned Scientists v. NRC, 824 F.2d 108 (D.C. Cir. 1987)), contemplates two distinct approaches to radiological regulation. First, a level of "adequate protection" must be defined and enforced without regard to economic cost. Second, risk may be reduced to a level below that associated with "adequate protection" to "minimize danger to life or property" with economic cost and other factors as permissible balancing considerations. See "Revision of Backfitting Process for Power Reactors," (53 FR 20603;

June 6, 1988). It is important to note that Section 161b of the Act authorizes the Commission to adopt and enforce generic requirements using either approach. Many recent NRC regulations (e.g., 10 CFR 50.63) have been directed at incremental risk reduction under the second approach based on a generic regulatory or backfit analysis which considered and balanced economic and other costs and safety backfits. These "minimize danger" regulations provide "limits" because they establish generic requirements directly enforceable against licensees. However, in a broad sense they are also ALARA regulations because cost, feasibility, and other relevant factors identified in 10 CFR 20.1003 are evaluated.

Viewed in its larger statutory context, the use of ALARA in 10 CFR 20.1003 is one means to implement the second approach to radiological regulation. However, other similar requirements can also be part of this second approach. While the ALARA concept in 10 CFR 20.1003 may not be consistent with a generic enforceable dose requirement, other concepts of ALARA premised on generic considerations are appropriate. This concept of ALARA as a broadly applicable dose requirement based on a generic weighing and balancing of health and safety, feasibility, and other factors is the basis for the longstanding limits on nuclear power reactor emissions in 10 CFR Part 50, Appendix I, and is the basis for the constraint rule. The ALARA rule imposes a limit in the sense that exceedance will lead to corrective action, but it is not a limit in the sense that exceedance *per se* would constitute a violation of any regulatory requirement. A violation occurs only when a licensee fails to report an exceedance or fails to take appropriate corrective actions. A limit would be appropriate if compliance were needed to ensure adequate protection of public health and safety. In this case, the constraint

is needed only to ensure that currently afforded levels of protection are not reduced. This will provide the basis for rescission of 40 CFR Part 61, Subpart I by EPA.

Thus, to say that the constraint rule cannot be based on ALARA because it is in effect a "limit," interchanges a narrow concept of "ALARA" with a broad concept of "limit." If a broad definition is used, the constraint rule withstands scrutiny as both ALARA and a limit. In the statutory context of the Atomic Energy Act and general principles of administrative law, the constraint rule is a limit based on generic ALARA considerations. The constraint rule is not a limit needed for adequate protection and the constraint rule is something more than a narrow translation of the particular ALARA concept contained in 10 CFR 20.1003. The term "constraint" was used for the rule to avoid confusion with the narrow concepts of ALARA and the limit employed in radiation protection discussion.

Three matters must be addressed:

(1) The comment that the rule cannot be based on ALARA because it will result in increased cost with no safety benefit;

(2) The problem of the licensee who cannot meet the dose constraint despite using all good radiation protection practices; and

(3) The allegedly inconsistent Commission discussion of reference levels in a recent revision to 10 CFR Part 20.

The Commission disagrees with the premise of the first comment. There was no disagreement with the Commission's conclusion that all of the licensees affected by the rule are achieving a level of control such that doses are below the 10 mrem (0.1 mSv) per year level and so there is no factual dispute over whether this level of radiation protection is readily achievable. The

final rule and EPA's rescission of its Clean Air Act emission limits and related requirements will result in a significant net cost savings to licensees. The NRC acknowledges that the positive direct health effects are likely to be small and possibly nonexistent in the near future, given the current level of controls. However, the rule can be said to offer a small, but positive, net health and safety benefit in that it will prevent a decrease in the level of protection afforded the public if Subpart I were rescinded in the absence of a rule like the constraint. Under the ALARA concept, it is appropriate to base a requirement on a small positive health and safety benefit when cost savings are also likely.

The NRC does not expect that any licensee subject to the rule will be unable to demonstrate that doses to members of the public from releases of airborne radioactive materials to the environment are less than 10 mrem (0.1 mSv) per year. In the unlikely case that this dose is exceeded or is projected to be exceeded, due to some temporary circumstances or lapse in controls, the NRC expects the licensee to take whatever corrective actions are necessary (if any) to protect public health and safety, to report the dose, to recommend further corrective actions if necessary, and take those corrective actions agreed upon with NRC. NRC staff will review and approve corrective actions to ensure that they are appropriate to reduce airborne emissions sufficiently to comply with the constraint in the future. In the unlikely case that a licensee is unable to take adequate corrective actions, because of limits in technology or cost constraints, these issues can be addressed in the future on a case-by-case basis.

The application of the ALARA principle used in this rule is not the same as the concept of reference level which was rejected by the Commission when

10 CFR Part 20 was recently revised. Commenters on the 1991 revision to 10 CFR Part 20 objected to the use of reference levels because they were implemented exactly the same as adequate protection limits. For that reason, the Commission did not adopt reference levels in the 1991 revision. Implementation of the constraint is different than such a limit because exceeding the constraint is not a violation, and only requires the licensee to report the dose and take corrective actions to reduce future doses.

Issue 3 --Whether the Constraint is Actually a Limit

Comments: Nine comments were received on whether the constraint is or should be a limit. Two commenters believed that the constraint was no different than a limit. One commenter agreed with the term constraint. Three commenters expressed concern that the constraint was an inappropriate relaxation of requirements.

Those commenting that the constraint was a de facto limit interpreted the requirements to indicate that a second exceedance of the constraint would result in enforcement action and therefore the constraint is a limit. Three commenters indicated that the rule should be a strict limit. They expressed concern that the constraint was less protective than EPA requirements.

Response: If a licensee exceeds a limit that is needed to protect health and safety, the NRC may take immediate enforcement action. If a licensee exceeds a constraint, the licensee will be required to notify NRC, take any actions that may be necessary to protect public health and safety, and implement any further corrective actions that NRC staff agrees are adequate to prevent further doses in excess of the constraint. However, if

the licensee failed to report a measured or calculated dose in excess of the constraint to NRC or failed to implement appropriate corrective actions as agreed upon, enforcement action would be expected. This is because, unlike an adequate protection limit, the constraint is not needed to provide adequate protection of public health and safety.

The NRC does not agree that the constraint is less protective than current EPA requirements. Both EPA's Subpart I and the NRC constraint require licensees to take actions to ensure that doses to members of the public do not exceed 10 mrem (0.1 mSv) per year from ambient air emissions. NRC routinely inspects licensed facilities to ensure that air effluents do not result in doses to members of the public that exceed the requirements in 10 CFR Part 20. The inspection and enforcement program will be amended as a result of this final rule to review licensee records used to demonstrate compliance with the constraint.

Issue 4 --Citizen Suits.

Comments: Three commenters opposed finalization of the constraint on the basis that it forfeits citizen rights to sue a licensee who exceeds the constraint.

Response: The Commission's regulations in 10 CFR 2.206 provide the public with the right to petition the NRC to take enforcement action against a licensee for a violation of the Commission's regulations. This would include the final constraint rule.

Issue 5 --Agreement State Compatibility.

Comments: Four commenters addressed the proposal that the constraint be a Division 2 matter of compatibility. Under Division 2, States could adopt similar or more stringent requirements. Three commenters agreed that this rule should not be codified as a Division 2 requirement, but rather as a Division 1 matter of compatibility. Under Division 1, the States would be required to adopt regulations that were essentially identical. These commenters believed that if stricter standards were permitted, reactor and non-reactor licensees would be under different requirements and certain practices, such as nuclear medicine, could be jeopardized. One commenter noted that because this is really a limit, it should be under 10 CFR 20.1301 and would be a Division 1 matter of compatibility. Another commenter stated that NRC should have provided a greater opportunity for State involvement in this rulemaking, and that as a division 2 rule, Agreement States would have to spend scarce resources to develop a compatible rule.

Response: Section 116 of the Clean Air Act specifies that nothing precludes States from imposing air emission requirements that are more stringent than those developed by EPA. Section 116(d)(9), which contains the provisions related to EPA's margin of safety determination for NRC or Agreement State licenses, specifies that: "Nothing in this subsection shall preclude or deny the right of any State or political subdivision thereof to adopt or enforce any standard or limitation respecting emissions of radionuclides which is more stringent than the standard or limitation in effect under Section 7411 of this title or this section." The Commission believes that this provision clarifies that EPA's determination regarding NRC

and Agreement State licensees has no effect on the existing authority of States to impose air emission standards that are more stringent than those of EPA.

With regard to the comment concerning involvement of the Agreement States in the development of this rule, NRC has routinely reported its progress on providing an adequate basis upon which EPA could rescind Subpart I to both the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors (CRCPD) at each of their annual meetings. The Agreement States were consulted extensively on this issue over the last several years. There were extensive discussions of the concept with the individual States and with the Executive Board of the OAS.

Issue 6 --Demographic Information Contained in Required Reports.

Comments: Seven commenters addressed the application of the requirement contained in 10 CFR 20.2203(b)(2) to the constraint. This section requires reports to contain demographic information on the exposed individual. These commenters expressed concern that a member of the public would be under no obligation to provide demographic information to licensees and that licensees would not always be able to comply with the requirement.

Response: NRC agrees that members of the public may choose to withhold the demographic information from licensees. Such information is only needed for occupationally exposed individuals to ensure that lifetime exposure records are accurate. Section 20.2203 has been changed to only require such information on occupationally exposed individuals.

Issue 7 --Effective Date.

Comment: One commenter requested that an effective date be added to the final rule to coincide with EPA's rescission of Subpart I.

Response: The NRC and EPA will, to the extent possible, publish both final rules so that they become effective concurrently.

Issue 8 --Enforcement.

Comments: Five commenters stated that NRC should establish a limit rather than a constraint. They believed that if the limit has been exceeded, a notice of violation and civil penalties should always result. One commenter expressed concern that "self-reporting and confession" is not adequate. Another stated that because ALARA is only guidance, it is not enforceable.

