



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

June 12, 1996

*C. Tratten*

AF 31-2-44  
PDR

MEMORANDUM TO: Michael F. Weber, Acting Deputy Division Director  
Division of Waste Management

FROM: Cynthia G. Jones *Cynthia G. Jones*  
Senior Level Advisor for Health Physics,  
Division of Industrial and  
Medical Nuclear Safety

SUBJECT: IMNS COMMENTS ON PROPOSED CHANGES TO 10 CFR PART 20  
REGARDING RESOLUTION OF DUAL REGULATION OF AIRBORNE  
EMISSIONS (CONSTRAINT RULE)

This Division has reviewed (with the Division Director) the attached proposed final rule, "Resolution of Dual Regulation of Airborne Emission, Clean Air Act - 10 CFR Part 20," and concurs pending incorporation of the following major changes:

- By the effective date of this rule*
1. Clarification of when the Regulatory Guide associated with this rule is to be finalized (or developed as a draft for public comment). Because much of this Commission paper and associated attachments reference the Regulatory Guide, it is not clear when the document will be complete, or whether or not it will be issued as a draft for comment. If the intent is to make it available at the time of the effective date of the final rule, then this should be clarified in the Commission paper as well as the supplemental attachment text. In addition, much of what will be in this Regulatory Guide will need to be incorporated into the development of licensing guidance, as well as changes to the inspection procedures. ☒
  2. We suggest replacing "...from a single source to 0.1 mSv (10 mrem) per year" with "...from a single licensed operation to 0.1 mSv (10 mrem) per year"...from a single licensed facility to 0.1 mSv (10 mrem) per year." The term "single source" is not defined in our regulations, and it is not clear what this would mean in practice. ✓
  3. Although the statements of consideration in both the proposed rule as well as the final Federal Register notice state that NRC and Agreement State licensees will be "required" to record the estimated or measured dose and the assumption used to calculate these doses from air effluents less than 10 mrem per year to members of the public (see page 6-7, FR). There is no requirement in the proposed §20.2103, nor a logical health physics reason for requiring licensees to maintain written records for doses greater than zero, yet less than 10 mrem. The current regulations ✓

under §20.2103(b)(4) are adequate for these recordkeeping purposes. We believe that this requirement should be eliminated from the proposed rule and have provided language changes to the FR to clarify this (see p. 7 FR).

4. The Federal Register states in many different places that there will be little or no additional burden to NRC as a result of the promulgation of the rule (see p. 2 Commission paper, p. 12 FR, etc.), and in supporting this assertion, states that "no additional resources will be required to implement the rule" (page 2, Commission paper). SECY-93-229, page 11, states, "Inspections against commitments made in accordance with the Regulatory Guide (and proposed rule) will require about 5 FTE per year which are currently not budgeted." NMSS believes that the resources will be approximately 3.5 FTE (see Attachment 1), as there are NRC resources needed for completion of the Regulatory Guide, development of materials (as well as non-power reactor) inspection and licensing guidance, as well as initial training of materials licensing and inspection staff. Except for IP 87102, which would need revision if the rule is made final, there has been no guidance developed, nor any FTE budgeted for changes to implement this rule in either the materials or non-power reactor licensing program. The 3.5 FTE estimate does not include resources estimates for either NRR's inspection and licensing program, nor RES's resource needs.
5. The word "environmental" should be removed from the phrase "environmental air emissions" to be consistent with 10 CFR Part 20. The key concept is dose to individual members of the public resulting from air emissions. We have substituted the words, "release of radioactive effluents to the environment," per §20.2103(b)(4). ✓
6. The Regulatory Analysis and the Environmental Assessment need to be updated with current (up through 1995) data. As an example, thus far, three States have been granted Clean Air Act authority by the EPA; however on page 12 of the Regulatory Analysis, it states, "The EPA Administrator has not at this time approved any State for Subpart I implementation." In addition, the Regulatory Analysis provided outdated (early 1990s) data regarding the cost of Subpart I implementation to licensees. The costs since that date for maintenance of the Clean Air Act for both EPA and NRC was drastically reduced from these initial estimated numbers. The EPA labor rates discussion beginning on page 20 of this section, was the EPA estimate from their original OMB clearance. We now have had several years of operating experience under dual regulations, and these cost estimates, as well as actual licensee reporting data (through 1995) to EPA need to be included in this discussion. Several changes to this section are proposed in Attachment 2. ✓
7. Since there are differing staff views as to the viability of this rule, we believe that the Commission paper, or alternatively, in the regulatory analysis section (under Alternative 1) should state that there are NRC staff who believe that the "status quo" option is be the ✓

preferred alternative. The Commission paper clearly states the staff *recommendation* as that being the elimination of dual regulation and to subsequently implement the Constraint Rule. A similar type of "differing view" was effectively communicated to the Commission in another Commission paper on the proposed rule changes to 10 CFR Part 50 and 100 (in that case, RES and NRR had differing opinions, yet proposed one staff recommendation to the Commission). We believe that it's important for the Commission to know that there are differing views, and that the alternatives provided by the staff in the SECY paper discuss the pros and cons of each.

In addition to the above requested changes, Attachment 1 provides specific clarifying changes needed in the SECY paper, the final rule, the Regulatory Analysis, and the Environmental Assessment. Attachment 2 provides specific mark-ups to the document to clarify the intent of the proposed rulemaking changes, or to provide more current information regarding the most recent results (1994-1995 timeframe) of EPA's jurisdictional activities associated with their implementation of the rule.

For additional clarification or discussion of the issues described above, please do not hesitate to contact me (e-mail:CGJ or phone 415-7853).

cc: D. Cocl, NMSS  
C. Paperiello, NMSS

**IMNS COMMENTS ON PROPOSED CHANGES TO 10 CFR PART 20  
REGARDING RESOLUTION OF DUAL REGULATION OF AIRBORNE EMISSIONS  
(CONSTRAINT RULE)**

- SI Units need to be used throughout per the NRC metrication policy. - after - Part 20 ✓
- Attachment 2 provides specific editorial changes for incorporation into the text.

Commission Paper

1. Page 1, 1st ¶. Add a reference to all earlier SECY papers such as SECY-93-229, SECY-95-133, and SECY-95-229, to name a few.
2. Page 2, 3rd ¶. Begin this paragraph with: "The final rule is basically unchanged from the proposed rule in order to provide EPA with a clear basis to rescind the Subpart I standards for all NRC licensed facilities. Incorporating the numerical standards, along with the associated licensee reporting provisions would make NRC's regulations compatible with EPA's."
3. Page 2, "Resources" section. Please see comment in the attached cover letter regarding NMSS concerns about FTE estimates in this paper.
4. Page 6, Last full ¶. As indicated above, we suggest replacing "...from a single source to 0.1 mSv (10 mrem) per year" with "...from a single licensed operation to 0.1 mSv (10 mrem) per year" "...from a single licensed facility to 0.1 mSv (10 mrem) per year." The term "single source" is not defined in our regulations, and it is not clear what this would mean in practice.
5. Pages 6-7. We do not believe that licensees should be required to record, and maintain for NRC inspection, doses to members of the public less than 10 mrem per year. See comment on this in cover letter.
6. Page 7, Middle ¶. It is not clear in this paragraph what time limits a licensee is allowed within which to correct the situation. Would a licensee have to institute corrective actions such that the following year's emissions will be within the constraint, or can the licensee propose reducing emissions to below the constraint within several years? A few words on this matter should be added to these Statements of Consideration and in the regulatory guide.
7. Page 11, 2nd ¶. Add the following (shown in italics) to the end of the third sentence, "NRC limits TEDE, requires that dose are maintained ALARA, and *actively maintains a large inspection programs for materials, fuel cycle, and non-power reactor licensees.* EPA

ATTACHMENT 1



limits dose from individual pathways of exposure and individual radionuclides to ensure that the total dose does not exceed the recommended levels, *and requires licensee to issue annual reports to the EPA if the standards are exceeded.*"

8. Page 11, 3rd ¶. Insert at the beginning of this ¶, *"Although there are differing views amongst the NRC staff that the adoption of the constraint is the best option at this time, the proposed staff position to the Commission is that adoption of the constraint..."*

9. Page 12, Top ¶. This section implies that COMPLY is the only method that is available to licensees to show compliance with Subpart I; this is not the case. EPA allows several other approaches, including any method developed or selected by the licensee, provided it is pre-approved by EPA. See suggested changes.

10. Page 12, Middle ¶. Delete the second sentence. There will be additional burden to NRC inspectors by implementing this rule (see NMSS FTE estimates at the end of this Attachment). We currently do not view licensees air emission records down to 1 mrem; we only review to see compliance with 100 mrem per year. Review of the licensees records at these low levels will require the inspectors to verify input and assumption parameters to the COMPLY code, or other alternative mechanisms that licensees use to show compliance. Simply stated, inspectors have to look harder to verify 10 mrem versus 100 mrem.

11. Page 12, last ¶. Currently, NRC materials inspectors do not take confirmatory measurements at licensees facilities. These types of measurements are extremely rare at materials facilities. See suggested word changes to text.

12. Page 13, Line 5 from the bottom. This statement is not correct and contradicts earlier statements. The purpose of the rulemaking is to assure EPA that the current levels are maintained in the future. The effort was undertaken to reduce costs, but the conditions for rescission were not costs, but to ensure future low doses. That is why we have a rulemaking effort instead of simply rescinding Subpart I, as was done for power reactors.

