RULEMAKING ISSUE
AFFIRMATION

September 13, 2007 SECY-07-0162

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish the enclosed final rule in the *Federal Register*. This rule amends certain requirements for the reporting of annual dose to workers, amends the definition of total effective dose equivalent (TEDE), amends certain container labeling requirements, and removes the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose for certain individuals.

SUMMARY

The staff has prepared a final rulemaking to (1) amend the provisions of 10 CFR 19.13, "Notifications and Reports to Individuals," to limit the routine reporting of annual doses to those workers whose annual dose exceeds a specific dose threshold or who request a report; (2) 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; (3) modify the provisions in 10 CFR 20.1905, "Exemptions to Labeling Requirements," for 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," that licensees attempt to obtain cumulative occupational exposure records for workers unless these individuals are being authorized to receive a planned special exposure. In addition, NRC Form 3, "Notice of Employees," NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," will be revised to be consistent with the provisions of the final rule. These revisions reduce the administrative and

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information collection burdens on NRC and Agreement State licensees without affecting the level of protection for either the health and safety of workers and the public, or for the environment.

BACKGROUND:

The U.S. Nuclear Regulatory Commission (NRC) Strategic Plan, Fiscal Year 2000–Fiscal Year 2005, included among NRC performance goals for nuclear reactor safety a performance goal for reducing unnecessary regulatory burden on stakeholders. The Strategic Plan defines unnecessary regulatory burden as requirements that go beyond what is necessary and sufficient to provide reasonable assurance that the public health and safety, environment, and common defense and security will be protected.

The NRC issued a proposed rule on September 22, 2006 (71 FR 55382), to revise 10 CFR 19.13, 10 CFR 20.1905, and 10 CFR 20.2104. The NRC also proposed to revise the definition of TEDE in 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions," to be consistent with current Commission policy. These revisions reduce the administrative and information collection burdens on NRC and Agreement State licensees without affecting the level of protection for either the health and safety of workers and the public or for the environment.

NRC had received 16 letters in response to the proposed rule. The commenters by the close of the comment period, included a number of individuals; industry organizations; and power reactor, uranium recovery, and fuel facility licensees. The majority of commenters supported this rulemaking. The enclosed Federal Register notice presents the staff's response to these comments. Resolution of the public comments resulted in no changes to the rule text.

DISCUSSION:

This final rule includes four principal amendments. These revisions are intended to reduce unnecessary regulatory burden on NRC and Agreement State licensees without affecting the level of protection for either the health and safety of workers and the public or for the environment. The following describes the main features of these amendments.

(1) Annual Dose Report to Workers

The first amendment revises 10 CFR 19.13. Under 10 CFR 19.13(b), licensees must make dose information available to workers as shown in records maintained by the licensees. The final rule revises 10 CFR 19.13(b) so that licensees must provide an annual report to each individual monitored of the dose received in that monitoring year if: (1) the individual's occupational dose exceeds 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or (2) the individual requests his or her annual dose report. However, the agency will not require licensees to provide unsolicited annual dose reports to those individuals whose annual dose does not exceed these limits. The criterion of 1 mSv (100 mrem) applies to the whole body, to any individual organ or tissue, to the lens of the eye, to the skin of the whole body, and to the skin of the extremities. If the dose to any one of these exceeds the criterion during a monitoring year, then the licensee must provide a dose report to the individual for that year. The agency will also revise NRC Form 3, "Notice to

Employees," to reflect the changes to the requirements for reporting doses to individuals. The final rule does not change the requirements in 10 CFR Part 20, "Standards for Protection Against Radiation," for monitoring, 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, "Reports of Individual Monitoring." It also appears in 10 CFR 20.2205, "Reports to Individuals of Exceeding Dose Limits," through the reference to 10 CFR 20.2206. To improve regulatory efficiency, this final rule removes the references to 10 CFR 20.2206 in 10 CFR 19.13(d) and 10 CFR 20.2205, and consolidates the requirement to report annual dose to the individual into a single requirement in 10 CFR 19.13(b).

