July 12, 2007

MEMORANDUM TO: Michael R. Johnson, Chairman
Committee to Review Generic Requirements

FROM: James T. Wiggins, Deputy Director ***/RA/***
Office of Nuclear Reactor Regulation

SUBJECT: REVIEW OF THE FINAL RULE TO AMEND 10 CFR PARTS 19, 20, AND 50: OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS, AND THE TOTAL EFFECTIVE DOSE EQUIVALENT

The Office of Nuclear Reactor Regulation (NRR) is requesting that the Committee to Review Generic Requirements (CRGR) waive its review of the attached rulemaking package for 10 CFR Parts 19, 20, and 50. The final rule (1) amends the provisions of 10 CFR 19.13 to limit the routine reporting of annual doses to workers to those whose annual dose exceeds a specific dose threshold or who request a report; (2) amends the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003 and 50.2 to be consistent with current Commission policy; (3) revises 10 CFR 20.1905 to add an exemption from the labeling requirements in 10 CFR 20.1904, for the labeling of certain containers within posted areas in nuclear power facilities; and (4) removes the requirement in 10 CFR 20.2104 that licensees attempt to obtain the cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure. 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.

The changes to Parts 19 and 20 allow light-water reactor licensees to continue current practices if they determine it is not cost beneficial to make the administrative changes needed to adopt the relaxed requirements of this rule, and this would not constitute a backfit.

All cognizant NRC offices have concurred in this final rule and the Office of the General Counsel has granted its finding of no legal objection. If CRGR believes that a formal briefing on this rulemaking is necessary, we are prepared to brief the Committee. However, we have committed to provide this final rule to the Commission by July 28, 2007, so we would like to schedule the meeting with the CRGR as soon as possible.

Enclosures:
1. Rulemaking Package
2. CRGR Appendix C Responses

cc: L. Cupidon

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

July 12, 2007

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The changes to Parts 19 and 20 allow light-water reactor licensees to continue current practices if they determine it is not cost beneficial to make the administrative changes needed to adopt the relaxed requirements of this rule, and this would not constitute a backfit.

All cognizant NRC offices have concurred in this final rule and the Office of the General Counsel has granted its finding of no legal objection. If CRGR believes that a formal briefing on this rulemaking is necessary, we are prepared to brief the Committee. However, we have committed to provide this final rule to the Commission by July 28, 2007, so we would like to schedule the meeting with the CRGR as soon as possible.

Enclosures:
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2. CRGR Appendix C Responses

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301-415-4123

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Enclosure 1

Rulemaking Package

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*.

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice (ML071360157)

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
   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.
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Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice (ML071360157)

ADAMS Accession No.: ML07071350655 (Package); ML071360124 (Memo)

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, and 50

RIN 3150 - AH40

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is amending its regulations related to the reporting of annual dose to workers, the definition of *Total Effective Dose Equivalent* (TEDE), the labeling of certain containers holding licensed material, and the determination of cumulative occupational radiation dose. This final rule limits the routine reporting of annual doses to those workers whose annual dose exceeds a specific dose threshold or who request a report. This final rule also modifies the labeling requirements for certain containers holding licensed material within posted areas in nuclear power facilities. This final rule also amends the definition of TEDE to be consistent with current Commission policy. Finally, this rule removes the requirement that licensees attempt to obtain cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure. 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.

DATES: *Effective Date:* This final rule is effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents can be viewed and downloaded electronically via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*.

Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/reading-rm/adams.html*. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at (800) 397–4209, (301) 415–4737, or by e-mail to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-4123; e-mail sxs4@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background.

II. Discussion.

III. Summary and Analysis of Public Comments on the Proposed Rule.

IV. Section-by-Section Analysis of Final Revisions.

V. Agreement State Compatibility.

VI. Availability of Documents.

VII. Voluntary Consensus Standards.

VIII. Environmental Impact: Categorical Exclusion.

IX. Paperwork Reduction Act Statement.

X. Regulatory Analysis.

XI. Regulatory Flexibility Certification.

XII. Backfit Analysis.

XIII. Congressional Review Act.

I. 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.

To further 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 TEDE in 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions," to be consistent with current Commission policy.

The NRC received 16 comment letters In response to the proposed rule. The commenters included a number of individuals; industry organizations; and power reactor, uranium recovery, and fuel facility licensees. A discussion of the issues raised by the commenters and the Commission's response is covered below in Section III.

II. 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. In finalizing this rule, no revisions were made to the regulatory language that was published in the proposed rule (71 FR 55382; September 22, 2006).

A. Annual Dose Report to Workers

The first amendment revises paragraphs (b) and (d) of 10 CFR 19.13 and 10 CFR 20.2205, "Reports to Individuals of Exceeding Dose Limits."

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 NRC 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 criterion of 1 mSv (100 mrem) was selected because it meets the Commission's regulatory objective to provide a significant reduction in administrative and reporting burdens on licensees. In addition, it is consistent with the occupational dose threshold for requiring

instruction to workers under 10 CFR 19.12, “Instruction to Workers.” As discussed in the Supplementary Information to the proposed rule, recent occupational radiation exposure data submitted to the NRC under 10 CFR 20.2206, “Reports of Individual Monitoring,” indicates that about 80 percent of the individuals monitored annually received a TEDE that did not exceed 1 mSv (100 mrem). Based upon this information, the final rule will result in a significant reduction in administrative and reporting burdens on licensees.

The final rule does not change the Commission’s requirements in 10 CFR Part 20, “Standards for Protection Against Radiation,” for monitoring, recordkeeping, or reporting to the Commission. Therefore, the final rule will not affect the level of protection for either the health and safety of workers and the public or for the environment.

Under the existing regulatory framework, 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. This 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 through the reference to 10 CFR 20.2206. To improve regulatory efficiency, this final rule removes the reference 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).

The NRC will also revise NRC Form 3, “Notice to Employees,” to instruct workers on how the licensee is to provide dose annually to workers consistent with the final rule.

B. Definition of *Total Effective Dose Equivalent* (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 (EDE)” for “deep-dose equivalent (DDE)” for external exposures. Conforming changes are also made to 10 CFR 1201, “Occupational Dose Limits for Adults.”

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. This policy explains that the EDE is the primary quantity in the definition of TEDE for external exposures but that licensees are required to use the DDE in place of the EDE when measuring dose from external exposure, unless the EDE is determined by a dosimetry method approved by the NRC.

In addition, 10 CFR 20.1201, paragraph (c) will be revised to add the requirement that when the external exposure is determined by measurement with an external personal monitoring device, the DDE must be used in place of the EDE, unless the EDE is determined by a dosimetry method approved by the NRC. In many external exposure monitoring situations, determining EDE from external exposures may not be practicable. The added administrative burden associated with determining EDE may not be warranted, or an applicable dosimetry method for determining EDE may not exist. The revised wording to 10 CFR 20.1201(c) clarifies that licensees can still use DDE in place of EDE for the external exposure in demonstrating compliance with the TEDE dose limit, consistent with the existing regulatory framework; however, the DDE must be for the part of the whole body receiving the highest exposure.

The final rule will not affect the level of protection for either the health and safety of workers and the public or for the environment because the revised definition of TEDE does not decrease the ability to determine dose.

The NRC will also revise NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” so that the licensee can enter either the DDE or EDE in Field 11 which currently is labeled “Deep Dose Equivalent (DDE).” In addition, the instruction sheets for completing both forms will be revised to clarify the method to be used to fill in Field 11, “Deep Dose Equivalent (DDE).” Until these forms are revised, licensees should enter in Field 11 the EDE from external exposure if this dose is assessed by means other than a single dosimeter worn by the exposed individual. Otherwise, the DDE is to be entered.

C. 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. The final rule exempts the licensee from providing detailed labeling information such as the radionuclide or radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, types of materials, and mass enrichment as required under 10 CFR 20.1905. One purpose of adding conspicuous markings on the containers is to indicate the potential for generating airborne contamination or high radiation dose rates if the containers were opened or mishandled. For example, these containers could be conspicuously marked by using a color-coding system to indicate high, medium, or low levels of activity or hazard. Containers such as 55-gallon steel drums holding contaminated gloves and booties could be marked with a color that represents low levels of activity or low potential for airborne contamination. At nuclear power facilities, containers located within a posted area are accessible only to individuals who have had instruction under 10 CFR 19.12 and who have been assigned a radiation work permit to control their activities. Consequently, workers will be instructed on the handling of marked containers before workers are given access to these containers.

The container marking system under this rule will reduce licensee administrative and information collection burdens, but serve the same health and safety functions as the current

labeling requirements. Therefore, the final rule will not affect the level of protection for either the health and safety of workers and the public or for the environment.

D. 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." Since the revision to 10 CFR Part 20 (56 FR 23391; May 21, 1991), cumulative lifetime dose is no longer used in Part 20, except for cases involving planned special exposures. That revision made it unnecessary for licensees to attempt to obtain lifetime exposures for workers who are not participating in a planned special exposure program. This issue was discussed further in the Supplementary Information to the proposed rule (71 FR 55382; September 22, 2006),

The final rule does not change the criterion under 10 CFR 20.1206, "Planned Special Exposures," that requires licensees to ascertain the exposure history of an individual's prior lifetime doses as required by 10 CFR 20.2104(b) before permitting an individual to participate in a planned special exposure.

The Commission believes that the final amendment to 10 CFR 20.2104(a)(2) will result in a significant reduction in administrative and information collection burdens on licensees. The final rule will not affect the level of protection for either the health and safety of workers and the public or for the environment, because the requirements to determine an individual's occupational radiation dose received during the current year or cumulative radiation dose prior to permitting a planned special exposure have not been amended.

In 10 CFR 20.2104, paragraphs (c) and (d) will also be revised to correct the omission of a reference to paragraph (b) in this section regarding planned special exposures. Paragraph (b) requires that prior to permitting an individual to participate in a planned special exposure, the licensee must determine the internal and external doses from all previous planned special exposures, and all doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual. This revision adds into paragraphs (c) and (d) that licensees obtain complete records of the worker's current and previously accumulated occupational dose in complying with the provisions of 10 CFR 20.2104(b).

