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RULEMAKING ISSUE
NOTATION VOTE

SECY-05-XXXX

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING TO AMEND 10 CFR PARTS 19, 20, AND 50: ~~COLLECTING AND REPORTING~~ OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS, AND ~~CLARIFYING~~ THE QUANTITY 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 ~~notification of workers~~the reporting of annual dose to workers, amend the definition of total effective dose equivalent, amend certain container labeling requirements, and remove the requirement to attempt to obtain the records of cumulative occupational radiation dose~~, and clarify the definition of total effective dose equivalent~~.

SUMMARY:

The staff has prepared a proposed rulemaking to (1) amend the provisions of 10 CFR 19.13, "Notifications and reports to individuals," to require that licensees provide ~~routine~~ annual occupational dose reports to individuals only when the annual dose exceeds 1 mSv (100 mrem) or when the individual requests the report (conforming changes would be made to 10 CFR 19.13(d) and 10 CFR 20.2205, "Reports to individuals of exceeding dose limits"); (2) ~~revise~~ amend the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions," to be consistent with current Commission policy by clarifying that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures); (3) revise 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption for the labeling of certain containers holding licensed material within posted areas in nuclear power facilities; and (4) remove the requirement in 10 CFR 20.2104, "Determination of prior occupational dose," to attempt to obtain the records of cumulative occupational radiation doses for all individuals requiring monitoring under 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose." These revisions are intended to reduce administrative and paperwork burdens on NRC and Agreement licensees without affecting the level of protection ~~of~~to either the health and safety of workers and the public or the environment.

BACKGROUND:

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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.

In developing the proposed rule ~~for these proposed requirement changes~~, 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.

~~NRC~~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 change 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 occupationally exposed individuals who annually exceed a dose of 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue. However, licensees would not be required to provide unsolicited annual dose reports to individuals when neither the TEDE nor the dose to any individual organ or tissue exceeds 1 mSv (100 mrem). Individuals 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 enacted. The proposed amendment would not change the current requirements for recordkeeping or reporting to the Commission.

~~The proposed revision would also remove~~Under the current provisions in 10 CFR 19.13(d) and 20.2205, licensees are required by the reference to ~~10 CFR 20~~10 CFR 20.2206, "Reports of individual monitoring," to provide an annual dose report to each individual for whom the report

was submitted to the Commission. In addition, the current provision in 10 CFR 19.13(b) requires licensees to advise each worker annually of the workers's dose. To improve regulatory efficiency, the proposed rule would remove the reference to 10 CFR 20.2206 in 10 CFR 19.13(d) and 20.2205 ~~so that~~, and the requirement ~~for annual reporting of doses to workers would appear only~~to report annual dose to the individual would be consolidated into a single requirement in 10 CFR 19.13(b). ~~Sections 19.13(d) and 20.2205 would only address the reporting of other than annual doses to an individual (a worker or member of the public).~~

(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 ~~current~~purpose of this revision is to clarify and make the definition ~~is not~~of TEDE consistent with ~~the intent of the regulations in 10 CFR Part 20~~Commission policy as ~~explained~~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~~RIS 2004-01, "Method for Estimating Effective Dose Equivalent From External Radiation Sources Using Two Dosimeters," dated February 17, 2004. ~~The revised definition of TEDE would be consistent with the Commission's policy~~This policy allows the use of the effective dose equivalent in place of the deep dose equivalent, for exposure situations.

The proposed ~~change~~amendment would clarify that the TEDE is ~~the sum~~defined primarily in terms of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). ~~It would also clarify~~In situations involving dose measurements, licensees may use the ~~use of effective~~deep dose equivalent ~~in place of deep dose equivalent when TEDE is calculated. If a licensee is not using a method approved by the NRC for determining effective dose equivalent with radiation measuring devices, the deep dose equivalent will be substituted~~as a surrogate for the effective dose equivalent ~~when the external dose is determined by monitoring~~. When deep-dose equivalent is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(i), the requirement in 10 CFR 20.1201(c) to determine the deep-dose equivalent for the part of the body receiving the highest exposure ~~would still apply~~will still apply. The revised definition of TEDE does not require licensees to change current procedures unless the licensee decides to use the proposed change to the definition.

(3) Labeling Containers

The third proposed change would revise 10 CFR 20.1905 to ~~create an exemption to the labeling requirements in 10 CFR 20.1904, "Labeling containers,"~~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"~~Facilities," or 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants~~.~~," ~~N~~providing certain conditions are met. Some nuclear power reactor licensees have ~~applied this requirement as though it~~interpreted 10 CFR 20.1904, "Labeling containers," to mean~~t~~ that all ~~of the~~ 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 ~~resulted in~~put an undue burden on these licensees.
Under the proposed revision, nuclear power reactor licensees ~~would~~will not be required to label containers holding licensed material that are within an area posted ~~in accordance with~~under 10 CFR 20.1902, "Posting requirements," if the containers are conspicuously marked (~~such as by color coding~~to indicate that they may contain licensed material) commensurate with the radiological hazard and accessible only to individuals who have sufficient instructions to minimize radiation exposure while handling~~,~~ or working in the vicinity of the containers. ~~T~~However, the proposed revision would ~~also~~ 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. ~~T~~Also, the staff ~~also proposes not~~does not propose 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 ~~moved around in the posted areas.~~

~~The proposed revision to 10 CFR 20.1905 would not apply to~~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 NRC 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 it would t~~. Therefore the proposed amendment would not ~~be appropriate to remove~~permit removal of their labels.

(4) Cumulative Occupational Radiation Dose

The fourth proposed ~~change~~amendment would ~~revise~~remove the ~~requirement~~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 on an individual's cumulative lifetime dose to evaluate the occupational dose received during the current monitoring year. ~~L~~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 publically available 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) 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 dose limit. No opposing comments were received on the proposed change to clarify the definition of TEDE in 10 CFR 20.1003 and 50.2. The State of Washington commented that the proposed revision of the requirements in 10 CFR 20.1904, for the labeling of containers 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 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 should not adopt the requirement. 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.

   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 an Office of Management and Budget information collection clearance package is required.

Luis A. Reyes
Executive Director
for Operations

Enclosure: As stated

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 an Office of Management and Budget information collection clearance package is required.

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Enclosure: As stated

*See previous concurrence.

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