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: Provide assurance to the Environmental Protection Agency (EPA) that future emissions from NRC licensees will not exceed dose levels that EPA has determined will provide an ample margin of safety; and 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.

EFFECTIVE DATE: This rule will become effective January 9, 1997.

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6223.

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 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 EPA rescinded Subpart T for NRC licensees after Appendix A to 10 CFR Part 40 was amended by the Commission to conform to changes EPA issued to 40 CFR Part 192.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

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

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 judgment, 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 offsite. 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.

Conforming Amendments To NRC's Enforcement Policy

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.

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, Office of Management and Budget.

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 bsj1@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.

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 Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6223.

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 the section heading is revised, a new paragraph (a)(2)(vi) is 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 3rd day of December, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 96–31221 Filed 12–9–96; 8:45 am]

BILLING CODE 7590–01–P

[7] With respect to the limit for the embryo-fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.