III. Summary and Analysis of Public Comments on the Proposed Rule

The NRC received 16 comment letters 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 NRC's approach. The significant comments discussed below are arranged by subject. No changes to the proposed rule language were made as a result of the comment letters.

A. Annual Dose Report to Workers

Ten commenters specifically addressed this issue. All agreed with the concept that there should be a defined dose threshold above which licensees are required to provide an annual dose report to monitored individuals. However, some took issue with the threshold proposed by the NRC.

Comment. Two commenters stated that in order to provide comfort or build trust, more employees are given dosimeters than necessary, and that the effort to provide dosimetry to individuals should not be complicated by a need to provide annual dose reports.

Response. The Commission's requirements on when to provide dosimetry to a worker are separate from the requirements to provide annual dose reports to workers. As explained in the Supplementary Information accompanying the proposed rule, the NRC agrees that many individuals required to be monitored receive very low doses but that, under the current regulations, employers still had to generate and provide reports of doses far below the regulatory limits in 10 CFR 20.1201(a).

Comment. One commenter said that there should be a reporting requirement at the termination of employment or if the employee develops a medical condition which could affect the employee's ability to receive occupational exposure because individuals seeking new employment need to be notified of their dose so that they can inform their new employer.

Response. 10 CFR 19.13(e) currently requires that a licensee provide at the request of a worker who is terminating employment with the licensee, a written report of the radiation dose received by that worker from the operations of the licensee during the current year or fraction thereof. Exposures received as part of medical procedures are not reported to the worker as part of the occupational exposure received at a licensed facility. In the case of a medical condition which could affect the worker's ability to receive occupational exposure, it is the worker's responsibility to notify the licensee of any condition that may interfere with the worker's duties. One example is a women declaring her pregnancy in order to be exposed to a reduced dose level during the pregnancy. Therefore, the commenter's concerns are addressed by the current regulations.

Comment. One commenter believed that the criteria for reporting annual dose should be based on a percentage of the applicable limits to preserve the graded approach to controlling

exposure that the NRC promotes in risk informed regulations, and recommended that licensees should not be required to report occupational doses to workers when their annual dose is less than 10 percent of the applicable dose limits.

Response. The NRC disagrees with basing the criteria on a percentage of the applicable limits. As explained in the Supplementary Information accompanying the proposed rule, the approach used is simpler because there is one reporting threshold instead of three (i.e, the whole body, lens of the eye, and skin of the whole body or skin of any extremity) and results in the same reduction in burden.

Comment. One commenter said that it is not clear why the NRC selected 1 mSv (100 mrem) to be identical with the criterion for requiring instruction to workers under 10 CFR 19.12. This commenter saw no advantage in using the same criterion for notification and instruction. This commenter also took issue with the NRC's position in the Supplementary Information to the proposed rule that raising the threshold from the proposed value of 1 mSv (100 mrem) would not significantly reduce administrative and information collection burdens on licensees. Another commenter believed it to be more logical to use 5 mSv (500 mrem) which is the threshold for requiring individual monitoring of external dose.

Response. The NRC disagrees with these commenters. An analysis of the occupational radiation exposure data in NUREG-0713, Volume 26, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2004" (December 2005), indicates that about 80 percent (i.e., 94,534 individuals) of the 122,322 monitored individuals received a TEDE that did not exceed 1 mSv (100 mrem). Furthermore, 61,725 of the monitored individuals received no measurable exposure. Therefore, the threshold of 1 mSv (100 mrem) meets the Commission's regulatory objective of providing a significant reduction in administrative and reporting burden on licensees without adversely impacting public health and safety. The analysis also indicates that raising the threshold from 1 mSv (100 mrem) to 5 mSv

(500 mrem) would not further reduce significantly administrative and reporting burdens on licensees.

Comment. A commenter objected to using a threshold of 1 mSv (100mrem) for providing annual dose reports to workers because it results in different requirements for a facility where individuals are monitored and for a facility where individuals are not monitored. The commenter believed that the rule provides a strong incentive for a licensee to cease monitoring workers who might exceed 1 mSv (100 mrem) in a year but are unlikely to exceed 5 mSv (500 mrem), the level of exposure for which licensees are required to provide individual monitoring of external occupational dose under 10 CFR 20.1502.

Response. The NRC disagrees with the commenter's assertion that the threshold for reporting results in different requirements for licensed facilities. The Commission's requirements for recordkeeping and reporting of dose depend only on the licensee's decision to provide or to not provide individual monitoring. The NRC also disagrees with the commenter's assertion that the rule provides incentive for a licensee to cease monitoring workers who might exceed 1 mSv (100 mrem) in a year but are unlikely to exceed 5 mSv (500 mrem). The NRC believes that licensees will choose to continue to provide monitoring to these individuals for operational convenience because this practice helps alleviate worker concerns of a possible significant exposure.

Comment. One commenter recommended allowing licensees to choose a reporting criteria that is either the proposed requirement of 1 mSv (100 mrem) or some optimal intermediate administrative threshold that best relates to the licensee's conditions and practices.

Response. The NRC finds it unacceptable to allow licensees to select the threshold value because it will result in a nonuniform approach to providing reports to individuals.

Comment. One commenter recommended that both the reporting requirements and the monitoring requirements use the same dose criteria so as to not compromise programs for

using dosimeters to confirm compliance. This commenter also stated that l mSv (100 mrem) per year is below the detection limit for thermoluminescence detectors that are used for dosimeter wear periods that are less than a month.

Response. The NRC disagrees with using the same dose criteria because the requirements for monitoring, recordkeeping, and reporting address different aspects of the licensee's operations. The Commission's requirements for recordkeeping and reporting of dose depend only on the licensee's decision to provide or to not provide individual monitoring.

Regarding the commenter's concern that l mSv (100 mrem) per year is below the detection limit for thermoluminescence detectors, the reporting requirements reflect entries on NRC Form 5, which is the form currently used by licensees to obtain the annual dose information that is reported to the workers. Where monitoring was provided but the dose was not measurable, the licensee can enter "ND" for "Not Detectable" on NRC Form 5.

Comment. Two commenters stated that the final rule language needs to explicitly state that the reporting threshold applies to the whole body, to the lens of the eye, to the skin of the whole body, and the skin of the extremities.

Response. The NRC believes that the final rule language in 10 CFR 19.13(b) requires no further clarification. Requiring licensees to provide an annual report to each individual when the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue is inclusive of the dose to any part of the body. If any dose value as reported on NRC Form 5 exceeds 1 mSv (100 mrem), then an annual dose report must be provided to the monitored individual. In addition, the revision to the reporting requirements in 10 CFR 19.13(b) does not change the methods for calculating doses to an individual.

Comment. One commenter stated that the Commission should consider a two-tiered threshold: (1) 100 mrem for whole body and lens of the eye, and (2) 1,000 mrem for extremities/organ, because there is a 10-fold difference in the dose limits involved. The

commenter also believed that this approach would result in major administrative savings for medical and research workers.

Response. The NRC disagrees with this comment. Several approaches were evaluated for establishing a threshold value above which licensees are required to provide an annual dose report to a monitored individual. The approach selected for the final rule has the merit of simplicity while also achieving the intended aim of reducing unnecessary regulatory burden. The regulatory analysis conducted for the final rule (Section X, below) shows that the 1 mSv (100 mrem) annual reporting threshold by itself results in a significant burden reduction for licensees as a whole.

B. Definition of *Total Effective Dose Equivalent* (TEDE)

Five commenters specifically addressed this issue. Most of these commenters agreed with the proposed revision to the definition of TEDE in 10 CFR 20.1003 and 10 CFR 50.2.

Comment. One commenter stated that the NRC has no basis to approve dosimetry methods for determining the effective dose equivalent and recommended allowing use of the effective dose equivalent when the methodology is in accordance with a nationally recognized standard or the radiation control agency with jurisdiction.

Response. The NRC disagrees that there is no basis to approve dosimetry methods, and has published guidance on acceptable dosimetry methods in RIS 2004-01, “Method for Estimating Effective Dose Equivalent From External Radiation Sources Using Two Dosimeters,” RIS 2003-04, “Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments,” and RIS 2002-06, “Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays.” Further guidance will be provided, as warranted, when additional methods are determined acceptable by the NRC.

Comment. One commenter said that the Supplementary Information to the proposed rule did not address how the change to the definition of TEDE is consistent with the recommendations of the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP).

Response. Total Effective Dose Equivalent (TEDE) in 10 CFR Part 20 is defined as the sum of two dosimetrically different quantities: the deep-dose equivalent (DDE) for external exposure and the effective dose equivalent (EDE) for internal exposure. This approach is not consistent with the basic radiation protection premise that risk is directly proportional to dose. The DDE is not, in many cases, proportional to risk and is often a poor indicator of the risk arising from radiation exposure. This approach of using mixed quantities to define the TEDE is also not consistent with the recommendations of national and international advisory groups such as the NCRP and the ICRP. These groups quantify the total dose by adding the EDEs for both internal and external exposures. The use of mixed quantities has caused significant difficulties to NRC licensees, and has led the Commission to permit substitution of EDE in place of DDE when calculating the TEDE, provided the dose from external exposure is not based on measurements using personnel dosimetry. This provision allows for the fact that the EDE cannot be measured in the field, and when measurements are necessary as the basis for quantifying the dose from external exposures, the DDE may be used as a surrogate quantity that was defined in such a manner that its magnitude provides a conservative numerical estimate for the EDE. The final redefinition of TEDE implements this policy formally, a policy that is now in effect and is being used by NRC licensees.

Comment. One commenter stated that NRC Forms 4 and 5 need to be revised because of the change to the definition of TEDE, and that the NRC provide options in guidance for reporting EDE versus DDE and for making appropriate calculations of the total organ dose equivalent and TEDE.

Response. The NRC agrees with the comment. NRC Forms 4 and 5 will be revised to reflect the changes to the definition of TEDE. In addition, the instruction sheets for completing both forms will be revised to clarify the method to be used to fill in Field 11, "Deep Dose Equivalent (DDE)." Guidance for estimating the EDE and DDE is provided in numerous NRC guidance documents.

