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:

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.

BACKGROUND:

The 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.

CONTACT: Stewart Schneider, NRR/DPR
301-415-4123

In furtherance of this goal, the NRC issued a proposed rule on September 22, 2006

(71 FR 55382), to revise 10 CFR 19.13, "Notifications and reports to individuals," 10 CFR 20.1905, "Exemptions to labeling requirements," and 10 CFR 20.2104, "Determination of prior occupational dose." The NRC also proposed to revise the definition of *Total Effective Dose Equivalent* 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 to either the health and safety of workers and the public or the environment.

Sixteen comment letters were received in response to the proposed rule. The commenters included a number of individuals, industry organizations, and power reactor, uranium recovery, and fuel facility licensees. The majority of commenters supported this rulemaking. The staff's response to these comments is presented in the enclosed *Federal Register* notice (Enclosure 1). Resolution of the public comments resulted in no changes to the rule text.

DISCUSSION:

Four principal amendments are included in this final rule. These revisions are intended to reduce unnecessary regulatory burden on NRC and Agreement State licensees without affecting the level of protection to either the health and safety of workers and the public or the environment. The main features of these amendments are as follows:

(1) Annual Dose Report to Workers

The first amendment revises 10 CFR 19.13. Under 10 CFR 19.13(b), licensees are required to 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, licensees will not be required to provide unsolicited annual dose reports to those individuals whose annual dose does not exceed these limits. The criterion of 1 mSv (100 mrem) is applicable 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. NRC Form 3, "Notice to Employees," will also be revised to reflect the changes to the requirements for reporting doses to individuals. The final rule does not change the Commissions requirements in 10 CFR Part 20 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. It also appears in 10 CFR 20.2205 through the reference to 10 CFR 20.2206. To improve regulatory efficiency, the final rule removes 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 is consolidated into a single requirement in 10 CFR 19.13(b).

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

The second amendment revises the definition of TEDE in 10 CFR 20.1003, "Definitions," and 50.2, "Definitions." 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. 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. NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," will also be revised to reflect the changes to the definition of TEDE.

A corresponding change in 10 CFR 20.1201(c) 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 will not be required to 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 instructions to minimize radiation exposure while handling or working in the vicinity of the containers. However, the final rule does require the container to be appropriately labeled under the requirements of 10 CFR 20.1904, "Labeling containers," before being removed from the posted area.

Under the preexisting regulatory framework, some nuclear power reactor licensees interpreted 10 CFR 20.1904 to mean that all containers in a posted area, whether they contained licensed material or not, had to be labeled because every container has the potential for internal contamination. This conservative interpretation of the previous 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. 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 COMPATIBILITY:

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 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 (ACRS) considered this final rule discussion and decided to decline the formal review. The Advisory Committee on Nuclear Waste (ACNW) considered this final rule discussion and decided to decline the formal review. 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. The Office of Information Services has reviewed the final rule for information technology and information management implications and concurs in the rule. {NOTE: Text related to CRGR, ACRS, and ACNW is filler until these bodies provide a final decision; at that time the text will be revised as appropriate.]

RESOURCES:

NRR has sufficient resources budgeted in FY 2007 and FY2008 to complete this rulemaking.

RECOMMENDATIONS:

That the Commission:

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

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. Note—

   a. That 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 environmental review and a regulatory analysis that indicates a substantial easing of regulatory burden on licensees.

   b. That the staff has determined that this action is not a "major rule," as defined in the Congressional Review Act (CRA) of 1996 (5 U.S.C. 804(2)) and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 2).

   c. That the appropriate congressional committees will be informed of this action.

   d. That a press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register.

   e. That 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 the OMB for its review and approval before publication of the final rule in the *Federal Register*.

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Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice (ML07XXXXXX)
2. CRA forms (ML07XXXXXX)

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