

RULEMAKING ISSUE NOTATION VOTE

April 27, 2006

SECY-06-0097

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING TO AMEND 10 CFR PARTS 19, 20, AND 50:
OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS, AND THE
TOTAL EFFECTIVE DOSE EQUIVALENT (RIN 3150-AH40)

PURPOSE:

To obtain Commission approval to publish the enclosed proposed rule in the *Federal Register* for public comment. This rule would amend certain requirements for the reporting of annual dose to workers, amend the definition of total effective dose equivalent, amend certain container labeling requirements, and remove the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose for certain individuals.

BACKGROUND:

In SECY-02-0081, "Staff Activities Related to the NRC Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees," dated May 13, 2002, the staff described its interactions with stakeholders regarding ways to reduce unnecessary regulatory burden and requested Commission approval of its plans to reduce burden. In SRM-SECY-02-0081, dated June 25, 2002, the Commission approved the staff's proposal to reduce unnecessary regulatory burden on power reactor licensees by developing proposed rulemakings from short-term, limited-scope initiatives without preparing formal rulemaking plans.

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In developing the proposed rule, the staff prepared draft rule language. The staff requested comments from the Agreement States and Minnesota and Pennsylvania (two Agreement State candidates) on the draft rule language in All Agreement State Letter STP-04-002, dated January 9, 2004. Comments were received from the Agreement States Illinois and Washington. Subsequently, the draft rule language was published in the *Federal Register* (69 FR 8350; February 24, 2004) to solicit public comment. Eight comment letters were received from three power reactor licensees, a fuel facility licensee, an individual, an alliance of six nuclear power plants (Strategic Teaming and Resource Sharing (STARS)), and two industry organizations (the Nuclear Energy Institute and the Council on Radionuclides and Radiopharmaceuticals).

DISCUSSION:

The proposed rule considers the recommendations of the Agreement States, as well as the eight comment letters on the draft rule language. Most of comments on the draft rule language supported NRC's approach.

The staff is considering four principal changes in this proposed rule. The main features of the proposed amendments are as follows.

(1) Annual Dose Report to Workers

The first proposed amendment would revise 10 CFR 19.13. The staff is proposing a change to the notification requirement in 10 CFR 19.13(b) so that licensees would continue the current reporting for all occupationally exposed individuals except for those individuals whose annual dose does not exceed 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue in the preceding year. However, licensees would not be required to provide unsolicited annual dose reports to those individuals whose annual dose does not exceed these limits. Individuals whose annual dose does not exceed these limits would still be provided with their dose reports upon request. The staff selected the criterion of 1 mSv (100 mrem) because it corresponds to the occupational dose threshold for requiring instruction to workers under 10 CFR 19.12, "Instruction to workers." NRC Form 3, "Notice to Employees," will also need to be revised to reflect the changes to the requirements for reporting doses to individuals if this rule is promulgated. The proposed amendment would not change the current requirements for recordkeeping or reporting to the Commission.

The requirement to inform individuals of their routine annual doses, when determined through the results of individual monitoring and when such a report is provided to the Commission, appears multiple times in the regulations. The requirement appears in 10 CFR 19.13(d) through the reference to 10 CFR 20.2206. It also appears in 10 CFR 20.2205 through the reference to 10 CFR 20.2206. To improve regulatory efficiency, the proposed rule would remove the reference to 10 CFR 20.2206 in 10 CFR 19.13(d) and 10 CFR 20.2205, and the requirement to report annual dose to the individual would be consolidated into a single requirement in 10 CFR 19.13(b).

(2) Definition of Total Effective Dose Equivalent (TEDE)

The second proposed change would revise the definition of TEDE in 10 CFR 20.1003 and 50.2. The purpose of this revision is to clarify and make the definition of TEDE consistent with

Commission policy as discussed in Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," dated April 16, 2002, and subsequently clarified in RIS 2003-04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," dated February 13, 2003, and RIS 2004-01, "Method for Estimating Effective Dose Equivalent From External Radiation Sources Using Two Dosimeters," dated February 17, 2004. This policy explains that the effective dose equivalent is the primary quantity in the definition of TEDE for external exposures but that licensees are required to use the deep-dose equivalent for the whole body in place of the effective dose equivalent when measuring dose from external exposure, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC.

The TEDE is currently defined as the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The proposed change would allow licensees to substitute "effective dose equivalent" for "deep-dose equivalent" for external exposures. A corresponding change in 10 CFR 20.1201(c) would add the requirement that when the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The current requirement in 10 CFR 1201(c) that the assigned deep-dose equivalent must be for the part of the body receiving the highest exposure remains unchanged.

(3) Labeling Containers

The third proposed amendment would revise 10 CFR 20.1905 to add an exemption for containers holding licensed material (other than sealed sources that are either specifically or generally licensed) within nuclear power facilities licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," or 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," providing certain conditions are met. Some nuclear power reactor licensees have interpreted 10 CFR 20.1904, "Labeling containers," to mean that all containers in a posted area, whether they contain licensed material or not, must be labeled because every container has the potential for internal contamination. This conservative interpretation of the regulations has put an undue burden on these licensees.