C. Labeling Containers

Four commenters specifically addressed this issue. All of the commenters disagreed with the approach taken by the NRC in the proposed rule to limit the exemption to labeling requirements under 10 CFR 20.1905 to nuclear power reactor licensees, and believed that additional categories of licensees should be granted the exemption to labeling requirements for containers holding licensed material.

Comment. Two commenters stated that the container labeling exemption should be granted to university and medical licensees. One commenter indicated that power reactors have more types of radioactivity and a great range of activity because of the mixtures of fission and activation products, while university and medical areas have pure and well-defined materials used under controlled conditions, mostly employing low quantities of materials with short half lives. The commenter indicated that therefore a dichotomy in the rules for nuclear power plants and other licensees is unjustified. The other commenter stated that the current exemptions in 10 CFR 20.1905 pertain to labeling of containers with applicability to all licensees, and that limiting this exemption to nuclear power facilities for the reasons stated in the Supplementary Information to the proposed rule demonstrates an incomplete understanding of the safety measures in large medical and research facilities. The commenter stated if an undue burden has been placed on the nuclear power industry because of an overly

conservative interpretation of the rules, the NRC should specifically be tasked to broaden that interpretation, not exempt a single licensee category from a rule applicable to all other licensees.

Response. The NRC disagrees with granting the exemption from labeling requirements to university and medical licensees. The burden imposed on nuclear power plant licensees by the current regulation is not due to an overly conservative interpretation. Rather, it is due to the existence of a large number of structures in a protected area of a nuclear power plant that may be inappropriately considered to be containers holding licensed material, such as pipes, cable trays, and containers holding contaminated tools or protective clothing. This situation does not exist at other types of licensed facilities. In addition, although the NRC agrees with the commenter that university and medical licensees implement stringent radiation control programs, the level of redundancy in protective measures in these programs is not as extensive as that found at nuclear power plants. The NRC believes that removing one such measure at nuclear power plants, i.e., labeling containers holding licensed material, will be compensated for by the redundancy in their radiation protection programs. Such extensive redundancy is not normally found in university and medical radiation protection programs.

Comment. Two commenters recommended that the container labeling exemption be granted to all licensees under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." One of these commenters believed that all Part 70 licensees now have this provision in their licenses. This commenter also noted that a Part 70 licensee's variance in radiological hazards is comparable to that of a Part 50 or Part 52 license.

Response. The NRC disagrees that there is a need to extend the exemption from labeling requirements to include Part 70 licensees. Currently, only Part 70 licensees subject to Subpart H requirements have a license condition that provides the exemption from the labeling requirements of this rule. The Commission has determined that for the remainder of the Part 70

licensees, this license condition is not required. The existing labeling requirements are not a burden to these licensees because they handle few containers holding radioactive material.

Comment. One commenter suggested that the exemption be expanded to include containers removed from a posted area as long as the container is under continuous direct or electronic surveillance while in transit between one posted area to another.

Response. The exemption from labeling requirements suggested by the commenter is already provided in 10 CFR 20.1905(c). That regulation specifies that a licensee is not required to label containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 10 CFR Part 20.

D. Cumulative Occupational Radiation Dose

Ten commenters addressed this issue. Most of the commenters agreed with removing 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.

Comment. Two commenters suggested that the cost savings to licensees from the revision to 10 CFR 20.2104 have been underestimated. Specifically, these commenters recommended that the NRC consider the savings to those licensees who no will longer have to provide prior dose records to a requesting licensee, stating that the savings of not having to provide prior dose records is $20 per new employee. This estimate is based on an assumption of a savings of $10 per request and on the fact that two licensees would be requested to provide the records per new employee.

Response. The NRC agrees with the comments and the regulatory analysis for the final rule found in Section X has been revised to use the suggested values.

Comment. One commenter expressed a concern that it is essential for the licensee to obtain current year dose records.

Response. The NRC agrees with the need for a licensee to determine and record the dose for an individual during for the current year. The final rule does not revise the requirements in 10 CFR 20.2104(a) that require a licensee to determine the occupational radiation dose received by an individual during the current year. The final rule removes only the requirement that licensees attempt to obtain cumulative exposure records for workers, i.e., exposure records for previous years, unless these individuals are being authorized to receive a planned special exposure.

Comment. One commenter suggested that an additional revision be made to 10 CFR 19.13 to remove the language in paragraph (a) regarding using an individual's social security number as an appropriate identifier for reports. This commenter was concerned about the risk of identity theft.

Response. Based on recent Office of Management and Budget guidance, Federal agencies, including the NRC, are reviewing their uses of Social Security numbers (SSNs) with the goal of eliminating unnecessary uses of SSNs. However, revision of 10 CFR 19.13(a) to remove the language specific to using the individual's social security number as an identifier is outside the scope of this rulemaking.

Comment. One commenter believed that removing the requirement in 10 CFR 20.2104(a)(2) to attempt to obtain the records of cumulative occupational radiation dose would eliminate lifetime dose records and the ability to do any retrospective, low dose occupational risk assessments.

Response. As explained in the Supplementary Information accompanying the proposed rule, occupational exposures were initially restricted by the cumulative lifetime dose received and, under certain circumstances, an individual could receive as much as 0.12 Sv (12 rems) in

a year. However, following revision to 10 CFR Part 20 (56 FR 23391; May 21, 1991), cumulative lifetime dose is no longer used in the Commission's regulations to restrict occupational exposures. The reduced occupational dose limit of 0.05 Sv (5 rems) per year in the current 10 CFR 20.1201(a)(1)(I) essentially accomplishes the same goal as the previous dose limit of 0.03 Sv (3 rems) per calendar quarter constrained by the then age-dependent, cumulative lifetime dose limit. (The goal is an average cumulative dose rate of 0.05 Sv (5 rems) per year to the individual.) Therefore, it is no longer necessary for licensees to obtain records of cumulative occupational dose. However, 10 CFR Part 20 still requires licensees to maintain records of individual monitoring results and to submit to the NRC an annual report of the results of individual monitoring. The ability to do a retrospective dose assessment is not affected by this final rule. The revision to 10 CFR 20.2104(a)(2) does not change the Commission's requirements for monitoring individuals or for maintaining records of doses received by individuals at licensed facilities. Thus, the dose records for individuals whose exposure histories span more than one licensed facility will still be available for risk assessments..

Comment. One commenter stated that removing the requirement in 10 CFR 20.2104(a)(2) will not reduce future burden on licensees because if the NRC implements the proposed International Commission on Radiological Protection (ICRP) recommendation on dose limits averaged over several years, then licensees will need to reconstruct a worker's prior dose records.

Response. The NRC has not initiated any changes to 10 CFR Part 20 to adopt the latest ICRP recommendations and has yet to decide when this would happen and the extent to which they would be adopted. The Commission's current regulations do not permit averaging annual dose over several years.

Comment. One commenter stated that the rule should be expanded to not require a licensee to obtain a worker's dose records prior to permitting the worker to participate in a

planned special exposure, but to require the worker to retrieve this data. The commenter believed that this would alleviate an administrative burden on the licensee.

Response. This comment is outside the scope of this rulemaking. The final rule does not address the methods used to obtain a worker's dose history when that dose history is required prior to permitting the worker to participate in a planned special exposure. The final rule only removes the requirement for a licensee to obtain the records of cumulative occupational radiation dose except when authorizing a planned special exposure.

IV. Section-by-Section Analysis of Final Revisions

This final rule amends 10 CFR 19.13, 20.1003, 20.1201, 20.1905, 20.2104, 20.2205, and 50.2.

Section 19.13—Notifications and Reports to Individuals.

Paragraph (b) is revised to require a licensee to provide an annual dose report to an individual when the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue, or when the individual requests a report of the individual's annual dose, and that all dose records shall be made available to workers onsite.

In order to consolidate the requirement to report annual dose to the individual into a single requirement in 10 CFR 19.13(b), paragraph (d) is revised to remove the reference to 10 CFR 20.2206.

Section 20.1003—Definitions.

In 10 CFR 20.1003, the definition of *Total Effective Dose Equivalent* (TEDE) is revised to state that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Section 20.1201—*Occupational Dose Limits for Adults*.

Paragraph (c) is revised to add 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.

Section 20.1905—Exemptions to Labeling Requirements.

A new paragraph (g) is added to 10 CFR 20.1905 to provide an exemption for containers holding licensed material (other than sealed sources that are either specifically or generally licensed) that are in an area posted under the requirements of 10 CFR 20.1902 at a nuclear power facility. The final rule does not require the licensee to label the container according to 10 CFR 20.1904 if it is conspicuously marked (such as by color coding) commensurate with the radiological hazard and accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers. The final rule also requires that the container must be appropriately labeled as required by 10 CFR 20.1904 before being removed from the posted area. This exemption to the labeling requirements for containers holding licensed material does not apply to non-power reactor and materials licensees, or for sealed sources.

Section 20.2104—Determination of Prior Occupational Dose.

Paragraph (a)(2) is removed to delete the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose. The introductory text of paragraph (a) and paragraph (a)(1) are combined and designated as paragraph (a). Paragraphs (c) and (d) are also revised to add a reference to paragraph (b) in this section regarding planned special exposures.

Section 20.2205—Reports to Individuals of Exceeding Dose Limits.

Section 20.2205 is revised to remove the reference to 10 CFR 20.2206, in order to consolidate the requirement to report annual dose to the individual into a single requirement in 10 CFR 19.13(b).

Section 50.2—Definitions.

In 10 CFR 20.1003, the definition of *Total Effective Dose Equivalent* (TEDE) is revised to state that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

V. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this rule is a matter of compatibility between NRC

and the Agreement States, thereby providing consistency among the Agreement States and the NRC's requirements. The NRC analyzed the rule in accordance with the procedure established 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" (which may be viewed at http://nrc-stp.ornl.gov/). The NRC has determined that the compatibility categories for the sections amended in this rule are the same as for the sections in the existing regulations, except for the new exemption (g) added to 10 CFR 20.1905.

The revisions to 10 CFR 19.13 and 20.2205 are classified as Compatibility Category C. A Compatibility Category C designation means the Agreement State should adopt the essential objectives of the requirement to avoid conflicts, duplications, or gaps.

