AF 31-2.35
PDR

From: Phyllis Sobel

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Date: 11/7/96

Subject: EPA's Federal Register Notice on Subpart I rescission

Attached is the EPA draft Federal Register Notice rescinding Subpart I for NRC and Agreement State licensees other than power reactors. Gale Bonnano of EPA would like a quick NRC review so the Administrator can sign the Federal Register Notice by December 31. Chip and I promised her responses by COB, Tuesday, November 12. We plan to meet at 9 am on November 12 in room O-6B13 to discuss NRC's comments.

Gale would also like the name of an NRC contact she can give OMB because she expects OMB will call us about this document. If you have not already done so, please give me your suggestion for a contact.

Thanks.

Phyllis

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61 SUBPART I

[FRL -]

National Emissions Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities not Covered by Subpart H

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: EPA is rescinding 40 CFR part 61, subpart I (subpart I) as it applies to facilities other than commercial nuclear power reactors licensed by the Nuclear Regulatory Commission (NRC) or NRC Agreement States. Subpart I is a National Emission Standard for Hazardous Air Pollutants (NESHAPs) which was published on December 15, 1989 and which limits radionuclide emissions to the ambient air from NRC-licensed facilities. As required by section 112(d)(9) of the Clean Air Act as amended in 1990, EPA has determined that the NRC regulatory program for licensed facilities other than commercial nuclear power reactors protects public health with an ample margin of safety, the same level of protection that would be afforded by continued implementation of subpart I.

EFFECTIVE DATE: This rule is effective [date of publication]. Under section 307(b)(1) of the Clean Air Act, judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of

Columbia Circuit no later than [insert date 60 days after publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Gale Bonanno, Center for Federal Guidance and Air Standards, Radiation Protection Division, 6602J, Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460 (202) 233-9219, or Eleanor Thornton, at the same address (202) 233-9773.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities affected by this action include facilities, other than commercial nuclear power generators, licensed by the Nuclear Regulatory Commission (NRC) or an NRC Agreement State. Subpart I continues to apply to federal facilities not ~~owned or operated~~ licensed by NRC the Department of Energy (DOE) ("non-DOE" federal facilities) are covered by Subpart H.

Affected categories and entities include:

Category	Examples of Facilities
NRC-Licensees	Uranium fuel cycle (those engaged in the conversion of uranium ore to produce electric power, e.g, uranium mills, fuel fabrication plants)
	Facilities licensed to use or possess nuclear materials such as hospitals, medical research facilities, radiopharmaceutical manufacturers, laboratories, etc.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other

types of facilities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in section 61.100 of today's rule which amends part 61 of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular facility, consult the persons listed in the preceding "FOR FURTHER INFORMATION CONTACT" section.

Docket

Docket A-92-50 (cross-referenced with Dockets A-79-11 & A-92-31) contains the rulemaking record. The docket is available for public inspection between the hours of 8 A.M. and 5:30 P.M., Monday through Friday, in room M1500 of Waterside Mall, 401 M Street, SW, Washington, DC 20460. A reasonable fee may be charged for copying. The fax number is 202-260-4400.

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A. Regulatory History

On October 31, 1989, EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) under Section 112 of the Clean Air Act to control radionuclide emissions to the ambient air from a number of different source categories. 54 FR 51654 (December 15, 1989). Subpart I of 40 CFR part 61 covers two groups of facilities: (1) Facilities licensed and regulated by the Nuclear Regulatory Commission (NRC) and its individual Agreement States ("NRC licensed facilities"), and (2) federal facilities which are not licensed by the NRC and are not owned or operated by the Department of Energy ("non-DOE federal facilities"). The first group is diverse, and includes facilities which have received a license to use or possess nuclear materials such as hospitals, medical research facilities, radiopharmaceutical manufacturers, laboratories and industrial facilities, as well as facilities involved in the uranium fuel cycle (the conversion of uranium ore to electric power) such as uranium mills and fuel fabrication plants. EPA estimates there are over 22,000 such NRC licensed facilities in the United States.

The present rulemaking concerns all NRC licensed facilities other than commercial nuclear power reactors, which are the subject of a separate rulemaking (60 FR 46206, Sept. 5, 1995). Non-DOE federal facilities are not affected in any way by the present rulemaking.

Same problem

Subpart I limits radionuclide emissions from NRC licensed facilities to the ambient air to that amount which would cause any member of the public to receive in any year an effective dose equivalent (ede) no greater than 10 millirem (mrem), of which no more than 3 mrem ede may be from radioiodine. These limits were established pursuant to an EPA policy for section 112 pollutants first announced in the benzene NESHAP (54 FR 38044, September 14, 1989), utilizing the two-step process outlined in the vinyl chloride decision. Natural Resources Defense Council v. EPA, 824 F.2d 1146, (D.C. Cir. 1987)(Vinyl Chloride).

When subpart I was originally promulgated in December 1989, EPA simultaneously granted reconsideration of the subpart based on information received late in the rulemaking on the subject of duplicative regulation by NRC and EPA of NRC licensed facilities and on the potential negative effects of the standard on nuclear medicine. EPA established a comment period to receive further information on these subjects, and granted a 90-day stay of subpart I as permitted by Clean Air Act (CAA) section 307(d)(7)(B), 42 U.S.C. 7607 (d) (7)(B). That stay expired on March 15, 1990, and was subsequently extended on several occasions. (See 55 FR 10455, March 21, 1990; 55 FR 29205, July 18, 1990; and 55 FR 38057, September 17, 1990).