13. Page 15, last ¶. This explanation of why the constraint was placed under ALARA is incorrect. The 10 mrem was not selected by us on the basis of ALARA considerations, but because it conforms to EPA's standard risk level to the public from hazardous materials and hence is the level adopted in Subpart I. EPA did some ALARA studies in connection with Subpart I, and these may help develop our position. We strongly suggest that this section be rewritten.

14. Page 17, Second line. "on" should be "in."

15. Page 23, last ¶ under Issue 8. Delete the first sentence, "ALARA is not a guidance."

16. Page 24, 1st response. Insert additional language here as to when the regulatory guide will be issued, and if it will be issued as a draft or final version for comment.

17. Page 26, First response. Licensees using only sealed sources should not be specifically excluded or exempted. Since there are no reporting requirements attached to this rule except in cases of exceeding the constraint, exclusion of sealed source users will serve no purpose and will complicate the rule. It is far better to follow the same approach used in §20.1302, namely that the dose from air emissions should be constrained to 10 mrem/yr, period. Licensees with sealed sources will not have air emissions and will therefore not have to worry about the constraint, until they do have emissions.

18. Page 26, Issue 10. The response doesn't adequately answer the commentors question. Suggest that we respond by stating that there are other ways of demonstrating compliance than by measuring dose, etc.

19. Page 29, 2nd line. Delete the words "*environmental air emissions*" and replace with "*the release of radioactive effluents to the environment*" to match the words in 10 CFR Part 20.

20. Page 30. Wherever the phrase "inspection procedures" is found in the text, add the phrase "*licensing and* inspection procedures."

21. Page 34, item (1). The word "environmental" should be removed to be consistent with 10 CFR Part 20. The key concept is dose to individual members of the public resulting from air emissions. We have substituted the words, "...shall constrain *radioactive effluents to the environment*" instead of "environmental air emissions of radioactive materials" per §20.2103(b)(4).

22. Page 34, Item (2). We suggest placing a time limit for compliance, e.g. by the next assessment period, or by the following calendar year.

23. Page 34, Item 4 (vi). Should be §20.1101(d) instead of (c).

#### Regulatory Analysis (See Attachment 2 for specific mark-ups)

24. Unnumbered page 3. Add information from 1994 and 1995 (DWM may have additional updated, yet informal, information from EPA).

25. Page 11, line 6. Strike the phrase, "*This licensee took corrective measures; no enforcement actions were taken by EPA*" and replace it with "*...Subpart I dose standard, which also exceeded the 10 CFR Part 20 limits for members of the public.*" The reason why EPA did not take enforcement action was because NRC discovered their non-compliance with our regulations, reported this to EPA, and then we took enforcement action.

26. Page 11 2nd ¶. See mark-up. Clarify that EPA has not been performing inspections; to date EPA has only been doing paper reviews, and then follow-up visits, as necessary due to their limitations with FTE for Subpart I.

27. Page 12, 2nd full ¶. Update the information (to 1995) regarding the number of States that EPA has approved for Subpart I implementation.

28. Pages 15-18. See numerous changes to text to more adequately describe the various options, and to indicate the needed 3.5 FTE.

29. Page 19, 2nd ¶. Suggest deleting the second sentence. States already have the authority to have more restrictive, potentially different compliance programs.

30. Pages 20-29. See specific changes to text. This part of the analysis needs to be totally re-done to: (1) incorporate the up-to-date 1994 & 1995 EPA information; (2) current FTE needs in EPA (not using their old OMB clearance estimates); (3) including the FTE estimates from NMSS (and NRR if they are provided to RES); and (4) re-doing the tables for burden estimates and cost/FTE.

### Environmental Assessment

Similar changes need to be made to the environmental assessment, as indicated in the changes in Attachment 2, as well as described above.

### FTE Estimates for NMSS

Assumptions used:

- Approximately half of the NRC licensees ( $\approx 6500$  licensees), or 3250 have the potential to release airborne effluents
- Assume 15% of these (or  $\approx 500$ ) need a cursory (0.5 hr) inspection regarding the effluent paperwork under the proposed constraint rule. Of the 500, 200 are large broad scope licensees and will require a more thorough review ( $\approx 2$  hrs) than the other 300 during the annual inspection. →

#### *Direct Inspection Effort (Annual):*

300 licensees x 0.5 hrs/inspection = 150 inspection hrs  
200 licensees x 2 hrs/inspection = 400 inspection hrs

- Of these 500 inspections, about 5-10% (25-50 licensees) need to be looked at in more depth, due to multiple stacks, review of assumptions and calculations:

#### *Direct Inspection Effort (Annual)*

25 to 50 licensees x 4 hrs/inspection = 100 to 200 hrs (assume 150 insp hrs)

### FTE Estimates for NMSS (continued)

- Assuming five licensees have exceedances of the constraint limit of 10 mrem/yr, as the SECY paper corrected states, 160 hours would be expended on each report. This value includes a reactive inspection, recalculation of dose, time for the inspector to review the licensees assumptions and necessary documentation per 20.2103(b)(4), time to write the inspection report, and time to write and process any facility modification (amendment or license condition), if necessary. Time to coordinate with Headquarters (through a technical assistance request), has not been included and may increase the time per report by 160 hrs. Time involved on-site as well as time needed for recalculation of dose is assumed to be 80 inspection hrs; the remainder of the time (80 hrs) is considered overhead.

$$\begin{aligned} 5 \text{ licensees} \times 80 \text{ hrs/inspection} &= 400 \text{ inspection hrs} \\ 5 \text{ licensees} \times 80 \text{ hrs review \& report preparation (overhead)} &= 400 \text{ hrs} \end{aligned}$$

Total Inspection Effort (Annual):

$$150 + 400 + 150 + 400 = 1100 \text{ hrs (1.8 FTE)}^1$$

Total Overhead Effort (Annual):

$$400 \text{ hrs} \times 1 \text{ FTE/1350 hrs} = 0.3 \text{ FTE}$$

Total Annual Effort = 2.1 FTE

### One Time (Start-Up) Expenditures

Overhead: Change IP 87102 = 0.1 FTE *200 hrs*  
Develop licensing guidance = 0.3 FTE  
Develop & complete training in all regions = 1.0 FTE<sup>2</sup> *16 hrs*

Total One-Time Effort: 1.4 FTE

Grand Total for NMSS Expenditures: 3.5 FTE

*Inspector time should come out of the 1400 hrs/yr left after the 600 hr FTE Above (see note 1)*

<sup>1</sup>NOTE: 600 hrs of on-site inspection effort is considered 1 FTE

<sup>2</sup> This 1 FTE includes the amount of time all inspection and licensing staff are in attendance for each of the training classes.



IMNS Mark-Up  
Comments.

✓ 6/26 ✓

**COMMISSION PAPER**

FOR: The Commissioners

FROM: James M. Taylor, Executive Director for Operations

SUBJECT: FINAL RULEMAKING - REVISION TO 10 CFR PART 20 RELATED TO  
CONSTRAINT FOR AIR EMISSIONS FROM NRC AND AGREEMENT STATE  
LICENSEES OTHER THAN POWER REACTORS

PURPOSE:

To request Commission approval to publish a notice of final rulemaking amending the regulations in 10 CFR Parts 20. ✓

BACKGROUND:

On November 15, 1995, the Commission directed the staff to publish a proposed rule amending 10 CFR Part 20, establishing a constraint of 10 mrem/yr 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. A proposed rule was published in the Federal Register (60 FR 63984) on December 13, 1995, amending 10 CFR Part 20 to include a constraint on air emissions (see also SECY-93-229, SECY-95-193, and SECY-95-229 on this same subject). ✓

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, resulted in a dose to a member of the public in excess of 10 mrem in any year. In addition, the licensee would be required to propose corrective actions adequate to ensure against future air emissions leading to doses in excess of the constraint. ~~The proposed rule exempted emissions of radon-222 from consideration.~~

*and its daughters*

*Suggest  
deleting  
the specific  
for  
SECY paper.* ✓

CONTACT:  
Charleen T. Raddatz, RES  
415-6215

The Commissioners

2

*in order to provide EPA a clear basis to rescind the Subpart I standards for all NRC-licensed facilities. Incorporating the minimum standards, along with the associated licensee reporting provisions would make NRC's regulations compatible with EPA's.*

#### DISCUSSION:

Fifty-seven comment letters were received on the proposed rule. Among the 57 letters, 24 were licensees, 7 professional organizations, 5 States, 16 members of the public, and 5 environmental organizations.

In general, those persons expressing the view that the proposed constraint was too restrictive, too burdensome, and unnecessary were licensees, members of the public and professional societies. In general, those persons expressing the view that the proposed constraint was too lax, inadequate to protect the health of the public, and not adequately enforceable were representatives of environmental groups. *Add a sentence or 2 about Agreement State comments.*

The final rule is basically unchanged from the proposed rule. However, in resolving public comments, a few minor changes were made in the final rule. The staff removed the requirement to report demographic information on exposed members of the public, as the information may not be available to licensees and is not needed by NRC for any purpose. A provision defining the effective date of the rule has been added to ensure that there is not a time when both NRC's and EPA's rule would be in effect. The rule has been revised to clarify that the constraint is intended to only apply to ~~environmental~~ air emissions. This is needed to more closely parallel the existing requirements of the EPA requirements. *from the release of radioactive effluent*  
*as described in* Subpart I. In addition, the regulatory guide will be revised to address additional public comments.