The revisions to 10 CFR 20.1003 and 20.1201(c) are classified as Compatibility Category A. A Compatibility Category A designation means the requirement is a basic radiation protection standard or related definition, sign, label, or term necessary for a common understanding of radiation protection principles. Agreement State requirements designated Compatibility Category A should be essentially identical to NRC requirements.

The new exemption (g) added to 10 CFR 20.1905 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 regulatory items that cannot be relinquished to Agreement States under the Atomic Energy Act or provisions of the regulations in title 10 of the CFR.

The revision to 10 CFR 20.2104(a) is classified as Compatibility Category D. A Compatibility Category D designation means the Agreement State is not required to adopt the requirement for compatibility.

VI. Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following methods.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Web site (RuleForum). The NRC's Interactive rulemaking Web site is located at http://ruleforum.llnl.gov. These documents may be viewed and downloaded electronically via this Web site.

NRC's Agency-wide Documents Access and Management System (ADAMS). The NRC's PARS Library is located at www.nrc.gov/reading-rm/adams.html.

The NRC staff contact (NRC Staff). Stewart Schneider, U.S. Nuclear Regulatory Commission, Mail Stop O-12D3, Washington, DC 20555-0001; telephone (301) 415-4123; sxs4@nrc.gov.

Document	PDR	RuleForum	ADAMS	NRC Staff
Final Rulemaking	X	X		X
Public Comments on Proposed Rule	X	X		X
Proposed Rulemaking (71 FR 55382; September 22, 2006)	X	X		X
NRC Form 3	X	X		X
NRC Form 4	X	X		X
NRC Form 5	X	X		X
RIS 2002-06	X	X		X
RIS 2003-04	X	X		X
RIS 2004-01	X	X		X
NUREG-0713, Vol. 26	X			X
NUREG-1350, Vol. 17	X			X
NUREG/BR-0184	X			X
NUREG/BR-0058, Rev. 4	X			X
Standards for Protection Against Radiation: Final Rule (56 FR 23391; May 21, 1991)	X	X		
NRC Strategic Plan, Fiscal Year 2000–Fiscal Year 2005	X	X		X

Copies of NUREGs may be purchased from The Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-0001; Internet: bookstore.gpo.gov; (202) 512-1800. Copies are also available from the National Technical Information Service, Springfield, VA 22161-0002; www.ntis.gov; 1-800-553-6847 or, locally, (703) 605-6000. Some publications in the NUREG series are included in the document collections in the Electronic Reading Room on NRC's Web site at http://www.nrc.gov/reading-rm.html.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this final rule, the NRC is revising requirements for the reporting of annual dose to workers, the definition of *Total Effective Dose Equivalent* (TEDE), the labeling of certain containers holding licensed material, and the determination of cumulative occupational radiation dose. This regulatory action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that the amendments to 10 CFR Parts 19, 20, and 50 are the types of actions described in categorical exclusion 10 CFR 51.22(c). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulatory action. Specifically, the revision to 10 CFR 19.13(b) to limit the routine reporting of annual doses to workers comes under the categorical exclusion in 10 CFR 51.22(c)(1), which covers all revisions to 10 CFR Part 19. The amendments to the definition of TEDE in 10 CFR 20.1003 and 10 CFR 50.2 and to 10 CFR 20.1201(c) to add the requirement that the effective dose equivalent be determined by a dosimetry method approved by the NRC come under the categorical exclusion in 10 CFR 51.22(c)(2) because these revisions are of a minor nature and do not substantially modify existing regulations. For the amendments to 10 CFR 20.1905 to revise the requirements for labeling containers and to 10 CFR 20.2104 to remove the requirement to obtain lifetime exposure records, these revisions involve

recordkeeping requirements and thus come under the categorical exclusion in 10 CFR 51.22(c)(3)(ii). Finally, because the amendment to 10 CFR 20.2205 involves a reporting requirement, this revision comes under the categorical exclusion in 10 CFR 51.22(c)(3)(iii).

IX. Paperwork Reduction Act Statement

This final rule amends information collection requirements contained in 10 CFR Parts 19, 20, and 50, and NRC Form 4 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0044, 3150-0014, 3150-0011, and 3150-0005. The changes to 10 CFR Parts 19, 20, and 50, and NRC Form 4 do not contain a new or amended information collection requirements. Existing requirements were approved by the Office of Management and Budget, approval number(s) 3150-0044, 3150-0014, 3150-0011, and 3150-0005.

Because the rule will reduce the burden for existing information collection requirements, the public burden for the information collections in 10 CFR Parts 19 and NRC Form 4 is expected to be decreased by 235 and 44 hours per licensee, respectively. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for further reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory

Affairs, NEOB-10202, (3150-0044, 3150-0014, 3150-0011, and 3150-0005) Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final rule and has included it in this *Federal Register* notice. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requested public comment on the draft regulatory analysis for the proposed rule (71 FR 55382; September 22, 2006). Two comments were received on the draft regulatory analysis and are discussed above in Section III. These comments were considered and the regulatory analysis revised appropriately.

1. Statement of the Problem and Objective

The NRC has determined that the regulations in 10 CFR 19.13, 20.1003, 20.1201, 20.1905, 20.2104, and 50.2 impose an undue regulatory burden on licensees. The final rule makes these regulations consistent with current Commission policy and reduces administrative and information collection burdens on NRC and Agreement State licensees. The final rule amends certain requirements for notification of workers, revises 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. These revisions do not affect the level of protection for either the health and safety of workers and the public or for the environment.

2. Identification of Regulatory Alternatives

This regulatory analysis evaluates the savings and costs of two regulatory alternatives. The following subsections describe these two alternatives.

2.1 No-Action Alternative

The no-action alternative is the status quo had this rule not been promulgated. Under that alternative, licensees would have been required to: (1) provide annual dose reports to all monitored individuals, (2) determine the TEDE by summing the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for external doses), (3) use the current exemptions to labeling requirements for containers holding licensed material, and (4) attempt to obtain the records of lifetime occupational radiation dose for all individuals. The no-action alternative is the baseline for analyzing the rule alternative. The no-action alternative does not accomplish the stated objective.

2.2 Rule Alternative

Under the rule alternative, the NRC is revising its regulations in 10 CFR Parts 19, 20, and 50 for: (1) reporting dose to workers, (2) the definition of TEDE, (3) the labeling of certain

containers holding licensed material, and (4) the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose for all individuals. This alternative makes the regulations consistent with current Commission policy and reduces administrative and information collection burdens on NRC and Agreement State licensees. Because this action is being taken to ease burden, the rulemaking process is the only regulatory option appropriate to make the changes effective.

3. Analysis of Values and Impacts

3.1 Identification of Affected Attributes

The attributes that the rule could affect were identified by using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" (January 1997).

Industry Implementation. This attribute is affected by three of the four principal revisions: the revisions to the requirements for the annual dose reports to workers, the labeling of containers holding licensed material, and the attempt to obtain the records of cumulative occupational radiation dose for an individual. In implementing these changes, licensees will incur the costs of revising procedures.

Industry Operation. This attribute is affected by three of the four principal revisions. Licensees will realize savings by only having to provide annual dose reports to individuals when their dose exceeds 1 mSv (100 mrem), by not having to label containers holding licensed material (except sealed sources that are already labeled) in a posted area in a nuclear power facility, and by not having to ascertain the exposure history of an individual's prior lifetime doses except to permit an individual to participate in a planned special exposure.

NRC Implementation. The NRC will incur costs to make minor revisions to NRC Form 3, "Notice to Employees," to account for the revisions to the reporting of annual dose to workers. In addition, the NRC will incur costs to make minor revisions to NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," and their instructions, to account for the revision to the definition of TEDE.

Regulatory Efficiency. All four of the principal revisions will enhance regulatory efficiency. The revisions are intended to reduce 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.

3.2 Methodology

The incremental savings and costs of the regulatory action are analyzed relative to the baseline described in Section 2.1 of this regulatory analysis. The savings come from any desirable changes in the affected attributes, while the costs come from any undesirable changes in the affected attributes.

Under Office of Management and Budget guidance and NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4 (September 2004), the results of the analysis are presented using a discounted flow of funds at a 3 and 7 percent real discount rate.

Under 10 CFR 20.2206, seven categories of NRC licensees are required to submit to the NRC annual radiation exposure reports for monitored individuals: commercial nuclear power reactors; industrial radiographers; fuel processors (including uranium enrichment), fabricators and reprocessors; manufacturers and distributors of byproduct material; independent spent fuel storage installations; facilities for land disposal of low-level waste; and

geologic repositories for high-level waste. (No NRC licensees are currently involved in operating low-level waste disposal facilities or geologic repositories for high-level waste.) In addition, 10 CFR 20.2206(b) requires that licensees submit annual reports using NRC Form 5 or electronic media containing all the information required by NRC Form 5. For the above licensees, the value-impact analysis uses the occupational exposure data maintained in the NRC's Radiation Exposure Information and Reporting System (REIRS) database (NUREG-0713, Volume 26, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2004" (December 2005)). While more recent data has been issued, the values have not changed significantly from those used in the regulatory analysis for the proposed rule. To simplify the analysis, the seven categories of licensees are consolidated into two groups. The first group contains only commercial nuclear power reactor licensees (nuclear power reactor licensees) and the second group contains all of the other licensee categories listed above (REIRS materials licensees).

The seven categories of licensees specified in 10 CFR 20.2206 do not include all NRC licensees. Most NRC licensees (e.g., hospitals, medical facilities, universities, radiological services, disposal) are not required to submit annual radiation exposure reports for monitored individuals. These licensees (non-REIRS materials licensees) constitute the third group of licensees for whom a value-impact analysis was done. This group contains both Agreement State and NRC licensees. For this group of licensees, the NRC has no records of the number of monitored individuals or the annual doses they received (except in the rare case of an overexposure). Based on professional judgment, the NRC assumes that 500,000 individuals are monitored annually by non-REIRS materials licensees. In addition, it is assumed that about 70 percent of them receive an annual dose that does not exceed 1 mSv (100 mrem). This factor is derived from the data in NUREG-0713 for REIRS materials licensees and is assumed to apply to non-REIRS materials licensees.