EPA later stayed subpart I for NRC and Agreement State licensees other than nuclear power reactors while EPA was collecting the additional information necessary to make a

determination under section 112(d)(9) of the 1990 CAA Amendments. See 56 FR 18735 (April 24, 1991), and 40 CFR 61.109(a). However, on September 25, 1992, the ~~D.C.~~ U.S. for D.C. Circuit Court of Appeals issued a decision that EPA had exceeded its authority by staying subpart I while the Agency was collecting information needed to make a determination under section 112(d)(9). Natural Resources Defense Council v. Reilly, 976 F.2d 36 (D.C. Cir. 1992)(NRDC). The stay for licensees other than nuclear power reactors expired before the NRDC decision could be implemented on November 15, 1992, and subpart I took effect for these licensees on November 16, 1992. EPA subsequently issued a notice confirming the effectiveness of subpart I for licensees other than nuclear power reactors. See 59 FR 4228 (January 28, 1994).

B. Clean Air Act Amendments of 1990

In 1990, Congress enacted legislation comprehensively amending the CAA, which included a section addressing the issue of regulatory duplication between EPA and NRC. CAA section 112(d)(9) provides that, "[N]o 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 [section 112] 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." This provision enables EPA to eliminate duplication of effort between EPA and NRC in instances where EPA can determine that the NRC program provides protection of public health equivalent to that required by the CAA.

C. Reconsideration of Subpart I

After the adoption of section 112(d)(9), EPA reviewed the information available to the Agency, including the information provided during the Agency's reconsideration of subpart I, to decide whether it could determine for particular categories of NRC licensees that the NRC regulatory program protects public health with an ample margin of safety. EPA's initial analysis focused on two general issues: (1) whether the NRC regulatory program in practice results in sufficiently low doses to protect the public health with an ample margin of safety; and (2) whether the NRC program is sufficiently comprehensive and thorough and administered in a manner which will continue to protect public health in the future.

After reviewing the available information for licensees other than nuclear power reactors, EPA concluded that it lacked sufficient information concerning actual emissions from these facilities to make the substantive determination contemplated by section 112(d)(9). Accordingly, EPA undertook an extensive study in order to determine the doses resulting from radionuclide emissions at facilities other than nuclear power reactors. As

discussed in detail below, EPA surveyed a randomly selected subset of all licensed facilities, as well as a group of "targeted" facilities chosen because of an expectation that they would have higher emissions. See Draft Background Information Document, "NESHAPs Rulemaking on Nuclear Regulatory Commission and Agreement State Licensees Other Than Nuclear Power Reactors" EPA430-R-92-011 (November 1992), Docket Entry A-92-50, II-B-1.

After evaluating the results of its study, reviewing the then current NRC regulatory program, and considering the likely effect of revisions of the NRC program which were pending at that time and of additional measures which NRC had agreed to adopt pursuant to a Memorandum of Understanding (MOU) with EPA, EPA proposed to rescind subpart I for NRC and Agreement State licensees other than nuclear power reactors on December 1, 1992. See 57 FR 56877 (December 1, 1992).

II. Rationale for Final Rule to Rescind 40 CFR Part 61 Subpart I for NRC and Agreement State Licensees

A. *1992 Proposal to Rescind Subpart I for Licensees Other Than Nuclear Power Reactors*

The 1992 proposal to rescind subpart I for NRC licensees other than nuclear power reactors was based on EPA's extensive study of those licensees and on commitments made by NRC in an MOU with EPA. See 57 FR 56877 (December 1, 1992).

1. EPA Study of Emissions From NRC Licensed Facilities

In order to determine whether NRC licensees other than nuclear power reactors were in compliance with those emission limits deemed necessary by EPA to protect public health, EPA undertook a comprehensive study to determine the doses that resulted from emissions from these facilities. See Draft Background Information Document, "NESHAPs Rulemaking on Nuclear Regulatory Commission and Agreement State Licensees Other Than Nuclear Power Reactors" EPA430-R-92-011 (November 1992), Docket Entry A-92-50, II-B-1. A major component of this study was a survey and analysis of a randomly selected subset of the approximately 6,000 NRC and Agreement State licensees. These consist of hospitals, radiopharmaceutical manufacturers and distributors, and laboratories for which the doses and other emissions data were not well characterized. In order to gather the necessary information, EPA sent a letter under the authority of section 114 of the CAA to the selected facilities requiring them to submit specific information concerning their emissions and proximity to the exposed population. Doses were then determined by EPA using the COMPLY computer program which was specified in subpart I for determining compliance with the standard. EPA also investigated a group of "targeted" facilities selected for their potential to cause high doses.

EPA obtained Office of Management and Budget approval to send questionnaires to as many as 670 of the approximately 6,000

facilities, requesting release rates and the other necessary parameters. Since facilities handling only sealed sources do not present the potential for airborne emissions, they had been exempted from the NESHAP and were also excluded from analysis in the EPA study. Because EPA could not accurately determine in advance whether a given NRC or Agreement State licensee handled only sealed sources and would therefore be excluded from the analysis, the Agency over sampled in order to obtain the required number of responses.

A sample of at least 300 facilities was needed in order to be 95 percent confident that EPA could establish a dose level below which the doses caused by emissions from 99 percent of the facilities lie. Over 600 letters were sent to a random subset of NRC or Agreement State licensees. Responses were submitted by all but three facilities and 367 of the responses were determined to be from facilities using unsealed sources.

The COMPLY computer program was used to estimate doses to the most exposed individuals located near the facilities. The National Oceanic and Atmospheric Administration's data base was used for meteorological data for the sites. Many facilities were contacted to obtain clarification or site-specific information. The dose to the nearest resident to each facility was calculated from the facility-specific information taken from the questionnaire and using meteorological data from the closest weather station.