*of 40 CFR Part 61.*  
The statements of considerations for the final rule addresses other comments by clarifying the purpose of the rule. It states that if a licensee exceeds the constraint, reports to NRC, and takes corrective actions, ~~as agreed upon,~~ that exceedence in subsequent years would not be violations. Rather, they would again be required to report and take appropriate corrective actions.

#### RESOURCES:

The current budget *does not* contain resources to conduct the inspection *licensing,* and enforcement of licensee programs to control air emissions in accordance with the existing rules. ~~No additional resources will be required to implement the provisions of the final rule.~~ *A additional 3.5 FTE will be required to implement and maintain the provisions of the final rule.*

#### 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 (Attachment 1) will be published in the Federal Register;
- b. A Regulatory Analysis has been prepared and will be made available in the Public Document Room (Attachment 2);
- c. 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 (Attachment 3);
- d. An environmental assessment and finding of no significant impact has been prepared and will be made available in the Public Document Room (Attachment 4);
- e. That, in accordance with the Regulatory Flexibility Act, a regulatory flexibility analysis has been prepared. The analysis is not a separate document but 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 and a copy will be sent to the Chief Counsel for Advocacy of the Small Business Administration.
- f. 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 OMB submittal before publication of the final rule;
- g. A public announcement will be issued (Attachment 5);
- h. The appropriate Congressional committees will be informed (Attachment 6); and



- i. 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

Attachments: As stated (6)

RECORD NOTE: A DRAFT COPY OF THE FINAL RULE WAS SENT TO OIG FOR INFORMATION ON \_\_\_\_\_, 1996.

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The Commissioners

4

- i. 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

Attachments: As stated (6)

IMNS Comments

✓ 6/26

ATTACHMENT 1

FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AF31

Resolution of Dual Regulation of Airborne Emissions,  
Clean Air Act

AGENCY: Nuclear Regulatory Commission.

*Include SI  
units throughout  
per the NRC  
metrication policy.*

ACTION: Final rule.

*0.1 millirem (mSv) ✓*  
SUMMARY: The Nuclear Regulatory Commission is amending its regulations to establish a constraint of *10 mrem per year* <sup>*ill*</sup> 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; <sup>*and (2)*</sup> ~~This action is expected to be the final step in providing EPA with a basis upon which to rescind its Clean Air Act (CAA) regulations for NRC licensed facilities (other than power reactors) and Agreement State licensees, thereby relieving these licensees from unnecessary dual regulations.~~ ✓  
*as defined in 40 CFR Part 61* ✓



EFFECTIVE DATE: This rule will become effective on the date of publication in the Federal Register of the rescission of 40 CFR 61, Subpart I by EPA.

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. Subpart I of 40 CFR <sup>Part</sup> 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 and are subject to the requirements of Subpart I. Initially, Radon-222 emissions from tailings were covered by 40 CFR 61, Subparts T and W. Subpart T was rescinded for NRC licensees after Appendix A to Part 40 was amended by the Commission to conform to changes EPA issued to 40 CFR 192 that adopted the provisions of Subpart T (Subpart W still applies to NRC licensees). Because Radon-222 is adequately addressed in Appendix A to Part 40 and other provisions of <sup>10 CFR</sup> Part 20 it is not covered in this proposed rulemaking.

✓

*0.1 mSv (10 mrem) per year<sup>1</sup>*

Under Subpart I, emissions of radionuclides must be limited so that no member of the public would receive an effective dose equivalent of greater than ~~10 mrem/yr<sup>1</sup>~~.

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 the 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/yr, based on very conservative modeling. In addition, 98 percent of the

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Subpart I expresses dose in effective dose equivalent (EDE). NRC expresses dose in total effective dose equivalent (TEDE). These terms are essentially equivalent. For the sake of consistency, this paper will refer to all doses in terms of TEDE.

*as well as the rule*

facilities surveyed reported doses to members of the public resulting from air emissions less than 1 mrem/yr. The second study evaluated dose from air emissions from 43 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/yr. For the licensees evaluated, none exceeded 10 mrem/yr.

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

Based on the result 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 the public health (57 FR 56880; December 1, 1992).

However, EPA continued to express concern regarding the adequacy of the measures to "assure EPA 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 air emissions 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 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 <sup>1 mSv per year</sup> ~~100 mrem/yr~~ 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 kept as low as is reasonably achievable (ALARA). Based on the aforementioned studies conducted by EPA and licensee reporting of doses to members of the public from air emissions to EPA, it is evident that less than <sup>0.1 mSv (10 mrem) per year</sup> ~~10 mrem/yr~~ to the maximally exposed member of the public from air emissions is reasonably achievable. ✓

NRC power reactor licensees subject to 10 CFR 50.34(a) must keep doses to members of the public from air emissions consistent with the numerical guidelines in Appendix I to 10 CFR Part 50. In addition, these licensees have for many years reported estimated doses to members of the public from air emissions well below the Subpart I value. 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 has already 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 herein, establish a constraint of 10 mrem/yr TEDE for dose to members of the public from air emissions of radionuclides from NRC-licensed ✓



facilities other than power reactors as a part of its program to maintain doses ALARA. The <sup>se</sup> amendments codify numerical values for NRC's application of ALARA guidelines <sup>for</sup> on 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 <sup>existing</sup> facility licensing conditions. These <sup>Final</sup> amendments ensure that air emissions are maintained at a very low <sup>level</sup> and, taking into consideration the elimination of dual regulation, at ~~little or no~~ <sup>relatively</sup> low cost. This action brings consistency between EPA's dose standard and the NRC's ALARA application, thereby providing EPA with a basis upon which to rescind Subpart I as it applies to 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 Subpart I for <sup>the remaining</sup> NRC licensees ~~other than power reactors~~. ND

NRC has been working cooperatively with EPA over the last <sup>seven</sup> ~~several~~ years M to support rescission of EPA's standards in Subpart I of 40 CFR Part 61 in accordance with Section 112(d)(9) of the CAA. The fundamental objective of this effort is to eliminate unnecessary duplicative regulations that provide no incremental benefit in terms of public and environmental protection.

The regulatory framework within which NRC is providing a basis for rescission of Subpart I consists of the requirements in 10 CFR Part 20 to limit doses to members of the public to <sup>1 mSv (100 mrem) per year</sup> ~~100 mrem/yr~~, to maintain these doses as far below this limit as is reasonably achievable (ALARA), and to constrain dose to members of the public from air emissions of radioactive materials from a single <sup>licensed operations</sup> ~~source~~ to ~~10 mrem/yr~~. <sup>D. 1 mSv (100 mrem) per year.</sup>

<sup>Final</sup> This rule will require that if the licensee estimates or measures a dose to a member of the public expected to receive the highest dose from air

Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment will still be required pursuant to 10 CFR 20.2103(b)(4). *see comment #3.*

~~effluents to be less than 10 mrem/yr, the licensee would be required to record the dose and the assumption used to calculate it, consistent with the requirements of § 20.2103. This data would be made available to inspectors upon request. If the licensee estimates or measures a dose to the member of the public expected to receive the highest dose from air effluents to be~~ *0.1 mSv per year* ~~greater than 10 mrem/yr, the licensee would be required to report the dose to NRC in writing within 30 days, In addition, the licensee would be required to~~ *which would* ~~include in that report the circumstances that led to the greater than~~ *0.1 mSv* ~~10 mrem/yr 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.~~

The constraint on dose from air emissions is different than a limit. Exceeding this constraint will not result in a Notice of Violation (NOV). Rather, a NOV will be issued only upon failure to report ~~that~~ *an* actual or estimated doses, from air effluent releases from a facility, ~~have~~ *that* exceeded the constraint value and/or failure to institute appropriate measures to correct and prevent further emissions in excess of those which would result in dose exceeding the constraint level.

The rule will apply to airborne releases, other than Radon-222 and daughters, from all NRC licensees except power reactors. Power reactors are exempt from this proposed rule because they are already required under 10 CFR 50.34(a) to identify, in their application, design objectives and the means to be employed for keeping doses to members of the public from air effluents ALARA. Appendix I to *10 CFR* Part 50 contains the numerical guidelines to meet this requirement. *NO*

## Response to Comments

Fifty-seven individuals and organizations provided written comments on the proposed rule and the regulatory guide. Among the 57 comments, 24 were licensees, 7 professional organizations, 5 States, 16 members of the public, and 5 environmental organizations. Since many letters of comment on the subject of the regulatory guide included comments on the rule, they 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 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 <sup>two</sup> EPA studies on doses from air emissions. Two-thirds of these commenters were opposed to going forward with the constraint as it was not needed and <sup>neither licensee nor regulator</sup> costs could not be justified given the expectation that risk <sup>to the</sup> would not be reduced. <sup>Public</sup> 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 stated that the risk was considerably less than estimated as excessively conservative calculational <sup>and safety</sup>

methods were used by EPA. A few compared the 10 mrem/y constraint to variability in background or doses from commercial air traffic as evidence that the dose, and the risk, is trivial. Of the seven agreeing that the constraint was preferable to dual regulation or EPA's Subpart I alone, burden reduction and single-agency oversight were the reasons cited.

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 do confirmatory measurements and therefore NRC jurisdiction was not adequate.