Response: ALARA is not guidance. As stated previously, the 1991 revision to 10 CFR Part 20 codified ALARA as a required part of the licensee's radiation protection program. A limit often implies that doses must be controlled below that level in order to provide adequate protection of health and safety of the public and workers. To meet ALARA requirements licensees are currently controlling effluents to levels below that which would be required under the constraint. If a licensee exceeds the constraint, the rule requires that this be reported and that corrective actions be promptly taken. If a licensee does not comply with the obligation to report and take corrective actions, enforcement action will result. In NRC's judgement, as a matter of enforcement policy, it is not necessary to issue a notice of violation or civil penalties upon exceedence of the constraint level; it is

sufficient that this be reported and that prompt corrective action is taken.

Issue 9 --Exemptions

Comments: Five commenters stated that the rule should only apply to members of the public off site. They cited the EPA's Subpart I requirement to calculate dose to the nearest resident or offsite individual likely to receive the highest dose. Under Subpart I, licensees would not calculate doses from air emissions to visitors in hospitals, workers that are not radiation workers within the facility, or other members of the public within the facility.

Response: The language in the rule has been changed to reflect that it is intended to apply to radioactive airborne effluents to the environment. The Draft Regulatory Guide DG-8016 will be revised to indicate that the dose limit is to be calculated or measured at the nearest resident or individual offsite likely to receive the highest dose. The final regulatory guide will be available when the rule becomes effective.

Comments: Two commenters stated that air emissions from adjacent nearby exempt uranium mills should not be included in the calculation of dose. One commenter stated that materials from unlicensed portions of the facility such as ore stockpiles should not be considered in the calculation of dose.

Response: Subpart I does not apply to disposal at facilities regulated under 40 CFR Part 191, Subpart B, or to any uranium mill tailings pile after it has been disposed of under 40 CFR Part 192. The constraint applies to airborne effluents of only licensed materials to the environment. Draft Regulatory Guide DG-8016 will be changed to clarify that windblown particulates from other licensed facilities or unlicensed materials do not

need to be considered in the calculation of doses used to demonstrate compliance with the constraint.

Comments: Four commenters stated that air emissions from patients should be exempted from this rule.

Response: The regulatory impact analysis (NUREG-1492) for a recent NRC rulemaking analyzed potential doses from exposure to patients who were released after administration of radiopharmaceuticals. This analysis concluded that internal doses from inhalation of radioactive materials in the exhaled air of a released patient are trivial. For licensees using an inventory approach to demonstrating compliance with the rule, such as the COMPLY computer code, there is no need to account specifically for the materials that might be released to the air through respiration or transpiration by patients. The Regulatory Guide will make it clear that dose from air emissions from patients do not need to be specifically addressed in the calculation of dose used to demonstrate compliance with the constraint.

Comments: Four commenters stated that in addition to Rn-222, all daughters produced after release should also be excluded.

Response: EPA's Subpart I exempts both Rn-222 and any daughters produced after release of Rn-222 because these types of releases are normally not attributable to licensed activities. The proposed rule was not intended to be more stringent than Subpart I. The rule language has been changed to reflect this exemption.

Comments: Two commenters recommended that in addition to Rn-222, Rn-220 and its daughters should also be exempted. One commenter stated that it was an EPA oversight that led to this erroneous omission from the final Subpart I.

Response: Rn-220 is normally attributable to licensed activities. EPA does not exempt Rn-220 or its daughters from consideration in the dose calculations in support of demonstrating compliance with Subpart I. The commenter's suggestion that an oversight led to the erroneous omission of this exemption from Subpart I is incorrect, and Rn-220 should not be excluded from the calculations that are used to demonstrate compliance with the constraint.

Comments: Six commenters requested that in addition to sealed sources, sealed containers should also be excluded from the rule.

Response: Paragraph 2(a) of Appendix D to 40 CFR Part 61 states: Radioactive materials in sealed packages that remain unopened, and have not leaked during the assessment period should not be included in the calculations." Subpart I exempts sealed packages, because any package that has remained sealed cannot contribute to airborne effluents. When a total inventory of licensed materials possessed during the year is used to model potential doses, it is unnecessary to include materials that could not have contributed to airborne effluents. The Regulatory Guide will provide further guidance on this issue.

Issue 10 --Measurability of 10 mrem (0.1 mSv) per year.

Comments: Three commenters stated that 10 mrem (0.1 mSv) per year was not measurable. One commenter stated that although 10 mrem (0.1 mSv) per year might be easily achievable, it is not easily measurable. Another stated that the exposure rate corresponds to 1 microR (0.01 micro-Sv) per hour and cannot be measured accurately.

Response: Draft Regulatory Guide DG-8016 provides several methods for demonstrating compliance with the constraint, and only one of the methods described would require direct measurement at the receptor location. If this method is not practical due to the emission characteristics of the radionuclide releases, there are other options cited in Draft Regulatory Guide DG-8016 that do not require a direct measurement to demonstrate compliance with the constraint.

Issue 11 --Scope of the Rule

Comments: One commenter stated that if there must be a constraint, it should apply to all licensees, including power reactor licensees.

Response: Although this rule only applies to licensees other than power reactor licensees, the Commission's existing regulations in 10 CFR Part 50, Appendix I, already establish a similar regulatory framework for power reactors. Appendix I includes separate requirements to develop design objectives and operational levels sufficient to demonstrate compliance with EPA's Subpart I. In addition, reactor licensees must annually report quantities of radioactive materials released into the environment, as well as the resulting doses.

Issue 12 --Location of Constraint in NRC Regulations.

The Commission requested specific comment on the question of whether the 10 mrem (0.1 mSv) per year constraint should be established in 10 CFR Part 20 as proposed or whether it should be established separately in each appropriate part of Title 10 instead.

Comments: Two comments were received in response to this issue. One commenter stated that the constraint should be in 10 CFR Part 20. The other commenter stated that the constraint should be in each appropriate part. Two other commenters stated that it should be in § 20.1301 with the dose limits.

Response: While the constraint could just as easily be included under other parts of the regulations, including it in 10 CFR Part 20 provides uniformity. Because 10 CFR Part 20 is the designated area for radiation protection standards and related requirements, it is the appropriate location for the constraint. The rule will be codified under § 20.1101 to make it clear that although the constraint is not the same as a limit, licensees are expected to develop radiation programs to ensure that doses from air emissions are below 10 mrem (0.1 mSv) per year.

Agreement State Compatibility

The Commission believes that the Division 2 compatibility designation for the rule is consistent with state authority in this area as described in the Clean Air Act. The Division 2 designation means that Agreement States

must address these rules in their regulations but may adopt requirements more restrictive than those of NRC. Accordingly, the authority of the Agreement States to impose air emissions standards under their Atomic Energy Act authority after the effective date of this rule will be consistent with their existing authority. Under Section 274 of the Atomic Energy Act the Commission reviews Agreement State programs to ensure that adequacy and compatibility of the State Program is maintained. The Commission has also approved procedures to suspend or terminate programs that are not adequate or compatible.

Summary of Changes in the Final Rule

Based on the responses to comments, a few changes were made in the final rule. Otherwise, the provisions of the final rule are the same as those presented in the proposed amendments. Specific changes to the final rule are summarized as follows:

(1) Section 20.2203(b)(2) has been changed to require the name, social security number, and date of birth only for occupationally overexposed individuals and not for members of the public who have received doses in excess of the public limits, including the constraint.

(2) The language of the rule has been changed to indicate that Rn-222 and all daughters produced after the release of the radon are categorically excluded from this rule.

(3) The language of the rule has been changed to indicate that the constraint applies only to release of airborne radioactive effluents to the environment and, thus, dose to the nearest resident, offsite business or school, is to be constrained.

In addition, the following changes will be made to Draft Regulatory Guide DG-8016:

(1) An inventory of radioactive materials used to model a potential dose to a member of the public need not include radioactive materials in sealed containers that have remained sealed throughout the compliance period.

(2) Airborne emissions of radioactive materials from patients does not need to be considered if the materials have already been included in the site inventory.

The Regulatory Guide was issued in draft for public comment concurrent with the proposed rule. The final regulatory guide will be available by the effective date of this rule.

Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required. This action is not expected to have any significant environmental impact because the programs will provide equivalent protection. Also, airborne effluents of radioactive materials to the environment are not expected to increase. The changes to the final rule are to the procedural methods for demonstrating compliance as well as licensing and inspection procedures. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection and photocopying for a fee at the NRC Public Document Room,

2120 L Street NW. (Lower Level), Washington, DC.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. Seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0014.

The public reporting burden for this collection of information is estimated to average 80 hours per response, including the time for reviewing instructions, searching existing data sources. gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments on any aspect of this collection of information, including suggestions for further reducing this burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to bsjl@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014), Office of Management and Budget, Washington, DC 20503.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a "major rule" and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

The NRC has prepared a regulatory analysis for this final rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. In the response to comments, the NRC concluded that only some minor changes to the draft regulatory analysis were necessary, corresponding to some minor procedural changes in the final rule. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW. (Lower level), Washington, DC 20555-0001. Single copies of the analysis may be obtained from Charleen T. Raddatz, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6215.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule only impacts NRC licensees with emissions of significant quantities of radioactive material who would be required to report the exceedance to the

NRC. It will relieve licensees from the unnecessary burden of dual regulation. The level of air emissions from NRC-licensed facilities has historically been well below the NRC dose limit and except for a few unusual cases, readily met the EPA standard.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule because it does not apply to power reactor licensees, and therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects In 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 20.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f); secs. 201, as amended, 202, 206, 88 stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1003, the definition of *Constraint* is added to read as follows:

§ 20.1003 Definitions.

* * * * *

Constraint (dose constraint) means a value above which specified licensee actions are required.

* * * * *

3. In § 20.1101, paragraph (d) is added to read as follows:

§ 20.1101 Radiation Protection Programs.

* * * * *

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive

the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

4. In § 20.2203 a new paragraph (a)(2)(vi)and (b)(2) are added and paragraphs (b)(1)(iv) and (b)(2) are revised to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

(a) * * *

(2) * * *

(vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(b) * * *

(1) * * *

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed[7] individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

* * * * *

Dated at Rockville, Maryland, this ___ day of _____, 1996.

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,

Secretary of the Commission.