The following assumptions and data were used to assess the incremental values and impacts associated with the regulatory action.

- Based on NUREG-0713, the number of nuclear power reactor licensees is 104 (NRC licensees only).
- Based on NUREG-0713, the number of REIRS materials licensees is 123 (NRC licensees only).
- Based on NUREG-1350, Volume 17, "NRC Information Digest: 2005 - 2006 Edition" (July 2005), there are approximately 17,298 Agreement State licensees. While more recent data has been issued, the values have not changed significantly from those used in the regulatory analysis for the proposed rule.
- The number of non-REIRS materials licensees (Agreement State and NRC licensees) was estimated as follows. A review of the NRC Licensing Tracking System database in October 2005 indicated that a total of 4,517 materials licensees are administered by the NRC. While more recent data has been issued, the values have not changed significantly from those used in the regulatory analysis for the proposed rule. Correcting for the 123 REIRS materials licensees in the database and accounting for Agreement State licensees, the total number of Agreement State and NRC licensees designated as non-REIRS materials licensees is approximately 21,692 licensees (17,298 Agreement State licensees + 4,517 NRC materials licensees - 123 REIRS materials licensees).
- The number of NRC licensees designated as non-REIRS materials licensees is 4,394 licensees (4,517 NRC materials licensees - 123 REIRS materials licensees).
- Based on NUREG-0713, the number of individuals working for all nuclear power reactor licensees is 110,290.
- The average number of individuals working at each of the 104 nuclear power plants is estimated to be 1,060.

- Based on NUREG-0713, the number of individuals working for all REIRS materials licensees is 12,032.
- Based on professional judgment, the NRC assumes that 500,000 individuals are monitored annually by non-REIRS materials licensees (Agreement State and NRC licensees).
- Based on NUREG-0713, 70 percent of the individuals monitored by nuclear power reactor licensees receive an annual dose that does not exceed 1 mSv (100 mrem).
- Based on NUREG-0713, 80 percent of the individuals monitored by REIRS materials licensees receive an annual dose that does not exceed 1 mSv (100 mrem).
- Based on NUREG-0713 and professional judgment, the NRC assumes that 80 percent of the individuals monitored by non-REIRS materials licensees receive an annual dose that does not exceed 1 mSv (100 mrem).
- The NRC estimates that procedural revisions will require 20 hours for each of the 104 nuclear power plants.
- For REIRS and non-REIRS materials licensees, the time needed to revise procedures ranges from 2 to 20 hours, depending on the size of the facility. This analysis uses 10 hours as the average time to revise procedures for these licensees.
- For nuclear power reactor licensees, it is assumed that the average life remaining for power reactor facilities is 49 years. For 3 and 7 percent real discount rates, the analysis uses present value multiplication factors of 25.50 and 13.77, respectively, following the guidance in NUREG/BR-0184.
- For REIRS and non-REIRS materials licensees, it is assumed that the average life remaining for the facilities is 20 years. For 3 and 7 percent real discount rates, the analysis uses factors of 14.9 and 10.6, respectively, following the guidance in NUREG/BR-0184.

3.3 Analysis

3.3.1 Annual Dose Report to Workers

Nuclear power reactor licensees.

In implementing the regulatory action, nuclear power reactor licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $2,100 per nuclear power plant (20 hours x $105/hour) and $220,000 for the nuclear power industry (104 licensees x $2,100/licensee).

With respect to industry operation, there will be a savings from not having to provide unsolicited annual dose reports (NRC Form 5) to workers when their doses do not exceed 1 mSv (100 mrem). As discussed in the regulatory analysis for the proposed rule (71 FR 55382; September 22, 2006), the NRC estimated the annual savings to be $3,000 per nuclear power plant and $310,000 for the nuclear power industry ($3,000 x 104 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $77,000 ($3,000 x 25.50) and $8 million ($310,000 X 25.50), respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $41,000 ($3,000 x 13.77) and $4.3 million ($310,000 x 13.77), respectively.

In order to provide an estimate of the “hourly” burden reduction, the NRC performed the following analysis. The NRC estimates it will take 5 minutes (0.083 hour) for a licensee to

prepare an annual dose report for each worker. Using the 2004 data in NUREG-0713, it was determined that about 80 percent of the monitored individuals had an annual dose that did not exceed 1 mSv (100 mrem). It is further assumed that 90 percent of this population will not request an annual dose report. Assuming an average of 1,060 workers per nuclear power plant, the annual burden reduction from implementing the regulatory action is estimated to be 63 hours per nuclear power plant (1,060 workers x 0.083 hour x 0.8 x 0.9) and the total annual industry burden reduction is 6,600 hours (63 hours/licensee x 104 licensees).

REIRS materials licensees.

In implementing the regulatory action, REIRS materials licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 10 hours to revise the procedures for each of the 123 REIRS materials licensees. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $1,050 per licensee (10 hours x $105/hour) and $130,000 for all licensees in this category (123 licensees x $1,050/licensee).

With respect to industry operation, using the 2004 data in NUREG-0713, it was determined that 8,254 workers (about 70 percent of the monitored individuals) had an annual dose that did not exceed 1 mSv (100 mrem). Assuming these workers are equally distributed among the 123 licensees in this group, about 67 workers per licensee will not receive an annual dose report. It is further assumed that 90 percent of this population will not request an annual dose report (NRC Form 5). The NRC estimates a savings of $10 per worker not receiving a dose report. Thus, the estimated annual savings is $600 per licensee (67 workers/licensee x $10/worker x 0.9) and $74,000 for all licensees in this category ($600/licensee x 123 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings per licensee and for all licensees in this category are $9,000 ($600 x 14.9) and $1.1 million ($74,000 x 14.9),

respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings per licensee and for all licensees in this category are $7,000 ($670 x 10.6) and $780,000 ($74,000 x 10.6), respectively.

In order to provide an estimate of the "hourly" burden reduction, the NRC performed the following analysis. The NRC estimates it will take 5 minutes (0.083 hour) for a licensee to prepare an annual dose report for each worker. Assuming that 90 percent of the 67 workers per licensee will not request a dose report, the annual burden reduction from implementing the regulatory action is estimated to be 5 hours per licensee (67 workers x 0.083 hour x 0.9) and 620 hours for all licensees in this category (5 hours/licensee x 123 licensees).

Non-REIRS materials licensees.

In implementing the regulatory action, non-REIRS materials licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 10 hours to revise the procedures for each of the 21,692 non-REIRS materials licensees. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $1,050 per licensee (10 hours x $105/hour) and $23 million for all licensees in this category (21,692 licensees x $1,050/licensee).

With respect to industry operation, the NRC assumes 500,000 monitored workers, 21,692 non-REIRS licensees, 23 workers per licensee, and a savings of $10 for each worker who does not receive a dose report. In addition, the previously defined factor of 70 percent for REIRS materials licensees is used to estimate the fraction of workers who will not receive an annual dose report (NRC Form 5). Thus, 16 workers per licensee are assumed to not receive an annual dose report. It is further assumed that 90 percent of this population will not request an annual dose report. The estimated annual savings is $140 per licensee

(16 workers/licensee x $10/worker x 0.9) and $3 million for all licensees in this category ($140/licensee x 21,692 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings per licensee and for all licensees in this category are $2,000 ($140 x 14.9) and $45 million ($3 million x 14.9), respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings per licensee and for all licensees in this category are $1,500 ($140 x 10.6) and $32 million ($3 million x 10.6), respectively.

In order to provide an estimate of the "hourly" burden reduction, the NRC performed the following analysis. The NRC estimates it will take 5 minutes (0.083 hour) for a licensee to prepare an annual dose report for each worker. Assuming that 90 percent of the 16 workers per licensee will not request a dose report, the annual burden reduction from implementing the regulatory action is estimated to be 1.2 hours per licensee (16 workers x 0.083 hour x 0.9) and 26,000 hours for all licensees in this category (1.2 hours/licensee x 21,692 licensees). For NRC licensees only, the total annual burden reduction is estimated to be 5,300 hours (1.2 hours/licensee x 4,394 NRC licensees).

3.3.2 Definition of *Total Effective Dose Equivalent* (TEDE)

The costs and savings associated with the revised definition of TEDE are minimal. The revision clarifies that the TEDE is defined in terms of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). This revision eliminates the need for licensees to repeatedly request guidance from the NRC and, in some cases, to request a license amendment to clarify the definition.

3.3.3 Labeling Containers

The revision to 10 CFR 20.1905, “Exemptions to labeling requirements,” applies only to nuclear power reactor licensees. These licensees will incur one-time implementation costs to revise procedures. The NRC estimates it will take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $2,100 per licensee (20 hours x $105/hour) and $220,000 for the nuclear power industry (104 licensees x $2,100/licensee).

With respect to industry operation, as discussed in the regulatory analysis for the proposed rule (71 FR 55382; September 22, 2006), the NRC estimated an annual savings of $30,000 per nuclear power plant from using the exemption to labeling requirements for containers holding licensed material within a posted area. For the entire nuclear power industry, the NRC estimates a savings of $3.1 million (104 licensees x $30,000/licensee). For a flow of funds at a 3 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $770,000 ($30,000 x 25.50) and $79 million ($3.1 million x 25.50), respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $410,000 ($30,000 x 13.77) and $43 million ($3.1 million x 13.77), respectively.

In order to provide an estimate of the “hourly” burden reduction, the NRC performed the following analysis. Using an annual savings of $30,000 per nuclear power plant and a staff rate of $105 per hour, the annual burden reduction from implementing the regulatory action is estimated to be 290 hours per plant ($30,000/licensee ÷ $105/hour) and the total annual industry burden reduction is 30,000 hours (290 hours/licensee x 104 licensees).

3.3.4 Cumulative Occupational Radiation Dose

Nuclear power reactor licensees.

In implementing the regulatory action, nuclear power reactor licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $2,100 per nuclear power plant (20 hours x $105/hour) and $220,000 for the nuclear power industry (104 licensees x $2,100/licensee).