Response: NRC and EPA have been working cooperatively 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 <sup>0.1 mSv per year</sup> 10 mrem/y <sup>per year</sup> to a member of the public. This has been demonstrated through the two studies undertaken by EPA and by licensee reporting of actual air emissions. The second component is a program to ensure that doses remain at this low level. In the absence of rulemaking requiring licensees to maintain doses to levels of no more than <sup>0.1 mSv</sup> 10 mrem/y, EPA would not rescind Subpart I, and dual regulation would continue. <sup>(10 mrem/y per year)</sup>

The Federal Radiation Council (FRC) was formed in 1959 to provide recommendations to the President for Federal policy on radiation matters affecting health. In May of 1960, FRC set forth basic principles for protection of both workers and members of the public. The council was

abolished in 1970 and its functions transferred to the Administrator of the newly formed Environmental Protection Agency. In 1981, EPA published proposed recommendations for new Federal guidance for occupational exposure. In 1987, President Reagan approved recommendations by the Administrator of EPA for new "Radiation Protection Guidance to Federal Agencies for Occupational Exposure." EPA has not yet issued recommendations on limits for members of the public. A working group comprised of representatives of affected Federal Agencies and experts has been developing these recommendations for several years. It is expected that they will do so within the next year.

The International Council on Radiological Protection (ICRP) issued its Report No. 26 "Recommendations of the International Council on Radiological Protection" in 1977. These recommendations included that the average doses to members of the public should not exceed <sup>1 mSv</sup> 100 mrem <sup>per year</sup> with a limit of <sup>5 mSv</sup> 500 mrem <sup>per year</sup> to any individual. ✓

The National Council on Radiation Protection and Measurements (NCRP) has the responsibility under its charter from the Congress of the United States to recommend limits for exposure to ionizing radiation. In June of 1987, NCRP issued its Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation." This report makes recommendations on 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 <sup>1 mSv</sup> to 100 mrem <sup>per year</sup> averaged over a lifetime, not to exceed <sup>5 mSv</sup> 500 mrem in any one year. ✓



Although some <sup>NRC</sup> staff believe that Alternative 1 (or maintaining the status quo) is a preferred alternative, the NRC staff's recommendation to the Commission is that

In 1981, NRC revised its 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 <sup>5 mSv</sup> (500 mrem) in any one year, the NRC established a limit of <sup>1 mSv</sup> (100 mrem) <sup>per year</sup> as it was deemed to be impractical to control dose in terms of lifetime average without keeping track of individual exposures. In addition, Part 20 requires that licensees use procedures and engineering controls to maintain doses as low as is reasonably achievable (ALARA). ✓

Both the NRC and EPA regulatory programs are designed to achieve the goals presented in the Federal guidance, ICRP recommendations, and NCRP recommendations. The approaches of the two agencies differ. NRC limits TEDE, and requires that doses are maintained ALARA. EPA limits dose from individual pathways of exposure and individual radionuclides to ensure that the total dose does not exceed the recommended levels, <sup>and requires licensees to issue reports to the public if standards are exceeded</sup>. Both programs achieve similar levels of protection. <sup>and maintains a large, active inspection program.</sup>

→ ~~NRC agrees that~~ adoption of the constraint in § 20.1101(d) is preferable to dual regulation ~~or regulation under 40 CFR 61, Subpart I alone~~ due to the reduction in burden on licensees as well as State and Federal Government agencies. Under the provisions of 40 CFR <sup>Part</sup> 61, licensees with doses to members of the public greater than <sup>5 mrem</sup> (1 mrem) <sup>per year</sup> but less than <sup>50 mrem</sup> (10 mrem) <sup>per year</sup> have to submit reports, recommend and implement corrective actions pursuant to Subpart I. These reporting requirements, even for licensees who have not exceeded any limit, are necessary under Subpart I as EPA does not perform routine inspections to ensure compliance with their regulations. However, under

§ 20.1101(d), these licensees will not have to file reports under for doses below the constraint level. The reason this is not necessary, is that doses can be evaluated at the time of routine inspections performed by trained inspectors. Under the new regime, the burden of calculating doses should be reduced for most licensees because the proposed guidance for demonstrating compliance with § 20.1101(d) allows significantly more flexibility and simpler methods for calculating doses than does the COMPLY <sup>or other alternative</sup> model <sup>currently used to demonstrate</sup> ~~compliance with~~ <sup>Compliance with</sup> implement 40 CFR 61. These new methods for calculating doses should result in fewer reporting and corrective actions. ✓

The Federal and State Government burden should be somewhat reduced as the number of annual reports requiring review and follow up actions should decline from several hundred per year to at most a few. Because NRC inspectors are already inspecting records of air emissions, there is ~~little~~ <sup>only a</sup> ~~additional burden to~~ <sup>the inspection program</sup> NRC as a result of the promulgation of this rule. There is the one time burden for promulgation of the rule, rescission of Subpart I, <sup>a Regulatory Guide, and development of licensing</sup> and development of ~~regulatory guidance~~ and inspection procedures. There is also a one time burden for <sup>training of the regional licensing and inspection</sup> implementation of compatible regulations. <sup>staff, as well as a one time burden for Agreement</sup> ~~Agreement States~~. Overall, the burden to State and Federal agencies should be reduced.

The NRC inspection program does not routinely include confirmatory measurements, but air effluent records are routinely inspected by NRC and confirmatory measurements <sup>may be</sup> ~~are~~ performed if it is deemed necessary by the inspector. Further, as previously stated, confirmatory measurements are not currently performed <sup>by NRC or EPA</sup> ~~to ensure compliance with Subpart I.~~

Finally, concerning those commenters that believe NRC's requirements less safe than Subpart I, in 1990, Congress enacted legislation comprehensively amending the Clean Air Act (CAA), which included a section addressing the issue of regulatory duplication between EPA and NRC. The 1990 CAA amendments permit the Administrator of EPA to rescind the CAA standards as they apply to radionuclides, at sites licensed by NRC and the Agreement States, if she finds that the NRC regulatory program provides an ample margin of safety to protect the 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/y and thereby provide evidence to EPA that the currently existing level of protection will continue to be afforded into the future. The purpose of this rulemaking is therefore not to reduce doses, as it has already been demonstrated that doses are sufficiently low. Rather, the primary purpose is to reduce costs associated with <sup>dual Federal regulation</sup> ~~the level of protection~~ ~~currently afforded~~, by providing a basis upon which EPA can find that doses will not increase as a result of rescission of Subpart I. Secondly, the

rule will ensure that doses are maintained at the low level currently achieved by NRC licensees.

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 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. Others similarly objected that ALARA is inherently site-specific and cannot be defined generically, or that the proposed dose constraint cannot be ALARA but must instead be a limit because the constraint contemplates some enforcement actions for exceedance even if the licensee has followed all good radiation protection practices. Finally, some argued that the rule cannot be ALARA because it adds costs with no safety benefit and others stated that the constraint is inconsistent with a prior NRC decision on "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 20 CFR 20.1003, is an operating philosophy which requires good radiation protection practice and the exercise of licensee expert judgement.

What the NRC had in mind in the proposed constraint rule is 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, and 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 Fed. Reg. 20603 (June 6, 1988). Of critical importance here, the Act provides the Commission with power to adopt and enforce generic requirements using either approach (Act § 161b). 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" in the sense that they establish generic requirements directly enforceable against licensees, but in a broad sense they are also ALARA regulations in that cost, feasibility and other relevant factors identified in 10 CFR 20.1003 are weighed and balanced. ✓

Viewed in its larger statutory context, ALARA in 10 CFR 20.1003 is one means to implement the second approach to radiological regulation but other similar requirements can also be part of this second approach. In particular, 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 also legally permissible. This broader concept of ALARA - 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. This kind of ALARA rule imposes a limit in the sense that exceedance will lead to enforcement action to achieve compliance, but it is not a limit in the sense that conformance is needed for adequate protection.

Thus, to say that the constraint rule cannot be based on ALARA because it is in effect a "limit" impermissibly 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 particular, 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 is something more than a narrow translation of the particular ALARA concept in 10 CFR 20.1003. Solely to avoid confusion with the narrow concepts of ALARA and limit often employed in radiation protection discussion, the term "constraint" was used for the rule under consideration.

This leaves three matters to be addressed - the comment that the rule cannot be based on ALARA because it will result in increased cost with no safety benefit, the problem of the licensee who cannot meet the dose constraint despite using all good radiation protection practices, and 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 licenses affected by the rule are achieving a level of control such that dose are below the <sup>0.1 mSv</sup> (10 mrem) level and so there is no factual dispute over whether this level of radiation protection is readily achievable. The

rule itself, considered with EPA's rescission of its Clean Air Act emission limits and related requirements, will result on a significant net cost savings to licensees. We acknowledge that, given the current level of controls, the positive direct health effects are likely to be small and possibly zero in the near future, ~~but the rule will have the effect of preventing possible future backsliding by licensees~~, and so can be said to offer <sup>a</sup> ~~some~~ small but positive net health and safety benefit. Under the broad ALARA concept described above, it is entirely appropriate to base a rule on a small positive health and safety benefit when cost savings are also likely. ✓

We do not expect that any licensee subject to the rule will be unable to comply. In the unlikely event that, due to some temporary circumstances or lapse in controls, the dose level is or is projected to be exceeded, licensee actions to come with compliance are expected and, if needed, will be enforced. The unforeseen and, given current information on the practicality of stringent controls, unlikely circumstance of a licensees being unable to comply, because of limits in the technology or exorbitant cost, can be <sup>be</sup> addressed in the future on a case by case basis. ✓

Finally, this rule is not inconsistent with the concept of reference level which was rejected by the Commission when <sup>10 CFR</sup> Part 20 was recently revised. Commenters on the 1991 revision to <sup>10 CFR</sup> Part 20 objected to the use of reference levels as they were implemented exactly the same as limits. For that reason the Commission eliminated reference levels from the final 1991 revision. Implementation of the constraint is different than a limit in that exceedence ✓

is not a violation, and it only requires licensee actions<sup>9</sup> It is not the purpose of the constraint rule to provide such added assurance. ✓

### Issue 3 - WHETHER THE CONSTRAINT IS ACTUALLY A LIMIT

Comments: Nine comments were received on whether the constraint is or should be a limit. These commenters were divided. Two commented 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 exceedence of the constraint would result in enforcement action and therefore is a limit. Three commenters indicated that the rule should be a strict limit. They expressed concern that the constraint was less protective than Subpart I.