ENCLOSURE 2

ENFORCEMENT POLICY: FRN

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NUREG - 1600]

Policy and Procedure for Enforcement Actions; Radiation Protection Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Amendment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions" to add an example for categorizing the significance of failure to report an exceedance of the dose constraint established in 10 CFR 20.1101(d), or failure to take corrective action for such an exceedance. By a separate action published in this issue of the Federal Register, the Commission has issued a final rule amending Part 20 to add §20.1101(d), which establishes the requirements for reporting and taking corrective action. This modification to the Enforcement Policy reflects that amendment.

DATES: This action is effective on the day that the addition of section 20.1101(d) to 10 CFR Part 20 becomes effective. Comments are due on or before [30 days after publication in the Federal Register].

ADDRESSES: Send written comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information Section.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301) 415-2741.

SUPPLEMENTARY INFORMATION:

The Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy or Policy) was first issued on September 4, 1980. Since that time, the Enforcement Policy has been revised on a number of occasions. On June 30, 1995 (60 FR 34381), the Enforcement Policy was revised in its entirety and was also published as NUREG-1600. The Policy recognizes that violations have differing degrees of safety significance. As reflected in the severity levels, safety significance

includes actual safety consequence, potential safety consequence, and regulatory significance.

The rulemaking to add §20.1101(d) establishes a dose constraint for radiation dose to members of the public from air emissions of radionuclides from NRC licensed facilities other than power reactors. As noted in the Statements of Consideration for that rulemaking, the dose constraint is not a dose limit necessary to provide adequate protection of public health and safety, but is a limit in the sense that exceedance triggers requirements to make a report to NRC and promptly take corrective action to ensure against a recurrence. Consistent with this rulemaking, the Commission has determined that a failure to make the required report or promptly take corrective action as required should be categorized at Severity Level IV. As defined in the Enforcement Policy, Severity Level IV violations are of less than significant regulatory concern but more than minor concern; *i.e.*, if left uncorrected, they could lead to a more serious concern.

Therefore, "Supplement IV--Health Physics (10 CFR Part 20)" of the Policy is being modified. Example D.8. is being renumbered as Example D.9., and a new Example D.8. is being added to provide an example of a violation categorized at Severity Level IV involving failure to report an exceedance of the dose constraint established in §20.1101(d), or failure to take corrective action for an exceedance.

Paperwork Reduction Act Statement

This policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011. The approved information collection requirements contained in this policy statement appear in Section VII.C.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Accordingly, the NRC Enforcement Policy is amended as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

In Supplement IV, paragraph D(8) is renumbered as paragraph D(9) and a new paragraph D(8) is added as follows:

Supplement IV--Health Physics (10 CFR PART 20)

D. Severity Level IV--Violations involving for example:

* * * * *

8. A failure to report an exceedance of the dose constraint established in 10 CFR 20.1101(d) or a failure to take corrective action for an exceedance, as required by 10 CFR 20.1101(d); or

9. Any other matter that has more than a minor safety, health, or environmental significance.

* * * * *

Electronic Access

Comments may be submitted electronically in either ASCII text or WordPerfect format (version 5.1 or later) by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications

software packages, or directly via Internet. Background documents on the related rulemaking also are available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number 800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS, 703-321-3339, or by using Telnet via Internet: fedworld.gov. If using 703-321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take the user to the NRC online main menu. The NRC online area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If NRC is accessed from FedWorld's main menu, the user may return to FedWorld by selecting the "Return to FedWorld" option from the NRC online main menu. However, if NRC is accessed at FedWorld by using NRC's toll-free number, the user will have full access to all NRC systems, but will not have access to the main FedWorld system.

If FedWorld is contacted using Telnet, the user will see the NRC area and menus, including the Rules Menu. Although the user will be able to download documents and leave messages, he or she will not be able to write comments or upload files (comments). If FedWorld is contacted using FTP, all files can be accessed and downloaded, but uploads are not allowed. Only a list of files will be shown without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP, that mode only provides access for downloading files and does not display the NRC Rules Menu.

For more information on NRC bulletin boards, call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555-0001, telephone 301-415-5780; E-mail AXD3@nrc.gov.

Dated at Rockville, Maryland, this ___ day of _____ 1996.

For the Nuclear Regulatory Commission.

_____
John C. Hoyle,
Secretary of the Commission.

ENCLOSURE 3

REGULATORY ANALYSIS

Regulatory Analysis for the NRC Constraint Rule on Radionuclide Air Emissions from NRC and Agreement State Licensees Other than Nuclear Power Reactors

1. Statement of Problem

Radionuclide air emissions from Nuclear Regulatory Commission (NRC) licensees other than power reactors, and NRC Agreement State licensees are currently regulated by both the NRC (or the Agreement State) and the Environmental Protection Agency (EPA). The NRC and Agreement State regulations have been issued under the authority of the Atomic Energy Act (AEA). The EPA regulations have been issued under the authority of the Clean Air Act (CAA). The purpose of this Regulatory Analysis is to evaluate a final NRC rulemaking that provides assurance to the EPA that future emissions from NRC licensees will not exceed levels that would provide an ample margin of safety. This action is expected to be the final step in providing EPA with a basis upon which to rescind 40 CFR Part 61 "National Emission Standards for Hazardous Air Pollutants" (NESHAPS), Subpart I, as it applies to NRC licensed facilities other than power reactors,[1] thereby relieving these NRC licensees from unnecessary dual regulation.

The EPA's regulations, 40 CFR Part 61, Subpart I, are currently in effect for all NRC and Agreement State licensees, except power reactors. The dose standard contained within this regulation is not consistent with those of NRC in 10 CFR Part 20. The EPA dose standard in Subpart I is 10 mrem

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1 EPA has rescinded Subpart I for power reactors based on requirements contained in 10 CFR Part 50, Appendix I, and a history of over 20 years of reported air emissions from power reactors resulting in doses well below 10 mrem/yr to the maximally exposed member of the public.

(0.1 mSv) per year, total effective dose equivalent (TEDE) for air emissions from any single facility (buildings, structures, and operations on one contiguous site). This standard is different in both numerical value and approach to that of the NRC. The EPA approach to ensuring that dose limits adequately protect the public with an ample margin of safety is to limit individual pathways and sources to a fraction of the 100 mrem (1 mSv) per year TEDE limit for members of the public. The NRC approach to ensuring that doses to members of the public are adequately protective is to require compliance with an upper limit of 100 mrem per year TEDE from all pathways, and to the extent practical, maintain doses as far below this limit as is reasonably achievable (ALARA), taking into account social and economic considerations and sound radiation protection principles.

There are three mechanisms for demonstrating compliance with the NRC limit and ALARA. For light water reactors, compliance is demonstrated if the design objectives in 10 CFR Part 50, Appendix I, are achieved. For other NRC and Agreement State licensees, compliance with the dose limit and the ALARA requirement is demonstrated in one of two ways: (1) Demonstrate that the average concentrations in air and liquid effluents released from the facility do not exceed the values in 10 CFR Part 20, Appendix B, and are ALARA, and that direct exposures do not exceed 50 mrem (0.5 mSv) per year, and are ALARA; or (2) Demonstrate that the dose to the member of the public likely to receive the highest dose from all pathways is less than 100 mrem (1 mSv) per year TEDE and is ALARA.

The NRC believes that for its licensees the application of ALARA goals and guidelines has been successful in maintaining actual air emissions to levels that are well below the EPA standard. Past experience and effluent

information reported to the NRC staff have indicated that ALARA dose goals in the range of 10 mrem (0.1 mSv) per year or less should be achievable for all materials licensees, including fuel cycle facility licensees. Studies conducted by EPA (Ref. 1) concluded that NRC and Agreement State licensees are, in general, maintaining air emissions and resulting doses to members of the public well below the 10 mrem (0.1 mSv) per year standard. This conclusion has been confirmed by a review of the annual reports submitted by licensees to EPA as required by 40 CFR Part 61, Subpart I. In 1995, only one licensee reported air emissions above the 10 mrem (0.1 mSv) per year standard. Corrective measures were initiated by the licensee and no enforcement actions were taken by EPA.

This rulemaking establishes a 10 mrem (0.1 mSv) per year TEDE dose constraint on radionuclide air emissions. Although it is not considered a health and safety limit such that adequate protection would not be assured otherwise, this regulatory action ensures that air emissions are maintained at a very low level, at little or no incremental cost (and considering the elimination of dual regulation, at a net savings), and brings consistency between EPA's dose standard and the NRC's ALARA application. The final rule provides EPA with a basis upon which to rescind Subpart I as it applies to NRC-licensed facilities other than power reactors.

1.1 Background on EPA's Implementation of Radionuclide NESHAPs for NRC Licensed Facilities

The 1977 amendments to the CAA required EPA to consider whether radionuclides should be identified as a hazardous air pollutant and, if so, to adopt standards to limit their emissions. Section 122(c)(2) of this 1977 amendment also required EPA and NRC to enter into a cooperative agreement to minimize duplication of effort and conserve resources in establishing, implementing, and enforcing standards for airborne radionuclide emissions from sources and facilities licensed by NRC. In 1979, EPA subsequently identified radionuclides as a hazardous air pollutant (44 FR 76738; December 27, 1979).

In April 1983, EPA proposed standards regulating radionuclide air emissions from four source categories, with one being NRC licensed facilities. In October 1984, EPA withdrew the proposed emission standards for certain sources, including NRC licensed facilities, based on a finding that controls already in-place protected the public with an "ample margin of safety" (48 FR 15076; April 6, 1983). In July 1987, the U. S. Court of Appeals for the District of Columbia Circuit, remanded to EPA the air emission standard for vinyl chloride because the Court found that EPA had improperly considered cost and technological feasibility in setting the standard without first determining a sufficient level of protection as required by the CAA. Later that year, EPA petitioned the Court for a voluntary remand of its existing air emission standard for radionuclides. In March 1989, EPA proposed a revised emission standard of 10 mrem/yr TEDE for NRC and Agreement State licensed facilities. This standard was established based on the concept of an "ample margin of safety" as directed by the Court in its remand of the vinyl chloride NESHAP.