A second component of the study was the targeted facilities, which fell into three sub-groups: (a) facilities determined to have potential for large emissions and which were not fully characterized in previous evaluations (examples included research reactors, rare earth producers, waste incinerators, low level waste facilities, and large university hospitals); (b) facilities with potential for large emissions which were more adequately characterized in previous assessments (these included fuel cycle facilities such as uranium mills, fuel fabrication plants, UF6 conversion plants); (c) atypical activities for which no formal evaluations had been made (these included activities such as depleted uranium weapons testing).

For facilities in sub-group (a), the data needed to characterize the emissions and doses were obtained from existing NRC docket information, supplemented as necessary with requests for missing data under authority of CAA section 114. The results of the previous assessments for facilities in sub-group (b) were summarized and updated to include more recent information. For the third sub-group, EPA reviewed the activity in question to ascertain the potential for significant airborne emissions, and evaluated the doses for these activities found to involve potentially significant emissions.

After evaluating both the randomly surveyed 367 facilities and the specifically targeted facilities using the COMPLY computer program, EPA determined that the highest estimated dose

received by any member of the public from airborne emissions of radionuclides from any facility was 8.0 mrem/yr ede. Thus, none of the facilities evaluated appeared to cause a dose exceeding the levels established by the Administrator in the radionuclides NESHAPs. The median dose for the population is 0.00069 mrem/yr. When the results of the survey were statistically extrapolated to the entire population of NRC or Agreement State licensees, EPA concluded that emissions from virtually all of the facilities were expected to be below the limits established by EPA. After evaluating the results of the study, EPA concluded that current emissions by NRC and Agreement State licensees other than nuclear power reactors result in doses less than the level found by EPA to provide an ample margin of safety to protect the public health.

2. Memorandum of Understanding (MOU) Between EPA and NRC

In an MOU executed on September 4, 1992, NRC committed to take several actions to implement "As Low As Reasonably Achievable" (ALARA) requirements for NRC licensees other than nuclear power reactors. This MOU was published on December 22, 1992, at 57 FR 60778.

Although the NRC regulatory program included mandatory dose limits that were higher than those established by subpart I, EPA's study demonstrated that the actual operation of the existing NRC program had resulted in lower doses to the public than those which would be allowed under subpart I. The steps

established by the MOU reflected an expectation by EPA that new mandatory ALARA requirements would operate to constrain future increases in radionuclide emissions by NRC licensees which might otherwise be permissible under the NRC program.

Under the provisions of the MOU, NRC agreed to develop and issue a regulatory guide on the design and implementation of a radiation protection program to ensure that doses resulting from effluents from licensed facilities would remain ALARA. NRC agreed that the guide would describe the types of administrative programs and objectives which would be considered acceptable in satisfying the requirements of 10 CFR 20.1101(b), and establish a specific design goal of 10 mrem/yr ede to the maximally exposed individual for radionuclide air emissions from affected NRC and Agreement State licensees.

B. Events Subsequent to the 1992 Proposal

1. Changes to NRC Regulatory Program After the 1992 Proposal

After EPA published its 1992 proposal to rescind subpart I, major revisions to NRC's regulations at 10 CFR Part 20 became effective. NRC's revised rule (effective January 1994) implements 1987 Presidential guidance on occupational radiation protection and the recommendations of scientific organizations to establish risk-based limits and a system of dose limitation in accordance with the guidance published by the International Commission on Radiation Protection (ICRP). In adopting the risk-based methodology, the NRC reduced the allowable dose limit

for members of the public from 500 mrem/yr ede to 100 mrem/yr ede from all pathways. Of the 100 mrem/yr ede, NRC allows only 50 mrem/yr ede by the air pathway, according to their Derived Air Concentration tables, which is then subject to further reduction under the ALARA provisions.

Another significant revision of Part 20 codified the ALARA principle, which previously was only general guidance for NRC licensees other than nuclear power reactors. All licensees must now conduct operations in a manner that keeps doses to both workers and members of the public ALARA. This is defined to mean:

> making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

10 CFR 20.1003. 56 FR 23360, 23392 (May 21, 1991).

2. EPA Concerns Regarding Basis for Required Statutory Finding Under Section 112(d)(9)

Based on the record compiled as part of its proposal to rescind subpart I for NRC licensees other than nuclear power reactors, EPA was able to conclude that the vast majority of NRC and Agreement State licensees were in compliance with the 10 mrem/yr standard established by subpart I. However, after

reviewing the language of the final Regulatory Guide issued by NRC pursuant to the September 4, 1992 MOU, EPA concluded that there was no element in the NRC regulatory program which expressly required or assured that licensees other than nuclear power reactors would maintain emissions of radionuclides below EPA's 10 mrem/yr standard. See NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993, Docket Entry A-92-50, II-F-4. Thus, it was not possible for the Agency to determine that radionuclide emissions would consistently and predictably remain below the EPA standard in the future if EPA were to proceed with rescission, or that NRC or the individual Agreement States would be in a position to require a particular licensee who did exceed 10 mrem/yr to reduce radionuclide emissions.

Another concern regarding the adequacy of the NRC program to support rescission of subpart I for licensees other than nuclear power reactors arose as part of an investigation by the General Accounting Office (GAO) of NRC's administration of its Agreement State program. Licenses for facilities other than nuclear power reactors are often administered by individual Agreement States rather than by NRC. In a report entitled "Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials," the GAO found that "NRC lacks criteria and data to evaluate the effectiveness of its two materials programs [agreement and non-agreement state]," and that "For agreement-

state programs, NRC does not have specific criteria or procedures to determine when to suspend or revoke an inadequate or incompatible program." GAO/RCED-93-90 Nuclear Materials Regulation at 3 (April 1993). In subsequent Congressional testimony concerning the GAO findings, the NRC Commissioners acknowledged that NRC criteria and procedures should be improved, and stated that NRC was developing new criteria to assess the adequacy and compatibility of individual Agreement State programs, and new procedures which would govern suspension and termination of Agreement State programs.