Response: A constraint is not the same as a limit. The constraint is a dose at which the licensee must notify NRC, but it is not a dose above which enforcement action would necessarily be taken. If a licensee exceeds a limit, the NRC may take immediate enforcement action. If a licensee exceeds a constraint, licensees will be required to notify NRC and implement corrective actions that are adequate to prevent further doses in excess of the constraint. In the unlikely event that calculations in the following year indicate that the constraint has again been exceeded, where agreed upon corrective actions had been appropriately implemented, enforcement action

would not necessarily be considered. If however, the licensee had failed to report it to NRC or had failed to implement the corrective actions as agreed upon, enforcement action would be expected.

The adoption of a constraint is not needed to provide adequate protection of the public and the environment. The existing regulatory program of established limits in Part 20 and the application of ALARA is adequate for that purpose. Therefore, it is not necessary to promulgate the constraint as a limit.

The NRC does not agree that the constraint is less protective than Subpart I. Both Subpart I and the constraint require licensees to take actions to ensure that doses to members of the public do not exceed <sup>0.1 mSv</sup> (10 mrem) <sup>per year</sup> from environmental air emissions. Enforcement would be similar under either requirement. NRC routinely inspects licensed facilities to ensure that air effluents do not result in doses to members of the public in excess of the requirements in <sup>10 CFR</sup> Part 20. Confirmatory measurements <sup>maybe</sup> are performed when they are deemed appropriate. A similar program of inspection and enforcement will be implemented as a result of this rulemaking.

#### Issue 4 - CITIZEN SUITS

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

Response: The lack of a citizen suit provision in the Atomic Energy Act is more appropriately a matter for the EPA to consider in reaching it's

rescission decision. However, it should be noted that the Commission's regulations in 10 CFR 2.206 do provide the public with the right to petition the Commission to take enforcement action against a licensee for such things as a violation of the Commission's regulations. This would include the constraint rule when finalized.

#### 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 division 1. Under division 1, the States would be required to adopt regulations that were essentially identical. These commenters said that if stricter standards were permitted, that reactors and non reactor licensees would be under different requirements, and that certain practices such as nuclear medicine could be jeopardized. One commenter noted that because this is really a limit, it should be under § 20.1301 and would therefore be 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 indicates that, with certain exceptions not applicable here, nothing in the Act precludes States from imposing air emission requirements that are more stringent than those



developed by EPA. Section 112(d)(9), which contains the provisions related to EPA's "ample 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 in Section 116(d)(9) 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.

Accordingly, 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 power of the Agreement States to impose air emission standards under their Atomic Energy Act authority after the effective date of this rule will be consistent with their existing authority.

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. While they were not formally sent an advance copy of the draft

rule, there were extensive discussions of the concept, not only with the individual States, but also with the Executive Board of the Organization of Agreement States.

#### Issue 6 - DEMOGRAPHIC INFORMATION CONTAINED IN REQUIRED REPORTS

Comments: Seven commenters addressed the application of the requirement contained in § 20.2203 (b)(2) to the constraint. This section requires that reports 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. Licensees would therefore 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. Section 20.2203 has been changed to delete that requirement.



#### 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: NRC agrees and this provision has been added. This provision is needed to ensure that there is not a time when both Subpart I and the constraint are in effect. Because it is very difficult to coordinate these rulemakings such that they are issued simultaneously, a delay in the effective date is appropriate.

## Issue 8 - ENFORCEMENT

Comments: Five commenters commented that NRC should establish a limit rather than a constraint. They stated that once 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 the only guidance, it is not enforceable.

Response: A limit implies that doses must be controlled below that level in order to provide adequate protection of the health and safety of the public and workers. A notice of violation and civil penalties are not needed to ensure that licensees will not exceed a constraint. Licensees are currently controlling effluents to levels below that which would be required under the constraint to meet current ALARA requirements. If a licensee exceeds the constraint, the rule requires that corrective actions be taken in a timely fashion. If a licensee is uncooperative or fails to take appropriate actions, a notice of violation and civil penalties are possible.  

~~ALARA is not a 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.

## Issue 9 - EXEMPTIONS

Comments: Five commenters stated that the rule should only apply to members of the public off site. They cited the Subpart I requirement to calculate dose to the nearest resident. 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: NRC agrees that Subpart I only applies to the nearest resident. The language in the rule has been changed to reflect that it is intended to apply to environmental air emissions. The <sup>Regulatory Guide that will be</sup> guidance will be <sup>issued</sup> revised to indicate that the dose limit is to be calculated to the nearest <sup>before the</sup> resident. <sup>constraint</sup>  
<sup>rule</sup>  
<sup>goes final</sup>

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 need to 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 environmental emissions of licensed materials only. The rule language has been changed to make it clear that windblown particulates from other nearby licensed facilities or unlicensed materials need not 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: NRC agrees that air emissions from patients are excluded from this rule. The Regulatory Impact Analysis for NRC's recent Patient Release

Rulemaking (NUREG-1492), analyzed potential doses from exposure to patients having been released following administration of radiopharmaceuticals. This analysis concluded that internal doses from intakes 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 final regulatory guide will make it clear that dose from air emissions from patients need not 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: Subpart I exempts both Rn-222 and any daughters produced after release of Rn-222 as it is 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 commenters suggestion that an oversight led to the erroneous omission of this



exemption from Subpart I is incorrect. Therefore, Rn-220 will not be excluded from the calculations demonstrating 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 <sup>Part</sup> 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, as any package that has remained sealed cannot contribute to airborne emissions. 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 emissions. The final regulatory guide will provide further guidance on this issue.

Issue 10 - MEASURABILITY OF ~~10 mrem/year~~ <sup>0.1 mSv (10 mrem) per year</sup>

Comments: Three commenters stated that ~~10 mrem/y~~ <sup>0.1 mSv (10 mrem) per year</sup> was not measurable.

One commenter stated that while ~~10 mrem/y~~ <sup>0.1 mSv (10 mrem) per year</sup> might be easily achievable, it is not easily measurable. Another stated that the exposure rate corresponds to <sup>(0.01 μSv)</sup> (1 microR) <sup>per hour</sup> and cannot be measured accurately. <sup>(spill out)</sup>

Response: The regulatory guide provides several methods for demonstrating compliance with the constraint. Only one of the methods acceptable to staff is direct measurement at the receptor location. If this method is not practical due to the emission characteristics of the

radionuclide releases, there are several valid options cited in the regulatory guide.

#### Issue 11 - SCOPE OF THE RULE

Comments: One commenter stated that if we must have a constraint, it should apply to all licensees, not just non-reactors.

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

#### Issue 12 - LOCATION OF CONSTRAINT IN NRC REGULATIONS

2.1msv (10 mrem) <sup>per year</sup> The Commission requested specific comment on the question of whether the 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 stated that the constraint should be in Part 20. The other stated that the constraint should be in each appropriate part. Two other commenters stated

that the constraint should be in § 20.1301 with dose limits.

Response: In order to make clear that the constraint is intended to control dose to members of the public, but that it is not the same as a limit, it will be codified in a separate Subpart E to Part 20, "Dose constraints for members of the public."

#### Summary of Changes in the Final Rule

Based on the response to comments, a few changes were made in the final rule. Otherwise, the final rule provisions are the same as those presented in the "background" section under the section titled proposed amendments. Specific changes made to the proposed rule in the final rule are summarized as follows.

(1) The requirement in § 20.2203(b)(2) has been changed to eliminate the requirement to report the name, social security number, and date of birth for each individual member of the public exposed to doses in excess of limits or constraints.

(2) Paragraph 20.1101(d)(2) has been added to indicate that the effective date of the rule imposing the constraint is to coincide with EPA's rescission of 40 CFR 61, Subpart I.

(3) 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.

*the release of radioactive effluents  
to the environment*  
(4) The language of the rule has been changed to indicate that the constraint applies only to ~~environmental air emissions~~ and <sup>this</sup> ~~thus~~ dose to the nearest resident is to be constrained. X

In addition, the following changes will be made to the regulatory guide:

(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 need not be considered if the materials have already been included in the site inventory.

(3) The example has been changed to demonstrate compliance with an environmental release constraint by calculating a dose to the nearest resident from a routine release point.

#### 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 would provide equivalent protection. Actual air emissions are not expected to change. The changes would be procedural methods for demonstrating compliance /

*as well as licensing and*  
~~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.



## 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 qualitatively 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, if adopted, 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. This category of licensee includes only a few small businesses.

#### 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.

#### 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, that 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:

use same words  
as 20.2103(b)(4)

(1) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, licensees other than those subject to §§ 50.34a or 50.36b, shall constrain ~~environmental air~~ <sup>radioactive effluents to</sup> ~~the environment~~ <sup>emissions of</sup> radioactive materials so that the individual member of the public likely to receive the highest dose will not be expected to receive a dose in excess of <sup>0.1 mSv</sup> ~~10 mrem~~ <sup>per year</sup> TEDE from these emissions.