On December 15, 1989 (54 FR 51654), the EPA issued its final rule on the NESHAPs under Section 112 of the CAA for emissions of radionuclides from numerous source categories, with one category including NRC and Agreement State licensees. The rule was issued as 40 CFR Part 61. Subpart I of this rule pertained to NRC and Agreement State licensees. The standard states that air emissions of radionuclides shall not cause any member of the public to receive more than 10 mrem (0.1 mSv) TEDE in any year, or more than 3 mrem (0.03 mSv) TEDE from radioiodines. Radon-222 and its decay products formed after release from the facility are excluded. Effective with the issuance, however, was a stay on Subpart I, which delayed the effective date of that part of the rule covering NRC and Agreement State licensees. Subpart I was stayed until March 15, 1990, to allow EPA time to consider concerns raised, in particular, by the NRC and the National Institute of Health (NIH), an NRC licensee, about unnecessary duplicative, and perhaps conflicting, standards for NRC licensees.

At the time of issuance of the rule, the EPA reaffirmed a previously stated position that it "...continues to believe existing emissions from these sources [NRC licensees] are already so low that public health and safety are already protected with an ample margin of safety" (50 FR 5190; February 6, 1985). The NRC had raised concerns about whether regulation of its licensees under the CAA provided any additional public health and safety benefit. The NIH, as an NRC licensee, voiced concerns about the potential negative effects of the dual standards on the use of nuclear medicine. Even recognizing these concerns, the EPA decided it was legally bound to include Subpart I in its final rule promulgation due to court-ordered deadlines. A 60-day comment period was established for the purpose of receiving further information and

comments related to these concerns. A 3-month stay of Subpart I was effected to allow further consideration.

The 1990 amendments to the CAA included provisions in Section 112(d)(9) that allow EPA to decline regulating airborne radionuclide emissions from NRC licensed facilities if it determines, through a rulemaking, that NRC's program provides protection of the public health with an "ample margin of safety." This legislative initiative, referred to as the Simpson Amendment, created the framework for cooperative activities between the agencies, which supported the rescission of 40 CFR Part 61 Subpart T (and Subpart I for power reactors). Subpart T covers radon emissions from disposed uranium mill tailings at sites where operations have ceased (59 FR 36280; July 15, 1994).

On April 24, 1991, the EPA issued a final stay until November 15, 1992, for all NRC and Agreement State licensees, except power reactors, which under separate ruling had been stayed indefinitely pending the rulemaking on Subpart I rescission (56 FR 18735; April 24, 1991). During this period of stay, EPA conducted two studies of the air emissions from NRC and Agreement State material licensees for the purpose of evaluating the state of compliance. The first was a survey of 367 randomly selected nuclear material licensees. The highest estimated dose to a member of the public from air emissions was 8 mrem (0.08 mSv) per year TEDE, based on very conservative modeling. In addition, 98 percent of the facilities surveyed had doses of less than 1 mrem (0.01 mSv) per year from air emissions.

The second EPA study evaluated doses from air emissions from 43 additional facilities that were selected because of their potential for air emissions with calculated annual doses to members of the public at a sizable fraction of the 10 mrem (0.1 mSv) per year dose standard. Of these, 75 percent had estimated maximum doses to a member of the public of less than

1 mrem (0.01 mSv) per year. None exceeded the 10 mrem (0.1 mSv) per year standard. The results of these studies were published by EPA (57 FR 56877; Dec 1, 1992) and, in summary, showed that radionuclide air emissions from the NRC and Agreement State licensees were typically, with the potential for few exceptions, well within the EPA's CAA standard of 10 mrem (0.1 mSv) per year.

EPA's conclusion, based in part on these studies, was that the current NRC program, which limits public dose to 100 mrem (1 mSv) per year, in concert with the requirement to keep doses ALARA, has been successful in maintaining air emissions well below the 10 mrem (0.1 mSv) per year Subpart I standard. However, because of EPA's concern regarding the litigative risk of extending stays of previously promulgated NESHAPs during pendency of a rescission rulemaking and that the D.C. Circuit had already reversed the previous stay for licensees other than power reactors, the stay on Subpart I was allowed to expire by its own terms on November 15, 1992 (57 FR 56877).

In July 1993, the EPA Administrator determined that there was insufficient basis at that time to rescind Subpart I. Concerns remained about the NRC's Agreement State program and the fact that there was no mechanism to ensure doses from air emissions would remain below 10 mrem per year in the absence of Subpart I. Consequently, licensed facilities other than power reactors are currently subject to dual regulation of air emissions of radionuclides under both the AEA and the CAA, with dual regulatory oversight by EPA (and/or authorized States) and NRC (or Agreement States).

1.2 Past NRC and EPA Efforts to Rescind Subpart I Under the Simpson Amendment

Over the past 16 years, the NRC and EPA have worked together on the objective of eliminating the duplicate regulatory oversight. The NRC and EPA entered into a Memorandum of Understanding (MOU) in November 1980, to work together in developing mutually acceptable procedures for implementing and enforcing EPA's standards in accordance with Section 122(c)(2) of the CAA (45 FR 72980; November 3, 1980). The 1980 MOU stated, "Under this agreement EPA shall promulgate standards for airborne radionuclide emissions under its Clean Air Act authority and NRC shall have the primary role in implementing and enforcing these standards where applicable for sources and facilities licensed by NRC."

In 1990, Congress amended the CAA specifically addressing the issue of duplicate regulation. This amendment enacted Section 112(d)(9) of the Act. It included provisions whereby standards for radionuclide emissions from NRC (or NRC Agreement State) licensees would not need to be promulgated if the EPA Administrator determined, by rule and after consultation with the NRC, that the regulatory programs established by the NRC provide an "ample margin of safety" to protect public health. Under these conditions, radionuclide NESHAPs for NRC and Agreement State licensees would not be required. This provision was enacted to enable EPA to eliminate duplicate regulation and eliminate redundant efforts between EPA's and NRC's regulatory programs.

In 1992, EPA proposed rescission of Subpart I, and subsequently allowed it to become effective, and NRC and EPA issued an MOU (57 FR 60778; December 22, 1992). Its intent was to determine NRC actions that could form the basis for EPA to rescind Subpart I. NRC was to put in place additional

regulatory guidance to ensure air emissions would be maintained at a level consistent with the level of protection afforded under EPA's Subpart I, i.e., "ample margin of safety." NRC was to develop and issue regulatory guidance for its licensees, other than power reactors, on designing and implementing a radiation protection program to ensure that doses resulting from effluents would remain ALARA. NRC also agreed to develop inspection guidance on ALARA considerations for effluents and incorporate ALARA in its Standard Review Plans. NRC was to work with Agreement States to adopt and implement a compatible program. EPA was to develop and publish in the Federal Register a Notice of Proposed Rulemaking, pursuant to its authority under the CAA, Section 112(d)(9), to rescind its existing regulations of 40 CFR Part 61, Subpart I, as applied to licensed facilities other than power reactors.

As an implementation of its ALARA guidelines, the NRC developed Regulatory Guide 8.37, which included a specific ALARA goal of 10 mrem (0.1 mSv) per year TEDE to the maximally exposed individual from radionuclide air emissions (Ref 2). Additionally, NRC Inspection Procedures (IP) 87102 was developed, 40750 and 80745 were revised, to include a review of emissions from those facilities with the potential of exceeding 20 percent of the 10 CFR Part 20, Appendix B, Table 2 values (Ref. 3). Generally, this 20 percent level corresponds to a calculated dose from air exposure of 10 mrem (0.1 mSv) per year, which is comparable with the EPA's Subpart I standard. An Inspection Referral Form was included within IP 87102, 40750, and 80745 which was completed by the NRC inspector and forwarded by the regional office to the cognizant EPA Regional Radiation Program Manager.

Under the Simpson Amendment and the 1992 MOU, EPA agreed to propose a rulemaking rescinding its existing regulations in 40 CFR Part 61, Subpart I, as applied to licensed facilities other than nuclear power reactors

(56 FR 18735; April 24, 1991). EPA announced its intent to propose rescission of Subpart I on September 18, 1992 (57 FR 43173). Later in 1992, EPA issued the Federal Register notice proposing the rescission on December 14, 1992 (57 FR 56877). However, on November 15, 1992, EPA allowed the stay on Subpart I to expire for facilities other than power reactors. This action was taken because of substantial doubts that EPA had concerning the legality of any further stay. A September 22, 1992, DC Court ruling in response to a Natural Resources Defense Council (NRDC) petition found that EPA had exceeded its authority by staying Subpart I for facilities other than power reactors, while it was collecting information to make a finding under Section 112(d)(9) (Simpson Amendment). Following this determination, in July 1993, the EPA Administrator decided there was insufficient regulatory basis to rescind Subpart I.

In its January 28, 1994 (59 FR 4228) Federal Register notice, EPA stated:

> At this time, EPA has not taken final administrative action concerning the rule to rescind Subpart I for NRC and Agreement State licensees other than commercial nuclear power reactors which it proposed on December 1, 1992. EPA is recommending that NRC make certain changes in its regulatory program in order to fully support the substantive finding which is required by CAA Section 112(d)(9) before EPA may rescind Subpart I for NRC licensees other than commercial nuclear power reactors.

EPA has historically identified two components to this finding: (1) that the facilities licensed by NRC and Agreement States are in compliance with the quantitative emission limits in Subpart I (10 mrem (0.1 mSv) per year TEDE);

and (2) that the NRC program must be sufficient to ensure that emissions would remain below this level in the future, thereby protecting the public with an ample margin of safety.

1.3 Issue of Unnecessary and Conflicting Dose Standards

The issues surrounding the necessity for duplicate regulation relate to EPA's need to demonstrate an "ample margin of safety" as called for in the CAA. Past studies conducted by the EPA have indicated that, except for unusual cases, all NRC and Agreement State licensees currently subjected to Subpart I meet the Subpart I dose standard. NRC's reviews of licensees' air emissions further support the position that the ALARA goals of Regulatory Guide 8.37 are consistently being met. For the calendar year 1993, the first year under which Subpart I reporting was required, EPA received approximately 670 reports from NRC and Agreement State licensed facilities. Of these, approximately 30 reported doses greater than 10 mrem (0.1 mSv) per year from air emissions. After clarification with several facilities in their use of the COMPLY code, only one licensee had radioactive air emissions in excess of the Subpart I dose standard which also exceeded the 10 CFR Part 20 limits for members of the public. This licensee took corrective measures; no enforcement actions were taken by EPA as enforcement action was taken by NRC. The 1995 annual reports have been submitted to EPA. No licensee reported air emissions above the Subpart I standard.