With respect to industry operation, there will be a savings from not having to obtain the records of cumulative occupational radiation dose (NRC Form 4) for a worker, unless these individuals are being authorized to receive a planned special exposure. As discussed in the regulatory analysis for the proposed rule (71 FR 55382; September 22, 2006), the NRC estimated the annual savings to be $8,500 per nuclear power plant and $880,000 for the nuclear power industry ($8,500 x 104 licensees). Based on NUREG-0713, each nuclear power plant will annually obtain the dose records for 230 workers. Also, based on public comment, the NRC assumes that each worker has previously worked for two other licensees and that these licensees will incur costs to provide the worker's dose record to the requesting nuclear power plant licensee. The average cost to each licensee to provide a dose record is estimated to be $10. Thus, the estimated savings from not having to obtain the dose records for each worker is $60 (($8,500/nuclear power plant ÷ 230 workers) + (2 x $10/licensee providing the dose record)).[1] The estimated annual savings is $14,000 per nuclear power plant ($60/worker x

[1] To simplify the expression of annual burden reduction (hours), the hours attributed to the requesting nuclear power plant and responding licensees are combined and attributed solely to the nuclear power plant.

230 workers) and $1.5 million for the nuclear power industry ($14,000 x 104 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $360,000 ($14,000 x 25.50) and $38 million ($1.5 million x 25.50), respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings per nuclear power plant and for the nuclear power industry are $190,000 ($14,000 x 13.77) and $21 million ($1.5 million x 13.77), respectively.

In order to provide an estimate of the "hourly" burden reduction, the NRC performed the following analysis. Using an annual savings of $14,000 per nuclear power plant and a staff rate of $105 per hour, the annual burden reduction from implementing the regulatory action is estimated to be 130 hours per plant ($14,000/licensee ÷ $105/hour) and the total annual industry burden reduction is 14,000 hours (130 hours/licensee x 104 licensees).

REIRS materials licensees.

In implementing the regulatory action, REIRS materials licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 10 hours to revise the procedures for each of the 123 REIRS materials licensees. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $1,050 per licensee (10 hours x $105/hour) and $130,000 for all licensees in this category (123 licensees x $1,050/licensee).

With respect to industry operation, using the 2004 data in NUREG-0713, the number of individuals working for REIRS materials licensees is 12,032. Assuming these workers are equally distributed among the 123 licensees in this group, there are about 98 workers per licensee. For this analysis, the NRC assumes that 20 percent of all workers will be affected and that 0.5 hours is required by each REIRS materials licensee (i.e., the requesting licensee) to complete, review, and authorize each NRC Form 4, "Cumulative Occupational Dose History.

Based on public comment, the NRC assumes that each worker has previously worked for two other licensees and that these licensees will incur costs to provide the worker's dose record to the requesting licensee. The average cost to each licensee to provide a dose record is estimated to be $10. Using a staff rate of $105 per hour for the requesting licensee, the estimated savings from not having to request the dose records (including the responses) for each worker is $75 (($105/hour x 0.5 hour/licensee requesting the dose record) + (2 x $10/licensee providing the dose record)).[2] The NRC is not aware of any licensee having authorized a planned special exposure. For this analysis, it is assumed that 99 percent of the NRC Forms 4 will not be needed as the basis for authorizing a planned special exposure. Thus, the estimated annual savings to industry is $180,000 (98 workers/licensee x $75/worker x 0.2 x .99 x 123 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings for industry is $2.7 million ($180,000 x 14.9), respectively. For a flow of funds at a 7 percent real discount rate, the estimated savings for industry is $1.9 million ($180,000 x 10.6).

In order to provide an estimate of the "hourly" burden reduction, the NRC performed the following analysis. The annual burden reduction from implementing the regulatory action is estimated to be 10 hours per licensee ((98 workers/licensee x 0.5 hour/worker x 0.2 x 0.99) + (2 x 0.10 hour/licensee providing the dose record)) and 1,200 hours for industry (10 hours/licensee x 123 licensees).

Non-REIRS materials licensees.

In implementing the regulatory action, non-REIRS materials licensees will incur a one-time cost to revise procedures. The NRC estimates it will take 10 hours to revise the

[2] To simplify the expression of annual burden reduction (hours), the hours attributed to the requesting REIRS materials licensee and responding licensees are combined and attributed solely to the REIRS materials licensee.

procedures for each of the 21,692 non-REIRS materials licensees. Assuming a staff rate of $105 per hour, the one-time cost of implementing the regulatory action will be $1,050 per licensee (10 hours x $105/hour) and $23 million for all licensees in this category (21,692 licensees x $1,050/licensee).

With respect to industry operation, the analysis assumes 500,000 individuals working under 21,692 non-REIRS licensees and an even distribution of workers per licensee (23 workers/licensee). The NRC also assumes that 20 percent of all workers will be affected and that 0.5 hours is required to complete, review, and authorize each NRC Form 4. Based on public comment, the NRC assumes that each worker has previously worked for two other licensees and that these licensees will incur costs to provide the worker's dose record to the requesting licensee. The average cost to each licensee to provide a dose record is estimated to be $10. Using a staff rate of $105 per hour for the requesting licensee, the estimated savings from not having to request the dose records (including the responses) for each worker is $75 (($105/hour x 0.5 hour/licensee requesting the dose record) + (2 x $10/licensee providing the dose record)).[3] The NRC is not aware of any licensee having authorized a planned special exposure. For this analysis, it is assumed that 99 percent of the NRC Forms 4 will not be needed as the basis for authorizing a planned special exposure. Thus, the estimated annual savings to industry is $7.4 million (23 workers/licensee x $75/worker x 0.2 x .99 x 21,692 licensees). For a flow of funds at a 3 percent real discount rate, the estimated savings for industry is $110 million ($7.4 million x 14.9). For a flow of funds at a 7 percent real discount rate, the estimated savings for industry is $78 million ($7.4 million x 10.6).

In order to provide an estimate of the "hourly" burden reduction, the NRC performed the following analysis. The annual burden reduction from implementing the regulatory action is

[3] To simplify the expression of annual burden reduction (hours), the hours attributed to the requesting non-REIRS materials licensee and responding licensees are combined and attributed solely to the non-REIRS materials licensee.

estimated to be 2.5 hours per licensee ((23 workers/licensee x 0.5 hour/worker x 0.2 x 0.99) + (2 x 0.10 hour/licensee providing the dose record)) and 54,000 hours for industry (2.5 hours/licensee x 21,692 licensees). For NRC licensees only, the total annual burden reduction is estimated to be 11,000 hours (2.5 hours/licensee x 4,394 NRC licensees).

3.3.5 NRC Implementation and Operating Impacts

Annual dose report to workers.

The NRC will incur costs to make minor revisions to NRC Form 3, “Notice to Employees,” to account for the revision to the reporting of annual dose to workers under 10 CFR 19.13(b). The one-time cost for this task is estimated to be $34,000 (320 staff-hours at $105 per hour). This is the only impact to the NRC for this action.

Definition of Total Effective Dose Equivalent (TEDE)

The NRC will incur costs to make minor revisions to NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” and their instructions, to account for the revision to the definition of TEDE. The one-time cost to revise NRC Forms 4 and 5 and their instructions is estimated to be $34,000 (320 staff-hours at $105 per hour). This is the only impact to the NRC for this action.

Labeling Containers

The NRC will incur no implementation or operating impacts due to the revision to the exemptions to labeling requirements for containers holding licensed material under 10 CFR 20.1905.

Cumulative Occupational Radiation Dose

The NRC will incur no implementation impacts due to the revision to remove the requirement that licensees attempt to obtain cumulative occupational radiation dose records for workers unless these individuals are being authorized to receive a planned special exposure.

With respect to NRC operation, there will be a savings from not having inspectors review the information on NRC Form 4, or its equivalent, and supporting records maintained by licensees. For nuclear power reactor licensees, it is estimated that 1 hour of inspection time is spent reviewing such records at each of the 104 nuclear power plants. Assuming an NRC staff rate of $105 per hour, the estimated annual savings to the NRC is $11,000 (1 hour x 104 licensees x $105/hour). For a flow of funds at 3 and 7 percent real discount rates, the estimated savings to the NRC are $280,000 ($11,000 x 25.50) and $150,000 ($11,000 x 13.77), respectively. The annual burden reduction to the NRC from implementing the regulatory action is estimated to be 104 hours (1 hour x 104 licensees).

For each of the 123 REIRS materials licensees, it is estimated that 6 minutes (0.1 hour) of inspection time is spent reviewing NRC Form 4, or its equivalent, and supporting records. The NRC is not aware of any licensee having authorized a planned special exposure. For this analysis, it is assumed that 99 percent of the NRC Forms 4 will not need to be inspected as the basis for authorizing a planned special exposure. Assuming an NRC staff rate of $105 per hour, the estimated annual savings to the NRC is $1,300 (0.1 hour x 123 licensees x $105/hour x 0.99). For a flow of funds at 3 and 7 percent real discount rates, the estimated savings to the

NRC are $19,000 ($1,300 x 14.9) and $14,000 ($1,300 x 10.6), respectively. The annual burden reduction to the NRC from implementing the regulatory action is estimated to be 12 hours (0.1 hour x 123 licensees x 0.99).

For each of the 4,394 NRC licensees designated as non-REIRS materials licensees, it is estimated that 6 minutes (0.1 hour) of inspection time is spent reviewing NRC Form 4, or its equivalent, and supporting records. As discussed above, it is assumed that 99 percent of the NRC Forms 4 will not need to be inspected as the basis for authorizing a planned special exposure. Assuming an NRC staff rate of $105 per hour, the estimated annual savings to the NRC is $46,000 (0.1 hour x 4,394 licensees x $105/hour x 0.99). For a flow of funds at 3 and 7 percent real discount rates, the estimated savings to the NRC are $685,000 ($46,000 x 14.9) and $490,000 ($46,000 x 10.6), respectively. The annual burden reduction to the NRC from implementing the regulatory action is estimated to be 435 hours (0.1 hour x 4,394 licensees x 0.99).