(2) If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedence as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

(3) This requirement shall be effective on the effective date of the rescission by EPA of 40 CFR 61, Subpart I for NRC licensed facilities other than power reactors.

4. In § 20.2203 a new paragraph (a)(2)(vi) is added and paragraph (b)(1)(iv) is 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 <sup>(d)</sup> ~~(a)~~; 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, for doses to occupationally exposed individuals in excess of limits, must include for each individual -

\* \* \* \* \*

Dated at Rockville, Maryland, this \_\_\_\_ day of \_\_\_\_\_, 1996.

For the Nuclear Regulatory Commission.

\_\_\_\_\_  
John C. Hoyle,  
Secretary of the Commission.



1 MNS comments

✓ 6/24

ATTACHMENT 2

REGULATORY ANALYSIS

IMNS Comments  
✓

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

use  
SI units  
throughout -  
+ page #15

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 Agreement State) and the Environmental Protection Agency (EPA). The NRC and Agreement State regulation 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,<sup>1</sup> thereby relieving these NRC licensees from unnecessary dual regulations.

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 <sup>0.1 mSv</sup> (10 mrem) per

---

<sup>1</sup> 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.

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 <sup>1 mSv</sup> 100 mrem <sup>per year</sup> 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 100 mrem/yr TEDE limit and ALARA. For light water reactors, compliance is demonstrated if the design objectives in Appendix I to 10 CFR Part 50 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. The first, is to demonstrate that the average concentrations in air and liquids released from the facility do not exceed values in Appendix B to 10 CFR Part 20, and are ALARA, and direct exposures do not exceed <sup>0.5 mSv</sup> 50 mrem <sup>per year</sup>, and are ALARA; or second, to demonstrate that the dose to the member of the public likely to receive the highest dose from all pathways is less than <sup>1 mSv</sup> 100 mrem/yr 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

[need page #'s]

the range of <sup>1 mSv</sup>(10 mrem) 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 <sup>1 mSv</sup>(10 mrem) <sup>per year</sup> standard. This conclusion has been confirmed by a review of the annual reports submitted by licensees to EPA as required by Subpart I. For 1993, only one licensee reported air emissions above the <sup>0.1 mSv</sup>(10 mrem) per year standard; corrective measures were initiated by the licensee and no enforcement actions were taken by EPA. *For 1994 \_\_\_\_\_; for 1995 only 1*

This rulemaking establishes a <sup>0.1 mSv</sup>(10 mrem) per year TEDE dose constraint on radionuclide air emissions. While not considered a health and safety issue such that adequate protection of the public health and safety 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, a net savings), and bring consistency between EPA's dose standard and the NRC's ALARA application, thereby providing 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 (4) 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 <sup>0.1 mSv</sup> (10 mrem) TEDE in any year, or more than <sup>0.3 mSv</sup> (3 mrem) 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) (as an NRC licensee) about unnecessary duplicative, and perhaps conflicting, standards on 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 the public health and safety is 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 Subpart T (and Subpart I for power reactors) of 40 CFR Part 61.

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 <sup>0.08 mSv</sup> (8 mrem) per year TEDE, based on very conservative modeling. In addition, 98 percent of the facilities surveyed had doses of less than <sup>0.01 mSv</sup> (1 mrem) 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 <sup>0.1 mSv</sup> (10 mrem) dose standard. Of these, 75 percent had estimated maximum dose to a member of the public less than <sup>0.01 mSv</sup> (1 mrem) per year. None exceeded the (10 mrem) 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) per year.

EPA's conclusion, based in part on these studies, was that the current NRC program, which limits public dose to (100 mrem) per year, in concert with the requirement to keep doses ALARA, has been successful in maintaining air emissions well below the (10 mrem) 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 fact, the DC Circuit has 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 <sup>16</sup>~~15~~ 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 the 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 <sup>0.1 mSv</sup>(10 mrem) per year TEDE to the maximally exposed individual from radionuclide air emissions (Ref 2). Additionally, <sup>NRC</sup> Inspection Procedure (IP) 87102 was developed to include a review of emissions from those facilities with the potential of exceeding 20 percent of the 10 CFR <sup>Part</sup> 20, Appendix B, Table 2 values (Ref. 3). Generally, this 20 percent level corresponds to a calculated dose from air exposure of <sup>0.1 mSv</sup>(10 mrem) per year, which is comparable with the EPA's Subpart I standard. An Inspection Referral Form was included within IP 87102, which ~~is~~ <sup>was</sup> ~~to be~~ completed by the NRC inspector and forwarded by NRC Region Management to ~~the~~ <sup>each</sup> cognizant Regional Radiation Program Manager of the EPA.

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 (57 FR 43173; September 18, 1992); and later in 1992, EPA issued the Federal Register notice proposing the rescission (57 FR 56877; December 14, 1992). 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 Federal Register notice (59 FR 4228), 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 currently in compliance with the quantitative emission limits in Subpart I (<sup>0.1 mSv</sup> ~~10 mrem~~ 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 <sup>0.1 mSv</sup> (10 mrem)/yr from air emissions. EPA staff told NRC staff that 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, <sup>which also exceeded the 10CFR Part 20 limits for members of the general public.</sup> This licensee took corrective measures; no

*Note: Enforcement action was taken by NRC; this is why EPA did not take enforcement action.*  
~~enforcement actions were taken by EPA.~~ The 1995 annual reports are currently <sup>ATM</sup> being submitted to EPA, and the reports reviewed to date have not identified any licensee with 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 NRC's <sup>as well as EPA's</sup> 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. ✓

*and* These unusual situations are best addressed on a case-by-case basis. Second, with this level of compliance, <sup>(EPA has not been doing inspections)</sup> subjecting facilities to dual reviews, reporting, <sup>and</sup> evaluations, ~~and inspections~~ is unnecessary for protecting the public safety. Compliance can most efficiently be covered by a single regulatory process. The NRC constraint rule <sup>therefore</sup> provides ~~an~~ ample margin of safety. ✓

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., <sup>0.01 mSv</sup> <1 mrem/yr TEDE) are exempt from the reporting requirement but must still monitor effluents and maintain records of dose calculations. <sup>necessary for the constraint rule</sup> Licensees subject to Subpart I annual reporting requirements (e.g., doses <sup>0.01 mSv</sup> >1 mrem/yr TEDE) are required to submit an annual report by March 31 of each year to EPA on air ✓

emissions for the previous calendar year. Licensees with air emissions in excess of the annual limit (e.g., <sup>1 mSv</sup> > (10 mrem)yr 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 <sup>6,000</sup> 7,000 NRC licensed facilities and about <sup>14,000</sup> 15,000 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 are not subject to Subpart I because of the 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, predominantly hospitals, clinics, radiopharmacies, research and academic facilities, fuel cycle facilities, and research reactors.

→ We should report the Current Status here.

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 not authorized to set standards less stringent than those promulgated by the EPA. The EPA Administrator has <sup>3</sup> ~~not at this time~~ approved <sup>(List States)</sup> any State 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. ✓

Still Current?

#### 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 the public health and safety with respect to the materials covered by the proposed agreement.

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 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 "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. To support the determination by EPA that NRC's programs provide an equivalent level of protection, this

rulemaking codifies a <sup>1 mSV</sup>(10 mrem) 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 essentially the same margin of public and environmental safety as that currently afforded under Subpart I. With the elimination of dual regulations, 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. 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, as required, conducting enforcement actions. NRC's programs will require essentially no additional efforts beyond its current inspection and enforcement programs. Agreement States have similar compliance evaluation programs, if they have not already done so.

### 3. Alternatives

- 1) Alternative 1 - Dual Regulation - NRC and EPA would each retain 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 <sup>that</sup> ~~that with few exceptions,~~ all NRC and Agreement State licensed facilities are maintaining air emissions well below the 40 CFR Part 61, Subpart I, dose standard of <sup>1 mSv</sup> (10 mrem) per year.<sup>2</sup> However, EPA determined that NRC's regulatory framework did not 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 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 ~~ALARA goals,~~ <sup>compliance with 10 CFR Part 20 which includes maintaining dose levels</sup> ~~which, in effect,~~ <sup>and</sup> 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. <sup>STET</sup> ~~However,~~ NRC would not be involved from a legal

<sup>2</sup> 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), <sup>as well as recent EPA reports from licensees (1994-1995).</sup>

compliance standpoint if a facility exceeded <sup>EPA'S 17MSV (10 mrem per year)</sup> the standard, unless NRC standards were also exceeded. EPA would retain its regulatory authority for enforcement actions. ✓

EPA would continue its compliance programs, including ~~developing and~~ <sup>maintainance of</sup> ~~maintaining~~ guidance programs, ~~training of EPA Regional staff,~~ <sup>delete (already done)</sup> 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(1)(1) of the CAA. ✓

The availability of citizen suits under the CAA would remain if Subpart I is not rescinded (however, if EPA does ultimately rescind, the public petition process for NRC enforcement action against a licensee under 10 CFR 2.206 would offset the unavailability of the CAA citizen suit provision; ~~however~~, judicial review of 2.206 petition denials is not readily available. EPA has stated that NRC's current regulatory framework did not provide a sufficient legal and technical basis for rescinding Subpart I (59 FR 4228; January 28, 1994). While 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. Over a period of time, this experience could provide the necessary information to support a decision by EPA to rescind Subpart I. ✓

and also allow NRC to stop expending addition resources on development of regulatory language, ~~guidance~~ as well as inspection and licensing guidance.