The dual regulations by EPA and NRC are considered unnecessary for the following reasons. First, the level of air emissions from NRC licensed facilities has historically been well below the EPA and NRC dose limits. The application of the ALARA principle has resulted in facility programs and

emissions that, except for a few unusual cases, readily meet the EPA standard. These unusual situations are best addressed on a case-by-case basis. Second, with this level of compliance, subjecting facilities to dual reviews, dual reporting, and evaluations, in addition to NRC inspections, is unnecessary for protecting public health and safety. Compliance can most efficiently be covered by a single regulatory process.

EPA's compliance program relies primarily on evaluations and reports prepared by the facility. Licensees emitting radionuclides in amounts that would cause doses less than 10 percent of the Subpart I limits (e.g., < 1 mrem (0.01 mSv) per year TEDE) are exempt from the reporting requirement but must still monitor effluents and maintain records of dose calculations. Licensees subject to Subpart I annual reporting requirements (e.g., doses > 1 mrem (0.01 mSv)/yr TEDE) are required to submit an annual report to EPA by March 31 of each year on air emissions for the previous calendar year. Licensees with air emissions in excess of the annual limit (e.g., > 10 mrem (0.1 mSv) per year TEDE) must include in the report proposed corrective measures to ensure future doses will be below the limit and report on a monthly basis until EPA determines that adequate corrective measures have been taken and reporting is no longer necessary.

There are currently about 6,000 NRC licensed facilities and about 14,000 Agreement State licensees. About half of these facilities use radioactive materials in the form of sealed sources (i.e., contained within a metal or other material casing). These licensees need only understand Subpart I and determine that their licensed activity has a negligible potential for any significant air emissions (see 40 CFR 61.100 applicability). The facilities (other than power reactors) with potential air emissions for which compliance evaluations are required are those that use materials in unsealed form,

Conforming regulations enacted by Agreement States are essentially identical, in level of protection afforded, to those of the Commission. Associated guidance and inspection efforts are normally similar.

2. Objectives of the Rulemaking

The objective of the rulemaking is to provide assurance that future emissions from NRC licensees will not exceed levels that will provide an ample margin of safety. This action is expected to be the final step in providing EPA with a basis upon which to rescind 40 CFR Part 61, Subpart I, "National Emission Standards for Hazardous Air Pollutants," as it applies to NRC and Agreement State licensed facilities other than power reactors, thereby relieving these licensees from unnecessary dual regulations. To support the determination by EPA that NRC's programs provide an equivalent level of protection, this rulemaking codifies a 10 mrem (0.1 mSv) per year dose constraint applicable to NRC licensed facilities, excluding power reactors.

This rulemaking, followed by an EPA rescission of Subpart I, will eliminate duplicate regulatory oversight of NRC and Agreement State licensees by EPA under the CAA and lessen the burden of regulatory compliance on licensees. It will eliminate redundancy in the regulatory processes between NRC and EPA, thereby reducing government's oversight effort. The resulting cost savings will be achieved while maintaining the same margin of public and environmental safety as that currently afforded under Subpart I. With the elimination of dual regulation, the burden of implementation and continued demonstration of compliance with duplicate regulations by the users will be reduced. Efforts will be reduced for maintaining compliance and enforcement programs by two separate government agencies for the same emission source.

predominantly hospitals, clinics, radiopharmacies, research and academic facilities, fuel cycle facilities, and research reactors.

The CAA, as amended, establishes in Section 112(l)(1) the basis upon which States may submit to the EPA Administrator a program for implementing and enforcing emission standards for hazardous air pollutants for stationary sources located in such State. The States are authorized to set standards at least as stringent as those promulgated by the EPA. At this time, the EPA Administrator has approved three States for Subpart I implementation. Presently, seven States are engaged in a demonstration program with the EPA focusing on the development of State compliance programs needed for implementation of radionuclide NESHAPs, covering NRC licensed facilities, DOE facilities, and other miscellaneous sources covered by 40 CFR Part 61.

1.4 Agreement States

Under the provisions of Section 274(b) of the Atomic Energy Act (AEA) of 1954, as amended, certain States have assumed the responsibility and authority for regulating radioactive material (byproduct material, source material, and special nuclear material in limited quantities) users within such State. These NRC Agreement States' rules and regulations replace those of NRC. However, adequacy and compatibility are assured because the AEA includes a provision that the Commission must find that the State program is compatible with the Commission's program for regulation of such materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed agreement.

EPA will be able to eliminate its continuing efforts required for maintaining a compliance evaluation program for NRC and Agreement State licensees, including developing and maintaining guidance programs, training of EPA regional staff, transition of authority to States, training of State agencies, reviewing emission reports, reviewing construction and modification applications, and conducting enforcement actions as required. NRC's programs will require some additional efforts beyond its current inspection and enforcement programs to verify that licensees are in compliance with the constraint. Agreement States will adopt similar compliance evaluation programs.

3. Alternatives.

1) Alternative 1 - Dual Regulation - NRC and EPA would each retain their existing regulations and compliance programs.

2) Alternative 2 - EPA Regulations Only - Revise NRC requirements to eliminate air effluents.

3) Alternative 3 - NRC Constraint Rulemaking and EPA Rescission of Subpart I. Codify constraint dose levels for air emissions from NRC licensed facilities (other than power reactors).

Each alternative is discussed below.

3.1 Alternative 1 - Dual Regulation

There is general agreement between NRC and EPA that all NRC and Agreement State licensed facilities are maintaining air emissions well below

the 40 CFR Part 61, Subpart I, dose standard of 10 mrem (0.1 mSv) per year.[2] However, EPA determined that NRC's regulatory framework did not fully support their substantive finding which is required by CAA Section 112(d)(9) before EPA may rescind Subpart I for NRC licensees other than power reactors (59 FR 4228, January 28, 1994).

Under this approach, NRC and EPA would each continue its existing regulatory requirements and compliance programs without substantive changes to reduce any burden of dual regulatory oversight. The NRC's inspection program would continue to provide on-site inspections and reviews of compliance with 10 CFR Part 20 which includes maintaining doses ALARA and in effect, would afford a basis for evaluating compliance with the dose standards of Subpart I. NRC would continue to provide letter summaries to EPA on licensee compliance. However, NRC would not be involved from a legal compliance standpoint if a facility exceeded EPA's 10 mrem (0.1 mSv) per year limit, unless NRC standards were also exceeded. EPA would retain its regulatory authority for enforcement actions.

EPA would continue its compliance programs, including maintenance of guidance, transition of authority to States, training of State agencies, reviewing emission reports, reviewing construction and modification applications, and as required, conducting enforcement actions. Many States can be expected to develop corresponding regulatory requirements with licensing (fee) and inspection programs under the authority of Section 112(l)(1) of the CAA.

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2 Refer to the Federal Register notice (54 FR 51654), promulgating Subpart I and EPA's subsequent study of radionuclide air emissions for NRC licensed facilities (Ref. 1), as well as recent reports to EPA by NRC and Agreement State licensees (1994-1995).

The availability of citizen suits under the CAA would remain if Subpart I is not rescinded. If EPA does ultimately rescind Subpart I, the public petition process for NRC enforcement action against a licensee under § 2.206 would offset the unavailability of the CAA citizen suit provision. However, judicial review of § 2.206 petition denials is not readily available.

3.2 Alternative 2 - EPA Regulation Only

Under this alternative, NRC would make a finding that the EPA regulatory framework adequately protects members of the public from air effluents of NRC licensees. Inspection Procedures IP-87102, 40750, and 80745; Regulatory Guide 8.37; and the MOU with EPA on inspection referrals would be withdrawn or revised. Section 20.1302 would be revised to indicate that compliance with Subpart I is sufficient to demonstrate that dose from air effluents does not exceed 10 mrem/yr. There would be some moderate savings (about 1 FTE) in inspection as the monitoring and recordkeeping reviews in the area of air emissions would no longer be performed. Appendix B, Table 2, Column 1 of 10 CFR Part 20 would be deleted.

As in Alternative 1, EPA would continue its compliance programs, also the option to file citizen suits under the CAA would remain.

3.3 Alternative 3 - Constraint Rulemaking

This alternative addresses NRC's development of a regulatory constraint within 10 CFR Part 20 on allowable releases of radioactive effluents to the environment from NRC licensed facilities, excluding power reactors. The regulation would constrain air emissions released to the environment to a

level corresponding to a calculated dose of 10 mrem (0.1 mSv) per year to the maximally exposed member of the public. This approach would add numerical criteria for material licensees, fuel cycle facilities, and test and research reactors, similar to that already in place for nuclear power reactors (i.e., §§ 50.34a, 50.36a, and Appendix I to Part 50). A licensee exceeding this constraint would be required to submit a report and implement appropriate corrective actions. Failure to report exceedance of the constraint or failure to implement agreed upon corrective actions would be a violation of NRC regulations subject to enforcement actions. Licensees exceeding the constraint level would be required to submit a report to the NRC identifying the situation and appropriate measures for reducing emissions to below the constraint. EPA has indicated that this approach would provide a sufficient legal and regulatory framework upon which EPA could rescind its regulation of Subpart I.

In accordance with Section 112(d)(9) of the CAA, for EPA to rescind Subpart I, a finding must be made that there is no decrease in the level of protection afforded the public. Therefore, the NRC rulemaking evaluated under this approach would be to impose a dose constraint that would provide compatibility with EPA's dose standard of Subpart I. An ALARA dose constraint of 10 mrem (0.1 mSv) per year TEDE to members of the public from air emissions of radionuclides would provide consistency. These requirements, codified within NRC's regulations, would provide a sufficient regulatory framework to support an EPA finding that NRC's regulations provide "an ample margin of safety."

4. Consequences

This Regulatory Analysis does not address a serious health and safety issue. Instead, the basis for evaluating consequences is eliminating regulations that are considered duplicative and unnecessary. The consequences are evaluated against a baseline comparison.