3.3.6 Other Government Implementation and Operating Impacts

The Agreement States will incur no implementation or operating impacts due to the revisions to the reporting of annual dose to workers, the definition of TEDE, or the labeling of containers holding licensed material. For the revisions to the reporting of annual dose to workers and the definition of TEDE, the only impacts are to the NRC to revise NRC Forms 3, 4, and 5. Also, because the revision to the labeling of containers applies only to nuclear power plants licensed by the NRC, there are no impacts to the Agreement States for this action.

Cumulative Occupational Radiation Dose

For each of the 17,298 Agreement State licensees designated as non-REIRS materials licensees, it is estimated that 6 minutes (0.1 hour) of inspection time is spent reviewing NRC Form 4, or its equivalent, and supporting records. As discussed above, it is assumed that 99 percent of the NRC Forms 4 will not need to be inspected as the basis for authorizing a planned special exposure. Assuming an Agreement State staff rate of $105 per hour, the estimated annual savings to the Agreement States is $180,000 (0.1 hour x 17,298 licensees x $105/hour x 0.99). For a flow of funds at 3 and 7 percent real discount rates, the estimated savings to the Agreement States are $2.7 million ($180,000 x 14.9) and $1.9 million ($180,000 x 10.6), respectively. The annual burden reduction to the Agreement States from implementing the regulatory action is estimated to be 1,700 hours (0.1 hour x 17,298 licensees x 0.99).

4. Presentation of Results

Because each revision to the Commission's regulations will reduce burden on licensees, which is the objective of this rulemaking, the costs and benefits have been aggregated for this analysis. The results of the NRC's value-impact assessment for industry implementation and operation are summarized in the following table.

Table 1. Summary of Industry Implementation and Operating Savings (Costs)				
Final Regulatory Action	Licensee Category	Implementation Savings (Costs) ($1,000)	Operating Savings (Costs)	
			Using 7 Percent Discount Rate ($1,000)	Using 3 Percent Discount Rate ($1,000)
Annual Dose Report to Workers	Nuclear power reactor	(220)	4,300	8,000
	REIRS materials	(130)	780	1,100
	Non-REIRS materials	(23,000)	32,000	45,000
TEDE	Nuclear power reactor	n/a	minimal	minimal
	REIRS materials	n/a	minimal	minimal
	Non-REIRS materials	n/a	minimal	minimal
Labeling Containers	Nuclear power reactor	(220)	43,000	79,000
	REIRS materials	n/a	n/a	n/a
	Non-REIRS materials	n/a	n/a	n/a
Cumulative Occupational Radiation Dose	Nuclear power reactor	(220)	21,000	38,000
	REIRS materials	(130)	1,900	2,700
	Non-REIRS materials	(23,000)	78,000	110,000
SUBTOTALS	Nuclear power reactor	(660)	68,300	125,000
	REIRS materials	(260)	2,680	3,800
	Non-REIRS materials	(46,000)	110,000	155,000
TOTAL (rounded)		(47,000)	180,000	280,000

The results of the NRC's value-impact assessment for NRC implementation and operation are summarized in the following table.

Table 2. Summary of NRC Implementation and Operating Savings (Costs)				
Final Regulatory Action	Licensee Category	Implementation Savings (Costs) ($1,000)	Operating Savings (Costs)	
			Using 7 Percent Discount Rate ($1,000)	Using 3 Percent Discount Rate ($1,000)
Annual Dose Report to Workers	Nuclear power reactor	(34)	n/a	n/a
	REIRS materials			
	Non-REIRS materials			
TEDE	Nuclear power reactor	(34)	n/a	n/a
	REIRS materials			
	Non-REIRS materials			
Labeling Containers	Nuclear power reactor	n/a	n/a	n/a
	REIRS materials			
	Non-REIRS materials			
Cumulative Occupational Radiation Dose	Nuclear power reactor	n/a	150	280
	REIRS materials		14	19
	Non-REIRS materials		490	685
TOTAL (rounded)		(68)	650	980

The results of the NRC's value-impact assessment for Agreement States implementation and operation are summarized in the following table.

Table 3. Summary of Agreement States Implementation and Operating Savings (Costs)			
Final Regulatory Action	Implementation Savings (Costs) ($1,000)	Operating Savings (Costs)	
		Using 7 Percent Discount Rate ($1,000)	Using 3 Percent Discount Rate ($1,000)
Annual Dose Report to Workers	n/a	n/a	n/a
TEDE	n/a	n/a	n/a
Labeling Containers	n/a	n/a	n/a
Cumulative Occupational Radiation Dose	n/a	1,900	2,700
TOTAL (rounded)	n/a	1,900	2,700

The results of the NRC's assessment of annual burden reduction in hours per licensee and industry are summarized in the following table.

Table 4. Summary of Annual Burden Reduction per Licensee and Industry			
Final Regulatory Action	Licensee Category	Annual Burden Reduction (hours)	
		Licensee	Industry
Annual Dose Report to Workers	Nuclear power reactor	63	6,600
	REIRS materials	5	620
	Non-REIRS materials	1.2	26,000
TEDE	Nuclear power reactor	n/a	n/a
	REIRS materials	n/a	n/a
	Non-REIRS materials	n/a	n/a
Labeling Containers	Nuclear power reactor	290	30,000
	REIRS materials	n/a	n/a
	Non-REIRS materials	n/a	n/a
Cumulative Occupational Radiation Dose	Nuclear power reactor	130	14,000
	REIRS materials	10	1,200
	Non-REIRS materials	2.5	54,000
SUBTOTALS	Nuclear power reactor	483	50,600
	REIRS materials	15	1,820
	Non-REIRS materials	3.7	80,000
TOTAL (rounded)		500	130,000

The results of the NRC's assessment of annual burden reduction in hours per NRC and Agreement States are summarized in the following table.

Table 5. Summary of Annual Burden Reduction per NRC and Agreement States		
Final Regulatory Action	Annual Burden Reduction (hours)	
	NRC	Agreement States
Annual Dose Report to Workers	n/a	n/a
TEDE	n/a	n/a
Labeling Containers	n/a	n/a
Cumulative Occupational Radiation Dose	550	1,700
TOTAL	550	1,700

The total implementation cost to the NRC for the regulatory action is $68,000. The total operating impact to the NRC for a flow of funds at 3 and 7 percent real discount rates is an estimated savings of $980,000 and $650,000, respectively.

There are no implementation impacts to the Agreement States for the regulatory action. The total operating impact to the Agreement States for a flow of funds at 3 and 7 percent real discount rates is an estimated savings of $2.7 million and $1.9 million, respectively.

The net present value of the regulatory action is $237 million at a 3 percent real discount rate [industry operation ($280 million) + NRC operation ($980,000) + Agreement State Operation (2.7 million)] - [NRC implementation ($68,000) + industry implementation ($47 million)]. The net present value of the regulatory action is $135 million at a 7 percent real discount rate [industry operation ($180 million) + NRC operation ($650,000) + Agreement State Operation (1.9 million)] - [NRC implementation ($68,000) + industry implementation ($47 million)].

The total reduction in annual burden from implementing the regulatory action is estimated to be 132,000 hours [industry (130,000 hours) + NRC (550 hours) + Agreement States (1,700 hours)].

5. Decision Rationale

The net present value of this regulatory action is $237 million and $135 million for 3 and 7 percent real discount rates, respectively. The total industry reduction in annual burden from implementing the regulatory action is estimated to be 132,000 hours. These savings are obtained by reducing administrative and information collection requirements on licensees. The Commission is implementing this rule because the changes improve the effectiveness of the Commission's regulations and reduce unnecessary regulatory burden without affecting the level of protection for either the health and safety of workers and the public or for the environment.

6. Implementation Schedule

The final rule will become effective 30 days after its publication in the *Federal Register*. No impediments to the implementation of the recommended alternative have been identified.

XI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact upon a substantial number of small entities. Although three of the changes (i.e., the reporting of annual dose to workers, the definition of TEDE, and the determination of cumulative occupational radiation dose) in the final rule pertain to all 21,692 licensees regulated by the NRC and Agreement States, licensees, including the affected small entities, could elect to continue their current practices and remain in compliance with the final regulations. Licensees will incur the costs of changing their procedures only if they determine that the changes will be cost effective; therefore, the NRC

has determined that the changes will not have a significant economic impact on licensees defined as small entities. The change related to labeling containers affects only licensees authorized to operate nuclear power reactors. These licensees do not fall within the scope of the definition of “small entities” in the Regulatory Flexibility Act or the scope of the size standards established by the NRC in 10 CFR 2.810.

XII. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this rule and that a backfit analysis is not required for this rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 19, 20, and 50.

PART 19—NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

1. The authority citation for Part 19 continues to read as follows:

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

2. In § 19.13, paragraphs (b) and (d) are revised to read as follows:

§ 19.13 Notifications and reports to individuals.

* * * * *

(b) Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

* * * * *

(d) When a licensee is required by §§ 20.2202, 20.2203 or 20.2204 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Commission. This report must be transmitted no later than the transmittal to the Commission.

* * * * *

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

3. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073,

2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

4. In § 20.1003, the definition of *Total Effective Dose Equivalent* is revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

* * * * *

5. In § 20.1201, paragraph (c) is revised to read as follows:

§ 20.1201 Occupational dose limits for adults.

* * * * *

(c) When the external exposure is determined by measurement with an external personal monitoring devise, 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. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating

compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

* * * * *

6. In § 20.1905, paragraph (f) is revised and paragraph (g) is added to read as follows:

<u>§ 20.1905 Exemptions to labeling requirements.</u>

* * * * *

(f) Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or

(g) Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed under parts 50 or 52 of this chapter, not including non-power reactors, that are within an area posted under the requirements in § 20.1902 if the containers are:

(1) Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard;

(2) Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and

(3) Subject to plant procedures to ensure they are appropriately labeled, as specified at § 20.1904 before being removed from the posted area.

7. In § 20.2104, paragraph (a), the introductory text of paragraph (c), and paragraph (d) are revised to read as follows:

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive an annual occupational dose requiring monitoring under § 20.1502, the licensee shall determine the occupational radiation dose received during the current year.

* * * * *

(c) In complying with the requirements of paragraphs (a) or (b) of this section, a licensee may—

* * * * *

(d) The licensee shall record the exposure history of each individual, as required by paragraphs (a) or (b) of this section, on NRC Form 4, or other clear and legible record, including all of the information required by NRC Form 4[4]. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the NRC Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on the NRC Form 4 indicating the periods of time for which data are not available.