As contemplated by CAA section 112(d)(9), EPA and NRC entered into consultations intended to resolve these concerns. The ALARA program, which requires NRC licensees to reduce emissions to the extent feasible below the mandatory ceiling in 10 CFR Part 20, was the principal focus of subsequent discussions between EPA and NRC. In these discussions, EPA and NRC discussed various NRC proposals for a rule which would "constrain" emissions from NRC licensees other than nuclear power reactors, either by establishing a rebuttable presumption that emissions causing a dose exceeding 10 mrem/yr are not ALARA, or by expressly finding that ALARA requires licensees to maintain emissions at or below the 10 mrem/yr level. During the course of these discussions, a new concern also emerged as to whether the NRC policies on Agreement States which were under development would enable NRC to require that an ALARA "constraint level" be a

mandatory element of compatibility. See letter from Mary D. Nichols, EPA Assistant Administrator for Air and Radiation, to NRC Chairman Ivan Selin, July 6, 1994, Docket Entry A-92-50, IV-C-4.

On July 22, 1994, NRC proposed a "constraint level" rule which would have required each licensee to develop an ALARA program to maintain or achieve emissions resulting in a dose at or below 10 mrem/yr or, in the alternative, to "justify" a conclusion that emissions resulting in a dose exceeding 10 mrem/yr are ALARA. See letter from NRC Chairman Ivan Selin to EPA Administrator Carol M. Browner, July 22, 1994, Docket Entry A92-50, IV-D-74. That correspondence also noted that new procedures to assure the adequacy and compatibility of Agreement States were under development, and indicated that NRC would also propose to require Agreement States to adopt the proposed "constraint level" rule as a matter of compatibility.

After reviewing the "constraint level" rule proposed by NRC on July 22, 1994, EPA concluded that the proposed provision permitting licensees to "justify" emissions in excess of 10 mrem/yr left uncertainty as to whether NRC or an individual Agreement State might accept or countenance as ALARA emissions resulting in a dose exceeding 10 mrem/year. As a consequence, EPA was concerned that it would still not be able to determine that future radionuclide emissions from affected licensees would be consistently and predictably at levels resulting in a dose

below 10 mrem/yr, or that NRC or an individual Agreement State would be able to compel a licensee to reduce emissions if the 10 mrem/yr level were exceeded. EPA then advised NRC that EPA did not consider it prudent to proceed with rescission of subpart I for NRC licensees other than nuclear power reactors based on a record which might not adequately support the legal determination required by section 112(d)(9). Docket entry A-92-50, IV-C-4.

3. NRC Actions Responsive to EPA Concerns

On December 21, 1994, after further considering the concerns expressed by EPA, NRC proposed to EPA a "constraint" rule construing ALARA as requiring each licensee to limit emissions to a level resulting in a dose no greater than 10 mrem/yr. See letter from NRC Chairman Ivan Selin to EPA Administrator Carol M. Browner, December 21, 1994, Docket Entry A-92-50, IV-D-26. Under this proposal, exceeding the ALARA constraint level would not itself be a violation, but any licensee exceeding the 10 mrem/yr constraint would be required to report the exceedance and to take corrective measures to prevent a recurrence. On March 14, 1995, NRC confirmed that it intended to make the proposed constraint rule a matter of Division Level 2 compatibility, which requires each Agreement State to incorporate in its program provisions at least as stringent as those established by the NRC rule. See letter from Robert M. Bernero, Director of the NRC Office Of Nuclear Material Safety and Safeguards, to Mary D. Nichols, EPA

Assistant Administrator for Air and Radiation, March 14, 1995, Docket Entry A-92-50, IV-D-27.

NRC has also taken steps which address concerns regarding the adequacy of criteria and procedures for the Agreement State program. NRC published a draft policy statement concerning adequacy and compatibility criteria, 59 FR 37269 (July 21, 1994), and a draft policy statement setting forth procedures which permit suspension or termination of individual Agreement State programs. 59 FR 40059 (August 5, 1994). In the March 14, 1995 letter, NRC assured EPA that the final policy statement on compatibility criteria would be consistent with the NRC proposal to make the ALARA "constraint level" rule a matter of Division Level 2 compatibility.

After reviewing the proposed rule described in the December 21, 1994 letter and the additional assurances provided in the March 14, 1995 letter, EPA advised NRC that it had concluded that adoption by NRC of the proposals and policies set forth in these letters should be sufficient to resolve the Agency's stated concerns regarding its ability to make the finding required to support rescission under CAA Section 112(d)(9). See letter from EPA Administrator Carol M. Browner to NRC Chairman Ivan Selin, March 31, 1995, Docket Entry A-92-50, IV-C-5. In that correspondence, EPA also stated its intent to publish a notice requesting supplementary comment concerning the proposed rule to rescind subpart I for NRC licensees other than nuclear power

reactors in conjunction with the publication by NRC of its proposed ALARA constraint rule.

4. EPA's Notice Reopening the Comment Period

EPA published a notice reopening the comment period for the rulemaking to rescind subpart I. 60 FR 50161,(September 28, 1995). The Notice reaffirmed EPA's proposal to rescind subpart I, described the expected proposed revisions to the NRC program which would support EPA's rescission, and invited additional comment on the sufficiency of the revisions to the NRC program to support the finding required by section 112(d)(9). The Agency extended the period for submitting comments in response to the Notice until February 22, 1996, to allow the public time to review NRC's proposed constraint rule prior to submitting comments to EPA. NRC published the proposed constraint rule on December 13, 1995. 60 FR 63984.