4.1 Dual Regulation

Dual regulation would not support a timely elimination of duplicate EPA and NRC regulation. It would not reduce the current level of effort for the EPA in its compliance programs. NRC's inspection and referral efforts would also be expected to be maintained to meet its regulatory responsibilities under the AEA and to fulfill the 1992 MOU with EPA. NRC and Agreement State licensees would continue to be subjected to dual regulation.

NRC and Agreement State licensees would have different regulatory requirements addressing air emissions within two different titles in the Code of Federal Regulations (i.e., Title 10 for the NRC and Title 40 for EPA). Each licensee would have to interact with two regulatory groups within a State relative to compliance, including possible on-site inspections by EPA methods for demonstrating compliance, licensing reviews (for NRC programs), facility modification reviews (EPA), and recordkeeping and reporting. Some Agreement State representatives have stated that qualified radiation protection personnel may move from the State's radiation protection program to the State's environmental program to administer Subpart I. This might result in personnel shortages in some States, and maintaining enough qualified radiation protection personnel has consistently been a problem for many State programs.

Increased efforts are associated with duplicate requirements, duplicate implementation programs, and duplicate regulatory inspections.

Maintaining dual regulation would not require a rulemaking. NRC's current regulatory programs would continue to support the established radiation protection framework in 10 CFR Part 20, including the public dose limit of 100 mrem (1 mSv) per year and the principle of maintaining doses ALARA. EPA's compliance programs would continue, including the selected reactive inspections, evaluations of licensee submitted annual reports, and continued financial as well as technical support to individual State program development. The EPA staff expects that individual State involvement would increase as individual compliance programs are implemented.

Based on the 1992 MOU, NRC has provided assistance through its inspection program to EPA for its Subpart I implementation. As an implementation of its ALARA guidelines and based in part on this MOU, the NRC revised its Inspection Procedure 87102 to include a review of emissions from those facilities with the potential of exceeding 20 percent of the 10 CFR Part 20, Appendix B, Table 2 values (Ref. 3). The procedure requires that an Inspection Referral Form be completed by the NRC inspector and forwarded by NRC regional management to the cognizant EPA Regional Radiation Program Manager.

For calendar year 1995, EPA received 300 reports from NRC and Agreement State licensees to comply with Subpart I reporting requirements. EPA estimates their burden for reviewing each report to be approximately 12 hours [compliance verification (9 hours) and filing (3 hours)]. Thus, EPA estimated its' total burden and cost for Subpart I as 3,600 hours or $167,400 for 1995.

In order to demonstrate compliance with Subpart I NRC and Agreement State licensees will have to take actions to show that doses are less than 1 mrem/yr or file reports with EPA. About half of the 20,000 licensees will only have to read and understand the rules and determine that there is no potential for effluents from their facility. This will take approximately 1 hour per licensee. In addition to the above actions, some licensees with air effluents will be able to compare the average annual effluent concentrations, calculated to show compliance with Part 20, with tables provided by EPA for that purpose. Some licensees will have to calculate the difference between the total radioactive materials possessed during the year and the amount of radioactive materials that remained in sealed containers throughout the year. This value can be compared to tables provided by EPA for this purpose. Some licensees will need to collect varying amounts of site specific data to use in the COMPLY computer code provided by EPA for this purpose. Licensees unable to demonstrate by any of the above methods that doses to members of the public are below 1 mrem/yr will be required to prepare and submit a report to EPA of the estimated doses. Licensees unable to demonstrate that the doses to members of the public are below 10 mrem/yr will be required to develop, negotiate, transmit to EPA, and implement corrective actions adequate to ensure that doses return to levels less than 10 mrem/yr on an agreed upon schedule. The following table summarizes these cost estimates.

		hrs/lic	licensees	hrs	Cost
1	Potential for effluents?	1	10,000	10,000	$500,000
2	Concentration Tables	2	2,425	4,850	$242,500
3	Quantity Possessed Tables	5	2,425	12,125	$606,250
4	COMPLY-1	10	2,425	24,250	$1,212,500
5	COMPLY-2	20	2,420	48,400	$2,422,000
6	Report Required	40	300	12,000	$600,000
7	Corrective Actions	80	5	400	$20,000
TOTAL			20000	112,025	$5,603,250

Thus, the average cost to NRC and Agreement State licensees is $280 per licensee ($ 5,603,250 / 20,000 = $ 280).

Since 1989, NRC has devoted about 15 FTE to the Subpart I issue. This effort has consisted of the interface with EPA in support of rescission, development of Regulatory Guide 8.37, "ALARA For Effluents For Materials Facilities", development of inspection guidance, inspection efforts, referral of inspection results to EPA, and development of the constraint rule.

The burden of Alternative - 1 (dual regulation) is summarized in the following table:

	Cost
NRC and Agreement State Licensees	$5,603,250
EPA	167,400
NRC (0.5 FTE for inspection and referrals to EPA)	50,000
TOTAL	$5,820,650

4.2 EPA Regulation of Air Emissions Only

Elimination of NRC regulation of air emissions would eliminate dual regulation. NRC's burden would be reduced as inspection of licensee records, review of calculations, and licensing reviews of the air emission program would no longer be performed. Agreement States radiation program concerns relative to the loss of qualified radiation protection personnel to State environmental programs would not be resolved. However, States would not have to enforce duplicative regulations in each of these programs.

Elimination of NRC regulations of air emissions would require rulemaking to revise § 20.1302. This revision would be necessary to make clear that NRC inspection and enforcement of compliance with public dose limits would not include air emissions unless the dose from direct exposure and liquid effluents exceeded 90 mrem/yr TEDE. It is expected that this rulemaking would take approximately 1 FTE (2,000 hours @ $50/hour) over a 2-year period. Similar revisions to Agreement State regulations would be needed. Because of the simplicity of this rulemaking, it is estimated that each of the 29 Agreement States would expend about 0.1 FTE (200 hours @ $50/hour) revising their rules.

The burden on licensees would be the same as under the dual regulation alternative. The burden to EPA may increase due to the potential need for EPA inspection of licensed activities as well as enforcement activities. The annual

burden to NRC would be reduced as routine inspection of doses to members of the public would include only doses resulting from direct exposures and liquid effluents. Because air effluents are a small portion of doses to members of the public for most facilities, this burden reduction is expected to be very small.

The burden associated with Alternative - 2 is summarized below:

Annual Burdens	Cost
NRC and Agreement State Licensees	$5,603,250
EPA	217,400
NRC	0.00
TOTAL	$5,820,650

One Time Expenditures	FTE	Costs
NRC Rulemaking	1.0	$100k
NRC Inspection Procedures and Inspector Training	1.5	150k
Agreement State Regulations Revision	2.9	290k
TOTALS	5.4	$540k

Alternative 3 - NRC Constraint Rule and EPA Rescission of Subpart I

A constraint level would be enforced by NRC through its current licensing and inspection and enforcement programs. The current IP 87102 (Ref 3), IP 80745 (Ref. 7), and IP 40750 (Ref. 8) would require modification in wording for consistency with the rule. The Referral Form and letter to EPA would be eliminated from the inspection procedures. NRC regulatory guidance would be

revised and issued before the constraint rule is in effect, to specifically address the constraint rule. Acceptable methods for demonstrating compliance and reporting guidelines would be added to the regulatory guide. For licensees, an overall simplification in compliance assessment methods would be expected due to the streamlining of methods needed for both Subpart I compliance and 10 CFR Part 20 compliance.

Significant savings may be realized for facilities that maintain effluents at a small fraction of the standard, i.e., those facilities for whom submission of annual evaluations, reports and overall dual regulatory oversight are not required for ensuring public safety with an ample margin of safety. Because doses from air effluents are currently being calculated using Appendix B to 10 CFR Part 20 to demonstrate compliance with the public dose limits, no additional effort would be expended to demonstrate compliance with the constraint rule if the dose did not exceed the 10 mrem/y. Very few licensees (if any) would have doses to members of the public in excess of the 10 mrem/y constraint, and therefore be required to submit a report to NRC or an Agreement State. It is assumed that an average of five reports per year will be submitted to NRC or an Agreement State. The burden is shown in the following table.

	Action Required	hrs/lic	licensees	hrs	Cost
1	Potential for effluents?	1	10,000	10,000	$500,000
2	Concentration Tables	2	9,000	18,000	$900,000
3	Quantity Possessed Tables	5	332	1,660	$83,000
4	COMPLY-1	10	332	3,320	$166,000
5	COMPLY-2	20	331	6,620	$331,000
6	Report Required	40	0	0	$0
7	Corrective Actions Required	80	5	400	$20,000
TOTAL			20,000	40,000	$2,000,000

The total licensee burden is estimated to be $1,993,250 annually or about $100 per licensee ($ 2,000,000 / 20,000 = $ 100). Licensees who exceeded the constraint level would be required to submit a report to NRC and to develop and implement corrective measures in keeping with ALARA, to reduce air emissions to within the constraint level. Enforcement actions would only be taken for those licensees that fail to perform the required evaluations and/or those licensees that fail to take appropriate measures, for reducing air emissions.

The burden of reviewing reports of doses in excess of the constraint, is estimated to be 0.2 FTE or $20,000 annually (based on an estimate of no more than 5 reports/yr x 80 NRC staff-hours/report x $50/NRC staff-hr = $20k/yr). The burden for inspection and enforcement is estimated at 1.8 FTE ($180,000). An additional 0.3 FTE would be needed for headquarters support of licensing and enforcement actions, training, and other overhead. Assuming that the burden on Agreement States would be proportional to the number of licensees, the total government burden would be approximately 0.9 FTE or $690,000 annually.

Under Alternative 3, the NRC would incur one time costs for completion of the rulemaking (0.5 FTE), completion of regulatory guidance (0.5 FTE), development of licensing procedures (0.3 FTE), modification of the inspection

procedures and training of inspection personnel (1.0 FTE). EPA will also incur a one-time cost for the rescission of Subpart I.

The constraint rule would be categorized as one of Division II compatibility under the current NRC Policy Statement governing the Agreement State Program (January 23, 1981; 46 FR 7540, July 16, 1981; 46 FR 36969, July 21, 1983; 48 FR 33376).[3] As such, Agreement States may choose to adopt a rule that is more restrictive but no less restrictive than the one approved by the Commission. Agreement States would have three years to adopt compatible or more stringent regulations. The Agreement States are expected to adopt similar compliance program guidance (i.e., regulatory guidance and inspection procedures). Therefore, the potentially significant impact would be that associated with a rulemaking. For cost comparisons, it is assumed that the 29 NRC Agreement States would each adopt a rule and compliance program similar to that of the NRC's.