Some NRC staff believe that this is an appropriate alternative to select, since licensees have been under dual regulation for more than 3 years without any undue harm to the public health and safety.

### 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 Procedure IP-87102, Regulatory Guide 8.37 and the MOU with EPA on inspection referrals would be withdrawn. 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. Appendix B, Table 2, Column 1 to Part 20 would be deleted.

As in Alternative 1, EPA would continue its compliance programs and 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 ~~air emissions~~ <sup>releases of radioactive effluents to the environment</sup> from NRC licensed facilities, excluding power reactors. The regulation would constrain air emissions, <sup>to the environment</sup> to a level corresponding to a calculated dose of <sup>0.1 mSv</sup> (10 mrem) per year to the maximally exposed member of the public. This approach would add numerical criteria for material <sup>licenses,</sup> and fuel cycle facilities, <sup>and</sup> 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). It would not be a regulatory limit. A licensee exceeding a limit would be in violation of NRC regulations and subject to enforcement. A licensee exceeding <sup>this</sup> a constraint would be required to submit a report, and recommend and implement appropriate corrective actions. Failure to report exceedence of the constraint or failure to implement agreed upon corrective actions would be a violation of NRC regulations subject to

*Need to expand here to state that significant (3-4 FTE) NRC resources will be saved by the elimination of this part of the program in NRC's NRC's.*

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 staff has indicated in meetings with NRC staff 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 <sup>0.1 mSv</sup> (10 mrem) 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, thereby supporting a finding by EPA 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 duplicate 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 of the Code of Federal Regulation (i.e., Title 10 for the NRC and Title 40 for EPA). In addition, ~~as individual States establish their EPA 40 CFR Part 61 compatible programs, licensees would be subjected to another, and potentially different, compliance program.~~ Each licensee would have two regulatory groups within a State with whom to interact relative to compliance, including <sup>possible</sup> on-site inspections, <sup>by EPA (currently not done on a routine basis)</sup> 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 radiation protection program to the environmental program to administer Subpart I. This might result in personnel shortages in some States. 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 <sup>public</sup> dose limit of

*delete.  
State  
already  
can do  
this  
now.*



1 mSv

doses being maintained

(100 mrem) per year and the principle of ALARA. EPA's compliance programs would continue, including the selected <sup>reactive</sup> inspections, evaluations of licensee submitted annual reports, and continued <sup>financial as well as technical</sup> support to individual State program development. EPA staff has indicated that they expect individual State involvement would increase as individual compliance programs are put in place.

Based on the 1992 NRC/EPA 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.

1993 date?

Based on EPA labor rates, the cost of Subpart I to licensees is \$517 per licensee or over \$3 million per year for all licensees. EPA estimated the burden to NRC and Agreement State licensees assuming that 6000 licensees would be affected and using 3 separate hourly rates for professional (\$27/hr), managerial (\$38/hr) and clerical (\$10/hr) personnel.

was estimated by EPA

In their OMB Clearance package

The burden estimated in EPA's <sup>OMB</sup> clearance assumed that 200 licensees would have had to file will file reports annually and that it would require 11 staff hours to review each report. The EPA estimated government burden for Subpart I is 2200 hours or \$44,600. For calendar year 1993, 670 licensees filed reports, For 1994-1 1995-1

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

Needs to be re-done; these values were from the original EPA OMB package;

During 1994-1 1995-1 dates #15.

*development of training for EPA and NRC  
region, as well as Agreement State,*

of inspection results to EPA, and development of the Constraint Rule. Under this alternative, it is expected that EPA's burden would remain at about 3 FTE annually, with periods of increased effort when facilities experience increased air emissions at or above the standard. NRC and Agreement State licensees' efforts can be expected to remain at about ~~138,000~~ hours annually (25 hours/licensee), provided facility design and/or operations do not significantly change. Licensees would continue to have to demonstrate compliance with dual regulatory requirements.

*How?  
impossible  
What is it  
now?*

*rule  
state  
80 hrs/licensee*

*(Dual Regulation)*

The burden of Alternative - 1 is summarized in the following table:

*Re-do TABLE E Current 1995 #'s.*

	Cost
NRC and Agreement State Licensees	\$3,100,000
EPA	44,600
NRC (0.5 FTE for inspection and referrals to EPA)	50,000
TOTAL	\$3,194,600

4.2 ~~Eliminate NRC Regulation of Air Emissions~~ *EPA Regulation Only*

Elimination of NRC regulation of air emissions would eliminate dual regulation. NRC's burden would be reduced as inspection of licensee records 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.

*revision of  
Calculations  
as well as  
licensing  
reviews  
of the  
air emission  
program*

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

However the burden to EPA may increase due to the potential need for EPA inspection of licensed activities as well as enforcement activities.

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 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 29 Agreement States would expend about 0.1 FTE revising their rules.

The burden on licensees and on EPA would be the same as under the dual regulation alternative. The annual burden to NRC would be slightly reduced as routine inspection of doses to members of the public would include <sup>data resulting</sup> only direct <sup>from</sup> exposures and liquid effluents. As air effluents are a very 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 in the tables below:

Annual Burdens	Cost
NRC and Agreement State Licensees	\$3,100,000
EPA	44,600
NRC (reduced inspection burden <sup>ask licensing</sup> 0.25 FTE)	<del>25,000</del>
(NRC + NAHS) <sup>0.75</sup>	TOTAL \$3,119,600

Still correct?

where are these #'s from?

One Time Expenditures	FTE	Costs
NRC Rulemaking	1.0	\$100k
NRC Inspection Procedures <sup>Licensing Procedures +</sup> and Inspector Training <sup>Regional</sup>	<del>0.5</del> 1.5	<del>50k</del>
Agreement State Regulations Revision	2.9	290k
TOTALS	<del>4.4</del>	<del>\$440k</del>

<sup>NRC</sup>  
Alternative 3 - Constraint Rulemaking and EPA Rescission of Subpart I.

A constraint level would be enforced by NRC through its current (Ref 3, 4, 5) licensing and inspection and enforcement programs. The current IP 87102, IP 80745 and IP 40750 (Ref 3) would require minor modification in wording for consistency with the rule; the Referral Form and letter to EPA would ~~be eliminated from the inspection procedure~~ no longer be needed. NRC regulatory guidance would be revised ~~and issued before the NRC Constraint rule is made final~~ to specifically address the constraint rule. Acceptable methods for demonstrating compliance and reporting guidelines would need to be added. 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.

The main savings would be for facilities that maintain effluents at a small fraction of the standard, i.e., those facilities for whom additional evaluations, reports and overall dual regulatory oversight are not required for ensuring public safety with an ample margin of safety. Annual reporting would not be required provided air emissions were maintained below the NRC's constraint level. NRC's routine inspection <sup>and licensing</sup> program would provide the necessary regulatory oversight.

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 facilities that fail to perform the required evaluations and/or those facilities that fail to take appropriate measures in keeping with ALARA, for reducing air emissions.

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



In addition approximately 1.5 FTE will be initially needed for review and modification of the inspection procedures, development of licensing guidance and initial training in all of the regional offices

the constraint rule if the dose did not exceed it. Very few licensees (if any) would have doses to members of the public in excess of the <sup>0.1 mSv</sup> (10 mrem) constraint, and therefore be required to make a report to NRC or an Agreement State. It is assumed that an average of <sup>five</sup> ~~three~~ reports per year will be received. The total licensee burden is estimated to be \$12,000 annually  
 $(2 \text{ reports/yr} \times 80 \text{ licensee-hours/report} \times \$50/\text{hr} = \$8k/\text{yr})$

The burden of reviewing <sup>and inspecting</sup> the air effluent control programs of licensees reporting doses to members of the public in excess of the constraint is estimated to be <sup>2.5 FTE</sup> ~~\$24,000~~ annually <sup>3</sup> ~~(3 reports/yr x 160 NRC staff-hours/report x \$50/NRC staff-hr = \$24k/yr)~~

The constraint rule is not considered a necessary public health and safety measure because adequate protection has been maintained. Therefore, efforts associated with the rulemaking would be limited to mainly administrative efforts for the preparation of appropriate legal notices and issuance. The basis for the rulemaking would be the elimination of unnecessary duplicate regulatory oversight. Public hearings, additional technical reviews, etc. would not be anticipated.

Under Alternative 3, NRC and the Agreement States would incur one time costs for completion of the rulemaking, <sup>completion</sup> ~~development~~ of regulatory guidance, <sup>development</sup> ~~development~~ of licensing procedures, modification of the NRC inspection procedures, and training of NRC inspection personnel. <sup>(NRC cost = 1.5 FTE; Agreement State costs = ?)</sup> EPA will also incur one time costs 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

③ This estimate is based on NMSS assumption that 160 hours would be expended per report. This cost includes a reactive special inspection, recalculation of dose, and modification of the facility license to incorporate approved corrective actions as license conditions, with headquarters concurrence.



State Program (January 23, 1981; 46 FR 7540, July 16, 1981; 46 FR 36969, July 21, 1983; 48 FR 33376).<sup>4</sup> 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 the compatible or more stringent regulations. The Agreement States are expected to adopt similar compliance programs 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 ~~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 development of compliance programs would be no more than <sup>0.5</sup>~~0.25~~ FTE per State or approximately <sup>\$ 980,000</sup>~~\$ 725,000~~ (29 States x <sup>0.5</sup>~~0.25~~ FTE/State x <sup>1350</sup>~~2000~~ hours/FTE x \$50/hr = <sup>\$ 980,000</sup>~~\$ 725,000~~). NRC would continue its evaluation of Agreement State programs for adequacy and compatibility.