5. NRC Constraint Level for Air Emissions of Radionuclides and Agreement State Policies and Procedures

On _____,1996, the NRC ~~Commissioners~~ adopted a final "constraint" rule modifying the NRC radiation protection program codified at 10 CFR part 20. The final regulations adopted by NRC establish a constraint of 10 mrem/yr total effective dose equivalent(TEDE)[1] for dose to members of the public from air emissions of radionuclides from NRC licensed

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[1] NRC expresses dose in total effective dose equivalent (TEDE), while subpart I expresses dose in effective dose equivalent (EDE). These two terms are equivalent.

facilities other than commercial nuclear power reactors. 10 CFR section 20.1101(d). A dose constraint is defined as "a value above which specified licensee actions are required." 10 CFR section 20.1003, as amended. Thus, the final rule codifies a numerical value, 10 mrem/yr TEDE, for NRC's application of its ALARA principles contained in 10 CFR part 20 for radioactive air emissions from NRC licensees other than commercial nuclear power reactors. In the event that the 10 mrem/yr constraint is exceeded, the exceedance must be reported to NRC by the licensee within 30 days and the licensee must also provide a description of the circumstances of the exceedance and describe the corrective steps that have been or will be taken to ensure that the exceedance will not reoccur. **Cite?** NRC regulations provide for licensees to propose corrective steps and NRC will approve such actions (e.g., installation of filters, installation of a new pump, etc.) if appropriate to effectuate a decrease in dose. **Cite?** See Memorandum to Docket A92-50 from Gale Bonanno, Workgroup Chair, _____, 1996, Docket Entry (analyzing final "constraint" rule).

The final constraint rule has been assigned a Division Level 2 compatibility. **Cite?** Thus, the NRC Agreement States must address the constraint rule in their regulations, but they may adopt more restrictive requirements than the constraint rule.

The Commission also finalized NRC Regulatory Guide _____ (Date_____) which outlines methods for demonstrating

compliance with the constraint level and the elements of the report required to be submitted in the event the constraint level is exceeded. This Guide also expresses the Commission's belief that based on EPA's study and NRC's ongoing licensing and inspection program, the constraint level for doses to members of the public from air emissions of radionuclides as codified at section 20.1101(d) is easily achievable by all materials licensees.

In addition, the Commission recently approved, in principle, final policy statements entitled "Statement of Principles and Policy for the Agreement State Program" and "Policy Statement on Adequacy and Compatibility of Agreement State Programs". 60 FR 39463 (August 2, 1995). These documents describe the principles of the Agreement State program including the roles and responsibilities of NRC and the States in administering the program, and outline a general framework for determining which NRC program elements and requirements should be implemented by the Agreement States.

[Include: description of forthcoming letter from NRC counsel assuring us that the Agreement State problems have been resolved to NRC's satisfaction, and that NRC is now able to decide whether an Agreement State program is inadequate or incompatible and to suspend or revoke an Agreement State program when appropriate.]

III. Final Rule to Rescind 40 CFR Part 61 Subpart I for NRC and Agreement State Licensees

A. EPA Determination Under CAA Section 112(d)(9)

Section 112(d)(9) authorizes EPA to decline to regulate radionuclide emissions from NRC licensees under the CAA provided that EPA determines, by rule, and after consultation with NRC, that the regulatory scheme established by NRC protects the public health with an ample margin of safety. The legislative history of section 112(d)(9) provides clear guidance as to what is meant by "an ample margin of safety to protect the public health" and what process the Administrator should follow in making that determination in a rulemaking proceeding under section 112(d)(9). The Conference Report accompanying S. 1630 points out that the "ample margin of safety" finding under section 112(d)(9) is the same "ample margin of safety" requirement that governed the development of standards promulgated under section 112 of the CAA prior to its amendment in 1990. The conferees also made clear that the process the Administrator is expected to follow in making any such determination under section 112(d)(9) is the process "required under the decision of the U.S. Court of Appeals in NRDC v. EPA, 824 F.2d 1146 (D.C. Cir. 1987) (Vinyl Chloride)." H. Rep. No. 101-952, 10st Cong., 2d Sess. 339 (1990), reprinted in 1 A Legislative History of the Clean Air Act Amendments of 1990, at 1789 (1993) (hereinafter "Legislative History CAAA90").

From the language of section 112(d)(9), it is apparent that where EPA has already specifically determined what level of emissions must be achieved to provide an "ample margin of safety," that level is the benchmark by which EPA must evaluate the adequacy of the NRC program. EPA specifically found when it promulgated 40 CFR part 61, subpart I, that 10 mrem/yr would provide the requisite "ample margin of safety." EPA conducted a two-step "ample margin of safety" analysis when it promulgated subpart I in 1989, and EPA hereby incorporates that analysis by reference as part of its present finding.

As EPA interprets section 112(d)(9), the Agency may rescind the subpart I NESHAP as it applies to NRC licensed facilities other than commercial nuclear power reactors *if* the Agency (1) consults with NRC, (2) engages in public notice and comment rulemaking, and (3) finds that the separate NRC regulatory program provides an equivalent level of public health protection (i.e., an ample margin of safety) as would be provided by implementation of subpart I. While a rulemaking to rescind a standard applicable to NRC licensees may commence prior to incorporation of all necessary elements in the NRC regulatory program, the elements of the NRC program must be deemed adequate by EPA to fully satisfy the statutory standard at the time EPA takes final action.