Currently, Agreement States have programs in place that implement and enforce the 10 CFR Part 20 dose limits and radiation protection programs including ALARA guidelines. Therefore, based on NRC's precedence in establishing the regulatory framework for a constraint rule, it can be assumed that additional efforts on the part of Agreement States for the development of compliance programs would be no more than 0.25 FTE per State or approximately $725,000 (29 States x 0.25 FTE/State x 2000 hours/FTE x $50/hr = $725,000). NRC would continue its evaluation of Agreement State programs for adequacy and compatibility.

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4 The NRC is in the process of revising its compatibility policy and has issued a proposed policy for public comment (59 FR 37269; July 21, 1994). Although, the compatibility policy has not yet been finalized, the NRC anticipates that a similar level of Agreement State compatibility will be required for air emissions under the new Policy as is required under a Division Level 2 designation.

Costs for Alternative 3 are summarized below:

Annual Burdens	Cost
NRC and Agreement State Licensees	$2,000,000
NRC and Agreement State Governments Report Review	6,000
NRC and Agreement State Governments Inspection	690,000
TOTAL	$2,696,000

One Time Expenditures	FTE	Costs
NRC Rulemaking	0.5	$50k
NRC Inspection/Licensing Procedures and Training	1.4	140k
NRC Regulatory Guidance Development	0.5	50k
Agreement State Regulations Development	7.25	725k
EPA Subpart I Rescission Rulemaking	0.5	50k
TOTALS	10.15	$1,015k

5. Decision Rationale

For the alternatives analyzed, the level of protection afforded the public health and safety is essentially the same. For each alternative, acceptable levels for radionuclide air emissions are based on a dose of 10 mrem (0.1 mSv) per year TEDE to the maximally exposed member of the public. Under Alternatives 1 (dual regulation) and 2 (eliminate NRC regulation of air emissions), the EPA Subpart I dose standard would remain in effect. Under Alternative 3 (constraint rule), NRC would enact a rule imposing a constraint dose of 10 mrem per year and EPA would rescind Subpart I.

It may be appropriate to select alternative 1, dual regulation, because licensees have been subject to dual regulation for more than 3 years without any undue harm to public health and safety. Although not supporting a timely rescission of Subpart I, maintaining dual regulation would allow time for EPA to gain additional experience with the implementation of the Subpart I standard on NRC and Agreement State licensees, and also allow NRC to discontinue work on revising inspection guidance, and finalizing regulatory guidance. Additional experience could provide the necessary information to support a decision by EPA to rescind Subpart I, without the need for additional NRC regulation.

In amending the CAA in 1990 to specifically address the issue of duplicate regulation, the NRC believes that Congress intended that dual regulatory oversight by EPA and NRC be eliminated if it could be done effectively. Alternative 1 (dual regulation) does not support the finding required by the CAA, Section 112(d)(9) and dual regulation would not be eliminated. Alternatives 2 and 3 are intended to be responsive to the congressional mandate to reduce duplicative regulations. Alternative 2 achieves this goal by discontinuing NRC inspection and enforcement of dose to members of the public

from air emissions, but is not the most cost effective choice. Alternative 3 achieves this goal by providing assurance that the NRC regulatory framework will provide an ample margin of safety at a significant savings in cost. This alternative will support an EPA finding to that effect, and thereby, support a subsequent rescission of Subpart I.

EPA has historically identified two components of the finding of sufficiency. First, NRC and Agreement State licensees must be in compliance with the quantitative emission limits of Subpart I (i.e., 10 mrem per year, TEDE). Overall, this condition has been demonstrated by studies conducted by EPA (Ref. 1) and by the recent reports submitted for Subpart I compliance to EPA by licensees. The second component is that the NRC's and Agreement States' compliance programs provide sufficient continued assurance that emissions would remain below the Subpart I standard, thereby protecting the public and environment with an "ample margin of safety." Of the alternatives, only Alternative 3 would be effective in achieving this second component. Alternative 1 would not support the goals of eliminating dual regulations. Alternative 2 would achieve the stated goals, but not at a savings in cost.

For Alternative 3, that of imposing controls by regulation, the relatively straightforward rule has been estimated to require 2 person-year of Federal Government effort (including finalization of the rule, regulatory guidance, inspection guidance, inspector training and EPA rescission of Subpart I). Assuming all twenty-nine Agreement States would process parallel rules, this effort has been estimated to require an additional 7.25 staff-year (0.25 staff-year per State). This lower level of effort for rulemaking by an Agreement State has been assumed considering the precedent established by NRC's rulemaking.

The total cost of each option is summarized in the table below:

Option	One Time Costs	Annual Costs
1 - No Action/Dual Regulation		$5,820,650
2 - Eliminate NRC Regulation of Air Emissions	$540,000	$5,820,650
3 - Constraint Rule and Rescission of Subpart I	$1,015,000	$2,696,000

Although Alternative 1 would be acceptable from a public health and safety perspective, it would not eliminate dual regulation. Alternative 2 would also be acceptable from a public health and safety perspective but would be far more burdensome to licensees than Option 3, because it would not support a rescission by EPA of Subpart I.

6. Implementation

No impediments to implementation of the recommended alternative have been identified. The documents necessary to support a final rule have been developed. The level of effort required for completing the rulemaking has been estimated at 0.5 staff-year, over a 6-month time period.

The NRC staff has prepared regulatory guidance that further clarifies the applicability of the rule and provides guidance on acceptable methods for demonstrating compliance, and for evaluating and reporting elevated effluents if the constraint level is exceeded. The final regulatory guide will be available at the time the final rule becomes effective. For Agreement States, a 3-year period is allowed from time of issuance of the final rule for the States to develop and implement compatible regulations.

References

1. EPA 430-R-92-011, "NESHAPS Rulemaking on Nuclear Regulatory Commission and Agreement State Licensees Other than Nuclear Power Reactors, Background Information Document," U. S. Environmental Protection Agency, November 1992 (available from Government Printing Office).

2. Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," U. S. Nuclear Regulatory Commission, July 1993 (available from Government Printing Office).

3. Inspection Procedure 87102, "Maintaining Effluents from Materials Facilities as Low as is Reasonably Achievable (ALARA)," NRC Inspection Manual, issued November 10, 1994 (available from the NRC Public Document Room).

4. ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection," Annals of the ICRP, Volume 21, No. 1-3, published for the International Commission on Radiological Protection by Pergamon Press, 1991.

5. ICRP Publication 64, "Protection from Potential Exposure: A Conceptual Framework," Annals of the ICRP, Volume 23, No. 1, published for the International Commission on Radiological Protection by Pergamon Press, 1993.

6. Draft Regulatory Guide DG-8016, "Constraint Level for Air Emissions of Radionuclides."

7. Inspection Procedure 80745, "Class I Non-Power Reactor Effluent and Environmental Monitoring."

8. Inspection Procedure 40750, "Class II Non-Power Reactors."

ENCLOSURE 4

NOTIFICATION FOR CONGRESSIONAL REVIEW

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Mr. Robert P. Murphy
General Counsel
General Accounting Office
Room 7175
441 G. St., NW,
Washington, DC 20548

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will constrain air emissions from NRC licensees so that no member of the public will receive a dose in excess of 10 mrem in a year from these emissions. This action is expected to be the final step in providing a basis under which the Environmental Protection Agency (EPA) can rescind 40 CFR Part 61, Subpart I, "National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H." Rescission of Subpart I will result in a significant reduction in burden to the Federal Government and to NRC licensees without any negative health and safety impact.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification is included in the final rule. Also enclosed is a copy of the Regulatory Analysis for this final rule that contains the NRC's cost-benefit determinations. This final rule is scheduled to become effective concurrent with the effective date of EPA's rescission of 40 CFR Part 61, Subpart I. A notice of its effectiveness will be published in the Federal Register.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures: Final Rule
Regulatory Analysis

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Al Gore
President of the United
States Senate
Washington, DC 20510

Dear Mr. President:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will constrain air emissions from NRC licensees so that no member of the public will receive a dose in excess of 10 mrem in a year from these emissions. This action is expected to be the final step in providing a basis under which the Environmental Protection Agency (EPA) can rescind 40 CFR Part 61, Subpart I, "National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H." Rescission of Subpart I will result in a significant reduction in burden to the Federal Government and to NRC licensees without any negative health and safety impact.

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures: Final Rule
Regulatory Analysis

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Newt Gingrich
Speaker of the United States
House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a final rule that will constrain air emissions from NRC licensees so that no member of the public will receive a dose in excess of 10 mrem in a year from these emissions. This action is expected to be the final step in providing a basis under which the Environmental Protection Agency (EPA) can rescind 40 CFR Part 61, Subpart I, "National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H." Rescission of Subpart I will result in a significant reduction in burden to the Federal Government and to NRC licensees without any negative health and safety impact.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the final rule that is being transmitted to the Office of the Federal Register for publication. The Regulatory Flexibility Certification is included in the final rule. Also enclosed is a copy of the Regulatory Analysis for this final rule that contains the NRC's cost-benefit determinations. This final rule is scheduled to become effective concurrent with the effective date of EPA's rescission of 40 CFR Part 61, Subpart I. A notice of its effectiveness will be published in the Federal Register.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures: Final Rule
Regulatory Analysis

ENCLOSURE 5

ENVIRONMENTAL ASSESSMENT

Environmental Assessment and Finding of

No Significant Impact

on

Final Rule on "Constraint For Dose to

Individual Members of the Public from Air Emissions"

I. THE ACTION

The action is a final rule to amend 10 CFR Part 20 to include a constraint for dose to members of the public from air emissions of radioactive materials from NRC licensed facilities other than power reactors. This action will provide assurance to the EPA that future emissions from NRC licensees will not exceed levels that will provide an ample margin of safety. It is expected to be the final step in providing EPA with a basis upon which to rescind 40 CFR Part 61, Subpart I, "National Emission Standards for Hazardous Air Pollutants," as it applies to NRC and Agreement State licensed facilities other than power reactors,[1] thereby relieving these NRC licensees from unnecessary dual regulations.