(2) Definition of TEDE

The second amendment revises the definition of TEDE in 10 CFR 20.1003 and 10 CFR 50.2. Under the final rule, TEDE means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition of TEDE will allow licensees to substitute "effective dose equivalent" for "deep-dose equivalent" for external exposures. This revision will 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. The agency will also revise NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," to reflect the changes to the definition of TEDE.

A corresponding change in 10 CFR 20.1201© adds the requirement that when the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. This revision clarifies that licensees can still use deep-dose equivalent, in place of effective dose equivalent, for the external exposure in demonstrating compliance with the TEDE dose limit, consistent with the preexisting regulatory framework. However, the deep-dose equivalent must be for the part of the whole body receiving the highest exposure.

(3) Labeling Containers

The third amendment revises 10 CFR 20.1905 by adding 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. Licensees of these facilities need not label containers holding licensed material that are 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 instruction to minimize radiation exposure while handling or working in the vicinity of the containers. However, the final rule does require the containers to be appropriately labeled under the requirements of 10 CFR 20.1904, "Labeling Containers," before being removed from the posted area.

Under the existing regulatory framework, some nuclear power reactor licensees interpreted 10 CFR 20.1904 to mean that they had to label all containers in a posted area, whether they contained licensed material or not, because every container has the potential for internal contamination. This conservative interpretation of the current regulations put an undue burden on these licensees. Thus, the final revision to 10 CFR 20.1905 requires containers to be conspicuously marked commensurate with the radiological hazard.

(4) Cumulative Occupational Radiation Dose

The fourth amendment removes 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, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose." 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 final rule does 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 COORDINATION:

Since the beginning of the rulemaking process, the staff has coordinated closely with the Agreement States to enhance State involvement, and to improve efficiency and effectiveness of rulemaking. 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 which were addressed in the Supplementary Information to the proposed rule (71 FR 55382; September 22, 2006). Subsequently, no State comments were received in response to the proposed rule.

The staff has analyzed the final 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 rule will be the same as for the sections in the preexisting 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 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 the regulations in Title 10 of the CFR.

COMMITMENTS:

In this paper the staff commits to undertake the following actions:

(1) Revise NRC Form 3, “Notice to Employees,” to reflect the changes to the requirements for reporting doses to individuals.

(2) Revise NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to reflect the changes to the definition of TEDE.

RECOMMENDATIONS:

The staff recommends that the Commission take the following actions:

(1) Approve publication of the *Federal Register* notice of final rulemaking (Enclosure).

(2) Certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

(3) The Commission should note the following:

a. The *Federal Register* notice contains the finding that the final amendments to 10 CFR Parts 19, 20, and 50 are categorically excluded and do not require an environmental review and a regulatory analysis that indicates a substantial easing of regulatory burden on licensees.

b. The staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 (5 U.S.C. 804(2)) and has confirmed this determination with the Office of Management and Budget (OMB).

c. The staff will inform the appropriate congressional committees of this action.

d. The Office of Public Affairs will issue a press release when the staff has filed the final rulemaking with the Office of the Federal Register.

e. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501, *et seq*.) that must be submitted to OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

The Office of Nuclear Reactor Regulation has sufficient resources (1 FTE) budgeted in fiscal year (FY) 2007 and FY 2008 to complete this rulemaking.

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 (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) considered this final rule discussion and decided to decline the formal review. The Advisory Committee on Medical Use of Isotopes (ACMUI) reviewed the Regulatory Information Summary regarding redefinition of the TEDE. The Committee to Review Generic Requirements (CRGR) reviewed the final rule and elected to waive a briefing of the final rule. The ACRS, ACNW, and CRGR have no objection to issuing this final rule.

/RA/

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Enclosure: *Federal Register* Notice

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Enclosure: *Federal Register* Notice

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