Section 112(d)(9) does not require exact equivalence between the EPA and NRC programs applicable to a particular category of

licensees before EPA may decline to regulate radionuclide emissions from that category. This construction of section 112(d)(9) was expressly affirmed by the Court of Appeals in its Memorandum opinion denying the petition for review of EPA's rescission of subpart I as applied to nuclear power reactors. *Sierra Club, et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996) at 4. Section 112(d)(9) requires that EPA conclude that implementation of the NRC program as a whole will achieve substantive protection of the public health equivalent to or better than that which would be achieved by enforcement of the EPA standard. Thus, if the NRC program as a whole will assure that emissions from all affected licensees remain below the EPA standard, the NRC program may be deemed to provide an ample margin of safety, regardless of whether this results from enforcement by NRC of a single numerical standard.

Based on its study of NRC and Agreement State licensees, EPA has already determined that current emissions from such licensees cause doses which are in compliance with the 10 mrem/yr standard in subpart I. However, as EPA construes section 112(d)(9), EPA must also evaluate the ability of the NRC and Agreement State program to assure that emissions remain below the level required to provide an "ample margin of safety." Thus, in deciding whether EPA may decline to regulate a particular category or subcategory of NRC or Agreement State licensees presently regulated under subpart I, EPA construes section 112(d)(9) as

requiring that EPA determine: (1) that emissions from NRC licensees (or Agreement State licensees when authority to regulate the licensees has been delegated by NRC) in that category or subcategory will be consistently and predictably at or below a level resulting in a dose of 10 mrem/yr, and (2) that NRC (or the Agreement States) can and will require any individual licensee in that category or subcategory with emissions that cause a dose exceeding 10 mrem/yr to reduce the emissions sufficiently that the dose will not exceed 10 mrem/yr.

EPA has previously concluded that radionuclide emissions from NRC and Agreement State licensees other than nuclear power reactors are generally well below the level that would result in a dose exceeding 10 mrem/yr. EPA experience in administration of subpart I since it became effective confirms this conclusion. Out of the thousands of licensees subject to the standard, only 16 facilities reported radionuclide emissions exceeding the EPA standard for calendar year 1993 and only one facility reported emissions exceeding the EPA standard for calendar year 1994. No facilities reported exceeding the subpart 10 mrem/yr standard for calendar year 1995. **Cite 1996 Addendum to BID** Most of the reported exceedances were resolved through EPA approval of appropriate site-specific adjustments to the input parameters for COMPLY, the computer code used for calculating doses.

EPA concludes that the final adoption by NRC of the ALARA constraint rule and the satisfactory resolution by NRC of prior

deficiencies in NRC Agreement State policies and procedures resolve all remaining concerns regarding the adequacy of the NRC program to provide an "ample margin of safety" and support the requisite determination for rescission under CAA section 112(d)(9). Promulgation of the ALARA constraint rule assures that radionuclide emissions by the affected licensees will be consistently and predictably below a level which would result in a dose exceeding 10 mrem/yr, and that NRC can require an individual licensee who exceeds the 10 mrem/yr level to take corrective actions to reduce emissions. By making the ALARA constraint rule a matter of Division Level 2 compatibility, NRC has assured EPA that those licensees regulated by individual Agreement States also will be subject to the 10 mrem/yr constraint level and will be required to report and correct any exceedances of that level. Finally, the adoption by NRC of policies establishing specific criteria for adequacy and compatibility, and procedures for suspension or termination of Agreement State programs resolves the Agency's concerns regarding the ability of NRC to act if it determines that an Agreement State program is inadequate or incompatible.

EPA is confident that NRC has the capability to enforce the provisions of the constraint rule. [Include a brief description of NRC inspection and enforcement procedures. Describe expected frequency of inspections, and procedures for resolving violations detected. -- NRC to provide a couple of paragraphs]

Based on the above analysis, EPA is today determining that the NRC regulatory program for licensees other than commercial nuclear power reactors provides an ample margin of safety to protect the public health under CAA section 112(d)(9).

IV. Summary of Comments and Responses to Comments from NPR and Notice Reopening Comment Period

This section briefly describes the major comments EPA received in response to the Agency's rulemaking to rescind subpart I for NRC and Agreement State licensed facilities other than commercial nuclear power reactors. EPA received numerous written comments in response to the December 1, 1992, proposal and the September 28, 1995, notice inviting additional comments. The Agency also received comments during public hearings conducted on January 14, 1993 and February 29, 1996. Additionally, the Agency received comments on the specific issue of whether to rescind subpart I for facilities other than commercial nuclear power reactors during the comment period for other rulemakings, e.g., the proposed stays discussed above. The Agency stated at the time of those rulemakings that such comments would be addressed in the context of this rulemaking on rescission. Comments received by the Agency during the pendency of this rulemaking, together with relevant comments received in other rulemakings, are addressed in the Response to Comments Document which has been placed in the docket for this rulemaking.

A major concern expressed by commenters relates to the lack of any provision in the Atomic Energy Act (AEA) equivalent to the broad authority to file citizen suits provided by Clean Air Act section 304. Commenters asserted that the absence of a citizen suit provision applicable to the NRC regulatory program would prevent a determination by EPA that the EPA and NRC regulatory programs are equally stringent. While EPA believes that this difference in the respective enabling statutes of the two agencies could be properly considered by EPA as one factor in deciding whether or not to exercise its discretion to rescind, EPA does not believe that this difference precludes the substantive finding required by section 112(d)(9). When Congress adopted section 112(d)(9), Congress was aware that the CAA includes citizen suit authority and that the AEA has no comparable provisions. Despite this difference, Congress clearly envisioned that circumstances might be such that EPA would make the finding required by section 112(d)(9) of the CAA. EPA notes that the same argument concerning the absence of citizen suit authority was recently rejected by the District of Columbia Court of Appeals in a decision upholding the Agency's rescission of subpart I for nuclear power reactors. *Sierra Club,et al., v. Environmental Protection Agency*, No.95-1562 (D.C. Cir. October 22, 1996).