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[1] EPA previously proposed rescission of Subpart I for power reactors based on requirements contained in 10 CFR Part 50, Appendix I, and a history of over 20 years of reported air emissions from power reactors resulting in doses well below 10 mrem (0.1 mSv) per year to the maximally exposed member of the public. The rescission of Subpart I for power reactors was finalized on September 5, 1995, independent of this rulemaking.

II. THE NEED FOR THE RULEMAKING ACTION

Subpart I currently limits doses to members of the public from air emissions of radionuclides from all NRC licensees except licensees possessing only sealed sources and uranium mill tailings piles disposed of in accordance with 40 CFR Part 192. Subpart I was promulgated to implement the Clean Air Act (CAA). The standard in Subpart I is that emissions of radionuclides to the ambient air from a facility regulated under this Subpart shall not exceed those amounts that would cause any member of the public to receive in any year an effective dose equivalent of 10 mrem (0.1 mSv) per year.

NRC licensees subject to Subpart I are also subject to NRC dose limits for members of the public contained in 10 CFR Part 20, Subpart D, entitled "Radiation Dose Limits for Individual Members of the Public." Under Subpart D, licensees shall ensure that doses to members of the public are less than 100 mrem (1 mSv) per year from all pathways (including air emissions) and all sources associated with the licensee's operation. In addition, doses to members of the public must be as low as is reasonably achievable (ALARA). Based on studies conducted by EPA and licensee reporting of doses to members of the public from air emissions, it is evident that a limit of 10 mrem (0.1 mSv) per year to the maximally exposed member of the public from air emissions is reasonably achievable.

To ensure that Federal regulations are not excessively burdensome on the regulated community and most efficiently use government and licensee resources, NRC and EPA are coordinating rulemakings. The effect of these rulemakings is to vest NRC with the principal responsibility for ensuring that

the health and safety of the public are protected from the potentially harmful effects of airborne emissions of radionuclides from NRC licensed facilities.

The NRC is establishing a constraint for dose to members of the public from air emissions of radionuclides of 10 mrem/yr total effective dose equivalent (TEDE). This action is necessary to provide a sufficient basis upon which EPA can rescind Subpart I for NRC licensees other than power reactors.

III. ALTERNATIVES TO THE RULEMAKING ACTION

As required by Sec. 102(2)(E) of NEPA (42 USC 4322(2)(E)), alternatives to the action have been considered. Three alternatives were considered.

Alternative 1 - Continuation of Dual Regulation

Alternative 1 maintains the status quo which involves licensees demonstrating compliance with the limits in Part 20 for doses to members of the public, including the ALARA requirement, and with the limits in 40 CFR Part 61 for doses to members of the public from air emissions of radionuclides. EPA has determined that it will not rescind Subpart I for NRC licensees other than power reactors without a codified or otherwise enforceable dose value that does not exceed 10 mrem (0.1 mSv) per year. The impact of this alternative would be the continued inefficient use of licensee, NRC, EPA, and State resources, less confidence in the NRC program to protect the health and safety of the public, and disregard of congressional requirements to avoid duplicative regulation through interagency cooperation.

Alternative 2 - EPA Regulation Only

Under Alternative 2, NRC would discontinue its inspection and enforcement activities with regard to air effluents. The impact of this option is that licensees would be subject to only one regulatory program for the control of doses to members of the public from air effluent releases. However, air emissions would be limited by 40 CFR Part 61, Subpart I and enforced by EPA. The burden on governments would be the same as for Alternative 1, but the inspection and enforcement burden now borne by NRC would be shifted to EPA. The burden on NRC and Agreement States is similar to that of Alternative 1, and significantly greater than Alternative 3. There would no change in the impact to the environment as air effluents would be limited to the same level as they are currently.

Alternative 3 - NRC Rulemaking and Rescission of Subpart I

Under Alternative 3, the NRC would amend the current regulations in 10 CFR Part 20 to include a section on constraints for doses to members of the public. The impact of this alternative is that licensees would be subject to only one regulatory program for the control of doses to members of the public and effluent release. Licensees would therefore need only calculate doses to members of the public against a single s of criteria which are risk based and use a common dosimetry. The burden of demonstrating compliance would be significantly less than for alternatives 1 or 2 as greater flexibility in demonstrating compliance is provided. Licensees and the pu will have a better understanding of how the Federal Government expects that the health and

safety of the public and the environment will be protected from activities that could lead to radiation exposure.

IV. ENVIRONMENTAL IMPACTS OF THE ACTION

The Commission has examined the current regulatory framework for controlling doses to members of the public to ascertain the appropriate regulatory path to take that would continue to assure the level of protection currently afforded under the duplicative regulations while minimizing the burden on licensees and the government. There are no adverse impacts associated with this rule as air emissions would continue to be constrained at the same level as exists today.

V. FINDING OF NO SIGNIFICANT IMPACT

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that the amendment to 10 CFR Part 20 will not have a significant impact on the quality of the human environment and that an environmental impact statement is not required. This determination is based on the foregoing environmental assessment performed in accordance with the procedures and criteria in 10 CFR Part 51 "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

VI. PERSONS CONTACTED:

The draft rule language has been discussed with the EPA and the Agreement States. Drafts of the rule were shared with EPA at several points during its development and it was discussed regularly with EPA staff. A draft of the package was provided to the Agreement States on April 18, 1995. This rulemaking has been discussed at meetings of the Organization of Agreement States and the Committee of Radiation Control Program Directors for the last several years. A hearing was held on this rulemaking and on the rescission of 40 CFR Part 61, Subpart I, by EPA in October of 1995.

ENCLOSURE 6

PUBLIC ANNOUNCEMENT

NRC REVISES REGULATIONS ON RELEASE OF RADIOACTIVE MATERIALS FROM NUCLEAR FACILITIES

The Nuclear Regulatory Commission is amending its regulation that governs release of radioactive materials from NRC-licensed facilities other than nuclear power plants.

The changes are expected to eliminate unnecessary dual regulation by both the NRC and the Environmental Protection Agency by providing a basis for EPA to rescind its regulations for NRC non-reactor licensees.

The revisions will require affected NRC licensees to constrain air emissions of radioactive materials from their facilities so that the highest radiation dose an individual member of the public would be likely to receive as a result of those emissions is 10 millirems per year. This proposal is part of NRC's program to maintain radiation doses from licensed facilities to levels that are as low as is reasonably achievable.

NRC requires its licensees to ensure that the dose to an individual member of the public does not exceed 100 millirems per year from all pathways (including air emissions). The Commission believes that these current regulations provide adequate protection of public health and safety. The revision will ensure that air emissions are maintained at a very low-level, while eliminating dual regulation.

Under the NRC's revised regulations, if the 10-millirem per year constraint level is exceeded, the licensee will have to report to the NRC and take prompt and appropriate corrective action to avoid recurrence.

The 1977 amendments to the Clean Air Act required EPA to consider whether radioactive materials should be identified as a hazardous air

pollutant and, if so, to adopt standards to limit their emissions. EPA decided that radioactive materials are a hazardous pollutant and issued standards for their emission in air on October 31, 1989. Later that year, Congress enacted amendments to the Clean Air Act that said (in the Simpson amendment) that EPA need not issue standards for emissions of radioactive material from facilities licensed by the NRC if the EPA Administrator determines that the regulatory program established by the NRC provides "an ample margin of safety to protect public health."

EPA stayed the effectiveness of its regulations for a while, but its regulations are now in effect for licensees other than nuclear power plants, which means that NRC-licensed facilities are currently subject to dual regulation of air emissions by both the NRC and EPA. (For nuclear power plants, EPA has rescinded regulation of air emissions, based on NRC regulations already in place for power reactors and a history of more than 20 years of reported air emissions well below 10 millirems per year for these plants.) The EPA regulations state that emissions of radioactive materials to air from NRC-licensed facilities must not exceed amounts that would cause any member of the public to receive a radiation dose of 10 millirems per year.

EPA conducted two studies of air emissions from NRC non-reactor licensees. For the more than 500 licensees evaluated, none exceeded 10 millirems per year. On the basis of these studies, it is evident that constraining air emissions of radioactive material to 10 millirems for the maximally exposed member of the public is reasonably achievable.

A proposed rule on this subject was published in the Federal Register on December 13, 1995. Changes made as a result of comments received are described in the _____ (date) edition of the Federal Register.

The revisions will be effective on _____ (date).

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ENCLOSURE 7

CONGRESSIONAL LETTERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Lauch Faircloth, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a notice of final rulemaking to be published in the Federal Register. This final rulemaking amends NRC regulations to constrain dose to members of the public from air emissions of radioactive materials from NRC licensed facilities other than power reactors.

This action is expected to be the final step in providing EPA with a basis upon which to rescind 40 CFR 61 "National Emission Standards for Hazardous Air Pollutants," Subpart I as it applies to NRC licensed facilities other than power reactors, thereby relieving these NRC licensees from unnecessary dual regulations. EPA has already rescinded Subpart I for power reactors based on requirements contained in 10 CFR Part 50, Appendix I, and a history of over 20 years of reported air emissions from power reactors resulting in doses well below 10 mrem/yr to the maximally exposed member of the public. This action will provide assurance to the EPA that future emissions from NRC licensees will not exceed levels that provide an ample margin of safety.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a notice of final rulemaking to be published in the Federal Register. This final rulemaking amends NRC regulations to constrain dose to members of the public from air emissions of radioactive materials from NRC licensed facilities other than power reactors.

This action is expected to be the final step in providing EPA with a basis upon which to rescind 40 CFR 61 "National Emission Standards for Hazardous Air Pollutants," Subpart I as it applies to NRC licensed facilities other than power reactors, thereby relieving these NRC licensees from unnecessary dual regulations. EPA has already rescinded Subpart I for power reactors based on requirements contained in 10 CFR Part 50, Appendix I, and a history of over 20 years of reported air emissions from power reactors resulting in doses well below 10 mrem/yr to the maximally exposed member of the public. This action will provide assurance to the EPA that future emissions from NRC licensees will not exceed levels that provide an ample margin of safety.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Frank Pallone