*Radiation Protection Programs which influence the ALARA concept.*

*0.5 FTE for each state since travel & time needed is significantly less than NRC*

<sup>4</sup> 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.

*regional training*

Costs for Alternative 3 are summarized below:

SEE ATTACHED  
NMSS ESTIMATES  
FOR FTE.  
NEED TO ADD  
IN NRC  
FTE  
ESTIMATE  
ASO.

Annual Expenditures	FTE	Costs
NRC and Agreement State Licensees	0.12	\$12K
NRC and Agreement State Governments	2.1	<del>21K</del>
<del>Agreement State Governments</del> (29 x 0.25 FTE)	7.25	—
TOTALS	9.47	\$20K

One Time Expenditures	FTE	Costs
NRC Rulemaking	0.5	\$50k
NRC Inspection <del>and licensing</del> Procedures <del>and</del> Inspector Training	0.5 1.4	<del>50K</del>
NRC Regulatory Guidance Development	0.5	<del>50K</del>
Agreement State Regulations Development	7.25 14.5	725K 980K
EPA Subpart I Rescission Rulemaking	0.5	50k
TOTALS	9.25 17.4	<del>\$925K</del> \$1080K

## 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 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.

The NRC believes that, in amending the CAA in 1990 to specifically address the issue of duplicate regulation, Congress intended that dual regulatory oversight by EPA and NRC be eliminated if it could be done effectively. Alternative 1 (dual regulation) makes no significant effort to support a finding required by the CAA, Section 112(d)(9), for the dual regulation to be rescinded. 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. Alternative 3 achieves this goal by providing assurance that the NRC regulatory framework will provide an ample margin of safety. This Alternative will support an EPA finding to that effect, and thereby, support a subsequent rescission of Subpart I. This decision can only be made by the EPA Administrator. Based on discussions with the EPA staff, the framework of Alternative 3 represents the EPA preferred approach.

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 of a finding 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 has been determined by the EPA not to provide the regulatory framework necessary to make this finding.

For Alternative 3, that of imposing controls by regulation, the relatively straightforward rule contemplated has been estimated to require <sup>use NRC staff 2-person-year</sup> of Federal Government effort (including development 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-years (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		\$3,194,600
2 - <del>Eliminate NRC Regulation of Air Emissions</del> EPA Regulations Only	\$445,000	\$3,119,600
3 - <sup>NRC</sup> Constraint Rule and <sup>EPA</sup> Rescission of Subpart I	\$925,000	\$36,000

Although there are differing staff views as to which alternative is best, the staff recommendation to the Commission is that <sup>Based on the above discussion, it is determined that</sup> Alternative 3 represents the preferred approach. Although Alternative 1 would be acceptable from a public health and safety perspective, it would not eliminate dual regulation. <sup>which is to eliminate dual regulation.</sup> Alternative 2 would also be acceptable from a public health and safety perspective but would be far more burdensome to licensees as 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 proposed rulemaking have been developed. The level of effort required for completing the rulemaking has been estimated at 0.5 staff-years, over a 6-month time period.

The staff will ~~prepare~~ <sup>prepare a</sup> regulatory ~~guidance~~ <sup>guide</sup> that will further clarify the applicability of the rule and will provide guidance on acceptable methods for demonstrating compliance and for evaluating and reporting elevated effluents should the constraint level be exceeded. 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.

*State if this will be issued in final or as draft for comment. Indicate when, this will be done (at the time of the final rule).*



## 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).

4.6. 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.

5.7. 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.

4. Add IP 80745  
5. Add IP 40750 > for non-power reactors.

IMNS Comments

Notification for Cong. Review

~~Cong. Ltr~~

~~SA~~

✓ CD

6/30/96

ATTACHMENT 3

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 licensed licensees such that no member of the public will receive a dose of 10 mrem in a year from such 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 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 which 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 61, Subpart I. A notice of its effectiveness will be published in the Federal Register.

Sincerely,

John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
Regulatory Analysis

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

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Sincerely,

John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
Regulatory Analysis

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

The Honorable Al Gore  
The President of the Senate  
S-212, The Capitol  
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 licensed licensees such that no member of the public will receive a dose of 10 mrem in a year from such 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 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 which 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 61, Subpart I. A notice of its effectiveness will be published in the Federal Register.

Sincerely,

John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
Regulatory Analysis



The Honorable Al Gore  
The President of the Senate  
S-212, The Capitol  
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 licensed licensees such that no member of the public will receive a dose of 10 mrem in a year from such 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 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,

John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
Regulatory Analysis

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

The Honorable Newt Gingrich  
The Speaker  
H-209, The Capitol  
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 licensed licensees such that no member of the public will receive a dose of 10 mrem in a year from such 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 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,

John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
Regulatory Analysis

The Honorable Newt Gingrich  
The Speaker  
H-209, The Capitol  
Washington, DC 20515

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John C. Hoyle  
Secretary of the Commission

Enclosures: Final Rule  
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ATTACHMENT 4

ENVIRONMENTAL ASSESSMENT

Environmental Assessment and Finding of  
No Significant Impact

on  
Proposed Rule on "Constraint For Dose to  
Individual Members of the Public"

*from Air Emissions  
of Radioactive Materials*

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. ~~Most of the provisions of this rule were previously inspected against and reported to the Environmental Protection Agency (EPA), under an agreement with EPA. 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. 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," Subpart I as it applies to NRC licensed facilities other than power reactors,<sup>1</sup> thereby relieving these NRC licensees from unnecessary dual regulations.~~

*Deletes  
We did  
not  
inspect  
against  
Subpart I*

*and Agreement State*

*ims*  
<sup>1</sup> EPA previously proposed rescission of Subpart I for power reactors based on requirements contained in 10 CFR 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. ~~It is expected that the rescission of Subpart I for power reactors will be finalized by mid 1995 independent of this rulemaking.~~

*give date.*



## II. THE NEED FOR THE RULEMAKING ACTION

Subpart I currently limits dose 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 <sup>0.1 mSv</sup> (10 mrem)/yr.

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" (Subpart D). Under Subpart D, licensees shall ensure that doses to members of the public are less than <sup>1 mSv</sup> (100 mrem)/yr 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 10 mrem/yr to the maximally exposed member of the public from air emissions is reasonably achievable. Therefore, EPA's Subpart I represents duplicate dose regulation for affected licensees.

The NRC is establishing a constraint for dose to members of the public from air emissions of radionuclides of <sup>0.1 mSv</sup> (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.

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.

### III. ALTERNATIVES TO THE RULEMAKING ACTION

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

*Use same titles as previous section —*

Alternative 1 - ~~No Action~~ Continuation of Dual Regulation. ✓

Alternative 1 maintains the status quo which involves licensees demonstrating compliance with the limits in Part 20 for dose to members of the public, including the ALARA requirement, and <sup>also</sup> with the limits in 40 CFR Part 61 for dose 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 not to exceed <sup>0.1 mSv</sup> (10 mrem) yr. ~~The impact of this action would be the continued inefficient use of licensee, NRC, EPA, and State resources, loss 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.~~ ✓

*see words  
from earlier,  
similar section.*

Alternative 2 - Rulemaking

*Is this not Alternative 3  
in Attachment 2?* ✓

Under alternative 2, the NRC would amend the current regulations in 10 CFR Part 20 to include a section on constraints for dose to members of the public. A codified or otherwise enforceable dose value is an EPA condition for rescission of Subpart I. The impact of this alternative is that licensees would be subject to only one regulatory program for the control of dose to members of the public and effluent release. Licensees would therefore need only calculate dose to members of the public against a single set of criteria which are risk based and use a common dosimetry. Failure to report a dose in excess of the constraint level or failure to take prompt corrective actions would result in a notice of violation. Licensees and the public 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.

Alternative 3 - License Amendments

*Should these be the  
same alternative  
as in Attachment 2?* ✓

Under alternative 3, the NRC would examine each license issued under 10 CFR Parts 30, 40, 50 excluding power reactors, 60, 72, those licensed for possession of sealed sources only, to determine if a probability existed that the licensee would have air emissions greater than a specified value (e.g., 10 percent of the constraint value, or a dose of 1 mrem/yr) and imposing individual conditions on each such licensee to constrain dose to members of the public from air emissions to less than 10 mrem/yr. The impact on licensees from this alternative would be similar to that of alternative 2. The impact on NRC would be significant as each of several thousand licenses

would have to be reviewed each year in conjunction with renewal or amendments as well as new applications to ensure that any licensee who might exceed the constraint would be required to report as a condition of the individual license.

#### IV. ENVIRONMENTAL IMPACTS OF THE ACTION

The Commission has examined the current regulatory framework for controlling dose 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 Part 51 "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Function."

VI. PERSONS CONTACTED:

Tim Backstrom, EPA, OGC

Gail Benano, EPA

The draft rule language has been discussed with the Agreement States. A draft of the package was provided to them on April 18, 1995.



IMNS

NONE

CC 6/30/96

ATTACHMENT 6  
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

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

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Office of Congressional Affairs

Enclosure:  
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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:

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Sincerely,

Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure:  
Federal Register Notice

cc: Representative Frank Pallone

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

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Office of Congressional Affairs

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DATE	5/8/96	5/8/96	5/18/96	5/18/96	1/96

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