In making today's ample margin of safety determination under section 112(d)(9), the Agency considered whether future emissions

from licensees will be consistently and predictably at or below a level resulting in a dose of 10 mrem/yr and whether, in the event a licensee exceeds that level, NRC or an Agreement State can and will require the licensee to reduce emissions. In the event that the NRC regulatory program does not assure that licensee emissions result in doses at or below 10 mrem/year, any interested person may petition EPA to initiate a rulemaking to reinstate subpart I. Furthermore, EPA can act on its own initiative to reconsider the rescission if new information indicates that the public health is not protected with an ample margin of safety.

Some commenters were also concerned about the regulatory authority of the states and how actions such as this rescission, taken pursuant to section 112(d)(9), might affect the states' authority under the CAA to establish radionuclide air emission standards. This issue was addressed in a July 2, 1993, letter from Robert M. Bernero, Director of the Office of Nuclear Material Safety and Safeguards to Margo Oge, Director of EPA's Office of Radiation and Indoor Air. Docket Entry A-92-50, IV-D-21. Mr. Bernero stated that the NRC Office of General Counsel has examined the CAA, and relevant portions of the legislative history, "and has concluded that the passage of the 1990 CAA amendments had no effect on the preexisting power of the States under section 116 to establish radionuclide air emission standards, regardless of any action EPA might take pursuant to

section 112(d)(9)." EPA concurs with NRC's construction. NRC has also stated in the preamble to the final constraint rule that "[T]he Commission believes that [CAA 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." **Cite** In addition, this issue was extensively discussed by the Senate during floor debate for the 1990 CAA amendments. Passage of the "Simpson Amendment" (section 112(d)(9)) failed on the first vote due to concerns that the amendment somehow affected states' rights and the question of state authority had to be addressed before the amendment ultimately succeeded in passage. As explained by Senator Burdick, "Section 112(d)(9) provides for State authority for radionuclide emissions in the same manner and to the same extent as does existing section 116" of the CAA, which contains the provision that "nothing in this Act shall preclude or deny the right of any state or political subdivision thereof to adopt or enforce any standard or limitation respecting emissions of air pollutants ***" April 3, 1990 Congressional Record S3798.

Some commenters object to the EPA rescission based on the argument that the NRC constraint rule is not an enforceable standard. As discussed above, section 112(d)(9) does not require exact equivalence between the EPA and NRC regulatory programs before EPA may decline to regulate radionuclide emissions from a

particular category or subcategory of NRC licensees. Rather, section 112(d)(9) requires EPA to determine that the NRC regulatory program as a whole will protect public health to the same or greater level as would implementation of subpart I. The study conducted by EPA as described above, the Agency's experience in implementing subpart I since it became effective in 1992, and NRC's recent adoption of the constraint rule and Agreement State policies provide ample basis for EPA to conclude that public health will be protected to the same level as would be achieved through continued implementation of subpart I. Although the NRC constraint level is not like the EPA standard in subpart I, in that exceeding the constraint is not itself an actionable violation, the constraint level is a value above which licensees must take actions to reduce emissions. Thus, EPA may conclude that future doses to members of the public caused by emissions of radionuclides from this category of facilities will be predictably and consistently at or below 10 mrem/yr and that NRC can and will take action in the event a facility exceeds the 10 mrem/yr level.

Commenters also expressed concern that the constraint rule does not limit doses from radioiodine to the 3 mrem/yr level of subpart I. Doses resulting from emissions of radioiodines were specifically considered as part of the EPA study described in detail above. The study demonstrated that no facility surveyed emitted a level of radioiodines causing a dose above 1 mrem/yr,

and extrapolation of the survey data indicated that no licensed facility was expected to have emissions exceeding the EPA standard. Based on all of the information now available concerning the activities of NRC and Agreement State licensees, EPA believes that it is very unlikely that any licensee who is in compliance with the ALARA constraint level for all radionuclides of 10 mrem/yr will have radioiodine emissions exceeding the present EPA standard. Accordingly, EPA does not consider the absence of a separate limit for radioiodines in the NRC program to be a factor which will prevent the NRC program from providing an ample margin of safety.

Some commenters expressed an additional concern regarding the adequacy of the constraint rule based on the fact that Agreement States have three years in which to adopt the constraint rule after it has been finally adopted by NRC. The commenters are apparently concerned that there will be up to a three year gap in regulatory coverage in some individual Agreement States before a state version of the constraint rule can be adopted. EPA understands this hypothetical concern, but believes that it is misplaced for the following reason. The general ALARA requirement is already legally enforceable in every Agreement State. Whatever the opinion of any individual Agreement State in the past as to what ALARA requires an individual licensee to do, the constraint rule constitutes an authoritative conclusion by NRC that ALARA consistently requires

that each licensee at least achieve emissions no greater than 10 mrem/yr. In light of the expert determination by NRC that licensees can readily achieve levels less than 10 mrem/yr, it would be difficult if not impossible for individual Agreement States to properly construe existing ALARA requirements less stringently. While EPA does not expect any individual Agreement State to accept emissions exceeding 10 mrem/year as ALARA, even before adoption of that State's own constraint level, were this to occur EPA would initiate consultations with NRC concerning the adequacy of that State's program and consider taking action to reimpose an EPA standard if the problem were not promptly corrected. EPA also notes that existing radionuclide standards adopted under State authority are not affected by today's rescission.