Under the proposed revision, nuclear power reactor licensees would not be required to label containers holding licensed material that are located within an area posted under 10 CFR 20.1902, "Posting requirements," if the containers are conspicuously marked (to indicate that they may contain licensed material) commensurate with the radiological hazard and are accessible only to individuals who have sufficient instructions to minimize radiation exposure while handling or working in the vicinity of the containers. However, the proposed revision would require the container to be appropriately labeled under the requirements of 10 CFR 20.1904 before being removed from the posted area.

The staff has determined that the exemption to labeling requirements under 10 CFR 20.1905 is not appropriate for materials licensees because of the many types of radioactive material in containers at facilities such as hospitals and universities. Also, the staff proposes not to make this exemption applicable to non-power reactor licensees because the operations at these facilities are not routine and must be addressed on a case-by-case basis. Highly radioactive

materials are frequently taken out of these reactors and exempting these reactors from the labeling requirements could potentially present a significant health and safety concern.

This proposed rule excludes sealed sources from the revision to the exemption to labeling requirements. The staff has determined that sealed sources such as those used for calibration or check sources should not be included in the proposed revision to 10 CFR 20.1905 because these sources are usually either specifically or generally licensed and should be managed, used, and stored in accordance with the regulations. Therefore the proposed amendment would not exempt them from the labeling requirements.

(4) Cumulative Occupational Radiation Dose

The fourth proposed amendment would remove the provision in 10 CFR 20.2104 (a)(2) that requires licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20.1502. Licensees do not need records of an individual's cumulative lifetime dose to evaluate the occupational dose received during the current monitoring year. Cumulative lifetime dose is only needed when a licensee authorizes a planned special exposure for an adult worker. The proposed revision would not change the criterion under 10 CFR 20.1206, "Planned special exposures," which requires licensees to ascertain the exposure history of an individual's prior lifetime doses as required by 10 CFR 20.2104(b) before permitting the individual to participate in a planned special exposure.

AGREEMENT STATE ISSUES:

Before the draft rule language was published in the *Federal Register* (69 FR 8350; February 24, 2004), the staff solicited comments from the Agreement States and Minnesota and Pennsylvania (two Agreement State candidates at the time) in All Agreement State Letter STP-04-002, dated January 9, 2004. The agency received comments from the Agreement States Illinois and Washington.

Regarding the proposed amendment of the requirements in 10 CFR Parts 19 and 20 that licensees provide annual radiation exposure reports to individuals receiving exposures below the occupational dose limits, the State of Washington stated that the reporting threshold should be 10 percent of the occupational dose limit instead of the 1 mSv (100 mrem) (2 percent or less of the occupational dose limit) being proposed. The State of Washington commented that the proposed revision of the requirements in 10 CFR 20.1904, for the labeling of containers located within posted areas in nuclear power reactor facilities would be less confusing if the exemption was placed in Part 50. No opposing comments were received on the proposed change to clarify the definition of TEDE in 10 CFR 20.1003 and 50.2 or on the proposed revision of 10 CFR 20.2104 to eliminate the requirement that licensees attempt to obtain the records of cumulative occupational radiation doses for all individuals. The staff's response to these comments is presented in the enclosed *Federal Register* notice.

The staff has analyzed the proposed rule under the procedures in Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs." The staff has determined that the compatibility categories for the sections amended in this proposed rule would be the same as for the sections in the current regulations, except for the new exemption in paragraph (g) added to 10 CFR 20.1905. This exemption is classified as Compatibility Category NRC. A

Compatibility Category NRC designation means the Agreement State is not required to adopt the requirement for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act or provisions of 10 CFR regulations.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection. The Advisory Committee on Reactor Safeguards elected not to review the proposed rule requirements and has no objection to the staff's proposal to issue this proposed rule for public comment. The Advisory Committee on Nuclear Waste has deferred its review of the rule until public comments on the proposed rule are resolved and has no objection to the staff's proposal to issue this proposed rule for public comment. The Committee to Review Generic Requirements has deferred its review of the rule until public comments on the proposed rule are resolved and office concurrence on the final rule is obtained.

RESOURCES:

The resources needed to complete this rulemaking are approximately 0.8 FTE (0.6 FTE in FY 2006 and 0.2 FTE in FY 2007). These resources are included in the current budget. Inspection of licensee implementation will be done through the normal inspection process.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the proposed amendments to 10 CFR Parts 19, 20, and 50 (Enclosure).
2. Certify that, based on the information currently available, the proposed rule, if adopted, is not likely to have a significant economic impact on a substantial number of small entities.
3. Note—
 - a. That the proposed amendments will be published in the *Federal Register* with 75 days for public comment.
 - b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
 - c. That the *Federal Register* notice contains the finding that the proposed amendments to 10 CFR Parts 19, 20, and 50 are categorically excluded and do not require environmental review and a regulatory analysis that indicates a substantial easing of regulatory burden on licensees.

- d. That the appropriate congressional committees will be informed of this action.
- e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.
- f. That the proposed rule amends information collection requirements; therefore, an Office of Management and Budget information collection clearance package is required.

/RA/

Luis A. Reyes
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for Operations

Enclosure: As stated

- d. That the appropriate congressional committees will be informed of this action.
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Enclosure: As stated

Package Accession Number: ML060090138

Enclosure Accession Number: ML060090141

ADAMS ACCESSION NUMBER: ML060090139

*via email

**via memo

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