The Agency also received several comments on the differences in compliance calculation methodologies between NRC and EPA. The computer code used to calculate compliance with Subpart I, COMPLY, considers inhalation, immersion, ingestion, and exposure to contaminated ground. Commenters question how the NRC constraint level, which only considers inhalation and immersion, could provide an ample margin of safety to protect the public health. As explained above, EPA does not believe that section 112(d)(9) requires that every program element in the NRC program be exactly equivalent to the corresponding element in the EPA program. Such a construction would frustrate the evident

Congressional intent to relieve licensees of duplicative regulation. Rather, section 112(d)(9) requires only that EPA conclude that the regulatory programs as a whole will provide the same level of protection of public health. While there are differences in the calculation methodologies used by EPA and NRC, neither of these methodologies is consistently more conservative than the other, and EPA does not expect the differences in the manner in which doses are calculated to lead to significant differences in the resultant level of protection of public health. While 16 facilities reported exceeding the subpart I standard for calendar year 1993, that number decreased significantly with no facilities reporting exceedances for calendar year 1995.

Another commenter was concerned that subpart I controls emissions of NARM [Naturally Occurring and Accelerator Produced Radioactive Materials] that are not subject to NRC licensing. EPA recognizes that emissions of NARM by NRC licensees are not formally subject to NRC licensure. However, although subpart I is nominally applicable to emissions of both licensed materials and NARM, EPA did not adopt subpart I in the first place based on any concern that emissions of unlicensed radionuclide materials by NRC licensees would present any hazard to public health. Moreover, whatever the subject of NRC licenses, the procedures applied to licensees by NRC and the Agreement States do not in practice distinguish NARM from licensed materials. In the

preamble to 10 CFR 20, NRC indicated its intention to restrict emissions from NARM although the AEA may not provide the legal basis. Moreover, in a letter to EPA, NRC stated that such emissions already are controlled and will continue to be controlled to levels which protect the public with an ample margin of safety. See Docket Entry A92-50, IV-D-21. NRC explained that "At NRC-licensed facilities, as a practical matter, licensees will control NARM emissions as if they were byproduct material emissions." Id. at p. 2.

V. Judicial Review

Any petition for judicial review of the final rule must be filed in the United States Court of Appeals for the District of Columbia on or before [insert date which is 60 days after publication in the FEDERAL REGISTER]. Only an objection to this rule which was raised with reasonable specificity during the period for public comment (including public hearings) may be raised as part of any petition for judicial review.

VI. Miscellaneous

A. Paperwork Reduction Act

There are no information collection requirements in this final rule.

B. Executive Order 12866

Under Executive Order 12866, (58 FR 57735, October 4, 1993) the Agency must determine whether this regulation, if promulgated, is "significant" and therefore subject to OMB review

and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising our of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This action is not a significant regulatory action as that term is defined in Executive Order 12866, since it will not result in an annual effect on the economy of $100 million or another adverse economic impact; it does not create a serious inconsistency or interfere with another agency's action; it does not materially alter the budgetary impacts of entitlements, grants, user fees, etc; and it does not raise novel legal or policy issues. Thus, EPA has determined that rescinding subpart I as it applies to facilities licensed by the NRC or NRC

Agreement States which are not engaged in the generation of commercial nuclear power is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

C. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not "major" as defined by 5 U.S.C. 804(2) because it will not result in an annual effect on the economy of $100 million or more; there is no major increase in costs or prices to consumers, industries, governments or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation and United States firms' ability to compete with foreign counterparts.

D. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant impact on a substantial number of small entities. Today's final action is deregulatory; effectively reducing the regulatory burden on NRC licensees other than commercial nuclear

power reactors by rescinding the applicable regulatory requirements.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act") requires that the Agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year. Section 203 requires the Agency to establish a plan for obtaining input from and informing, educating, and advising any small governments that may be significantly or uniquely affected by the rule.

Under section 205 of the Unfunded Mandates Act, the Agency must identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a budgetary impact statement must be prepared. The Agency must select from those alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, unless the Agency explains why this alternative is not selected or the selection of this alternative is inconsistent with law.

The Agency has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative because this final rule is estimated to result in expenditures by State,

local, and tribal governments or the private sector of less than $100 million in any one year. Because small governments will not be significantly or uniquely affected by this rule, the Agency is not required to develop a plan with regard to small governments. As discussed in the preamble, the final rule has the effect of reducing overall regulatory burdens on NRC licensed facilities other than commercial nuclear power reactors.

List of Subjects in 40 CFR Part 61

Environmental protection, Air pollution control, Benzene, Hazardous substances, Radionuclides, Radon, Vinyl Chloride.

Dated:

_____

Carol M. Browner
Administrator

Part 61 of chapter I of title 40 of the Code of Federal Regulations is amended as follows:

Part 61-[AMENDED]

1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 7401, 7412, 7414, 7416, 7601.

2. Part 61 is amended by revising the heading for subpart I and by revising section 61.100 to read as follows:

Subpart I-National Emission Standards for Radionuclide Emissions From Federal Facilities Other than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H

Section 61.100 Applicability.

The provisions of this subpart apply to facilities owned or operated by any Federal agency other than the Department of Energy and not licensed by the Nuclear Regulatory Commission or an Agreement State, except that this subpart 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, or to low energy accelerators.

* * * * *

Section 61.101 [Amended]

3. Section 61.101 is amended by removing paragraphs (a) and (e) and redesignating paragraphs (b),(c),(d) and (f) as (a),(b),(c),(d) respectively.

Section 61.107 [Amended]

4. Section 61.107 is amended by removing paragraph (c)(1) and by redesignating paragraph (c)(2) as paragraph (c)(1).