* * * * *

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[4] Licensees are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on NRC Form 4 before January 1, 1994, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

8. Section 20.2205 is revised to read as follows:

§ 20.2205 Reports to individuals of exceeding dose limits.

When a licensee is required by §§ 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to Commission. This report must be transmitted no later than the transmittal to the Commission.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

9. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat.

2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80--50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

10. In § 50.2, the definition of *Total Effective Dose Equivalent* is revised to read as follows:

§ 50.2 Definitions.

* * * * *

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

* * * * *

Dated at Rockville, Maryland, this XXX day of XXXXX, 2007.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary for the Commission.

Enclosure 2

CRGR Appendix C Responses

**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)**

**APPENDIX C TO THE
COMMITTEE TO REVIEW GENERIC REQUIREMENTS (CRGR) CHARTER**

(I) The final generic requirement or staff position as modified based on public comments on the proposed rule.

The final rule revises 10 CFR 19.13, "Notifications and reports to individuals," 10 CFR 20.1905, "Exemptions to labeling requirements," 10 CFR 20.2104, "Determination of prior occupational dose," and the definition of *Total Effective Dose Equivalent* in 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions." This final rule limits the routine reporting of annual doses to workers to those whose annual dose exceeds a specific dose threshold or who request a report. This final rule also amends the definition of TEDE to be consistent with current Commission policy. This final rule also modifies the labeling requirements for certain containers holding licensed material within posted areas in nuclear power facilities. Finally, this rule removes the requirement that licensees attempt to obtain cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure. 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.

The NRC issued the proposed rule on September 22, 2006 (71 FR 55382). 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.

(ii) Draft papers or other documents supporting the requirements or staff positions. (A copy of all materials referenced in the document shall be made available upon request to the CRGR staff. Any Committee member may request the CRGR staff to obtain a copy of any reference material for his or her use.)

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 meet this goal. In SRM-SECY-02-0081 dated June 25, 2002, the Commission approved, subject to certain comments, the staff's proposal of reducing unnecessary regulatory burden on power reactor licensees by initiating and developing proposed rulemakings arising from short-term, limited scope initiatives without formal rulemaking plans.

As part of the development of the proposed rule, the staff drafted proposed 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 of 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). The majority of comment letters supported NRC's approach.

(iii) Each final requirement or staff position shall contain the sponsoring office's position as to whether the requirement will modify requirements or staff positions, implement existing requirements or staff positions, or will relax or reduce existing requirements or staff positions.

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.

10 CFR 19.13, Notifications and reports to individuals. 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.

Conforming changes would be made to 10 CFR 19.13(d) and 10 CFR 20.2205, "Reports to individuals of exceeding dose limits." The proposed rule does not change the current requirements for recordkeeping or for reporting to the NRC. The final revision will reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

10 CFR 20.1003, Definitions, and 10 CFR 50.2, Definitions. 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.

10 CFR 20.1905, “Exemptions to labeling requirements. 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. This revision will reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers.

10 CFR 20.2104, “Determination of prior occupational 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. This revision will reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

(iv) The final method of implementation and resource implications, along with the concurrence (and any comments) of OGC on the method proposed, and the concurrence of all affected program offices or an explanation of any non-concurrences.

The method of implementation is rulemaking. The resources needed to complete the final rule were 1.1 FTE, about 0.6 FTE in FY 2006 and 0.5 FTE in FY 2007. These resources were included in the current budget.

All affected program offices have concurred here in. The NRC's Office of the General Counsel (OGC) has no legal objection to the final rulemaking, and the NRC staff incorporated OGC's comments into the final rule.

(v) Regulatory analyses generally conforming to the directives and guidance of NUREG/BR-0058 and NUREG/BR-0184, as applicable. (This does not apply for backfits that ensure compliance or ensure, define, or re-define adequate protection. For power reactors, a documented evaluation is required as discussed under item (ix) of this Appendix.)

The staff has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the staff. The regulatory analysis is included in the *Federal Register* Notice for the final rule.

(vi) Identification of the category of power reactors to which the generic requirement or staff position is to apply (that is, whether it is only applicable to future plants, operating plants, all pressurized water reactors (PWRs), all boiling water reactors (BWRs), specific nuclear steam supply system (NSSS) vendor types, plants of specific vintage, gaseous diffusion plants (GDPs), etc.)

The final revisions to 10 CFR 19.13, 20.1003, 20,2104, 20.2205 and 50.2 will apply to all NRC licensees. The final revision to 10 CFR 20.1905 will apply only to 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."

(vii) For proposed backfits, other than either the compliance or the adequate protection backfits, a backfit analysis as defined in the Backfit Rule (10 CFR 50.109 for power reactors and 10 CFR 76.76 for the GDPs) should be performed. The backfit analysis shall include, for each category of nuclear power reactor or nuclear materials facility or activity, an evaluation which demonstrates how the proposed action should be prioritized and scheduled in light of other ongoing regulatory activities. The backfit analysis shall document for consideration pertinent information available concerning any of the following factors, as appropriate, and any other information, which is relevant and material to the proposed action:

(a) Statement of the specific objectives that the proposed action is intended to achieve;

(b) General description of the activity that the licensee or applicant would be required to perform in order to complete the action;

(c) Potential change in the risk to the public from the accidental offsite release of radioactive material;

(d) Potential impact on radiological exposure of facility employees and other onsite workers;

(e) Installation and continuing costs associated with the action, including the cost of facility downtime or the cost of construction delay;

(f) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements and staff positions;

(g) The estimated resource burden on the NRC associated with the proposed action and the availability of such resources;

(h) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed action;

(I) Whether the proposed action is interim or final, and if interim, the justification for imposing the proposed action on an interim basis;

(j) For both rulemaking actions and proposed generic correspondence, staff evaluation of comments received as a result of the notice and comment process;

(k) How the action should be prioritized and scheduled in light of other ongoing regulatory activities. The following information may be appropriate in this regard:

The proposed priority or schedule,

A summary of the current backlog of existing requirements awaiting implementation,

An assessment of whether implementation of existing requirements should be deferred as a result, and

Any other information that may be considered appropriate with regard to priority, schedule, or cumulative impact. For example, could implementation be delayed pending public comment?

The NRC staff believes that the backfit rule does not apply to this final rule because these amendments do not involve any provision that imposes backfits as defined in 10 CFR Chapter I. The final revisions do not impose new requirements on NRC licensees. These revisions either maintain without substantive change existing

requirements or reduce current regulatory requirements. Therefore, a backfit analysis is not required for this final rule.

(viii) For each proposed backfit analyzed pursuant to 10 CFR 50.109(a)(2), 10 CFR 72.62(c), or 10 CFR 76.76(a)(3), (i.e., for backfits other than either adequate protection backfits or compliance backfits), the proposing office director's determination, together with the rationale for the determination based on the consideration of the previous paragraphs (I) through (vii), that

(a) a substantial increase in the overall protection of public health and safety or the common defense and security will be derived from the proposal; and

(b) the direct and indirect costs of implementation for the facilities affected are justified in view of this increased protection.

The Commission has determined that the backfit rule does not apply to this final rule because these amendments do not involve any provision that imposes backfits as defined in 10 CFR Chapter I. The final revisions do not impose new requirements on NRC licensees. These revisions either maintain without substantive change existing requirements or reduce current regulatory requirements. Therefore, a backfit analysis is not required for this final rule.

(ix) For adequate protection or compliance backfits affecting power reactors, evaluated pursuant to 10 CFR 50.109(a)(4) (or analogous provisions in 10 CFR 72.62 or 10 CFR 76.76, as appropriate),

(a) A documented evaluation consisting of:

(1) the objectives of the modification
(2) the reasons for the modification
(3) if the compliance exception is invoked,

(A) the requirements (e.g., Commission regulation, license condition, order) or written licensee commitments, for which compliance is sought.

(B) an assessment of risk/safety implications of not requiring licensees to immediately restore compliance, and the basis for determination that a reasonable concession could be allowed to defer restoration of compliance at a later time (e.g., next refueling outage).

(C) demonstrated consideration of other possible alternatives and rationale for rejecting them in favor of compliance backfitting.

(D) evaluation from cost-benefit considerations (not a full-blown regulatory analysis) and a rationale for compliance exception.

(4) If the adequate protection exception is invoked, the basis for concluding that the matter to be addressed involves adequate protection, and why current requirements (e.g., Commission regulation, license condition, order) or written licensee commitments do not provide adequate protection.

(b) In addition, for actions that were immediately effective (and therefore issued without prior CRGR review as discussed in Section III of the CRGR Charter), the evaluation shall document the safety significance and appropriateness of the action taken and (if applicable) consideration of how costs contributed to selecting the solution among various acceptable alternatives.

The Commission has determined that the backfit rule does not apply to this final rule because these amendments do not involve any provision that imposes backfits as defined in 10 CFR Chapter I. The final revisions do not impose new requirements on NRC licensees. These revisions either maintain without substantive change existing requirements or reduce current regulatory requirements. Therefore, a backfit analysis is not required for this final rule.

(x) For each request for information from power reactor licensees under 10 CFR 50.54(f), which is for purposes other than to verify compliance with the facility's licensing basis, an evaluation that includes at least the following elements:

(a) A problem statement that describes the need for the information in terms of potential safety benefit.

(b) The licensee actions required and the cost to develop a response to the information request.

(c) An anticipated schedule for NRC use of the information.

(d) A statement affirming that the request does <u>not</u> impose new requirements on the licensee, other than submittal of the requested the information.

(e) The proposing office director's determination that the burden to be imposed on the respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information.

Under the provisions of 10 CFR 50.54(f), unless the request for information is for the purpose of verifying compliance with the licensing basis of a facility, the EDO shall approve the staff's justification. Additional guidance for preparing this evaluation is provided in Section 5.4 of NUREG/BR-0058, Revision 2.

Include an analogous evaluation addressing items (a) through (e) for each information request directed to the licensees of the selected nuclear materials facilities or referred to in Section III of the CRGR Charter.

This item is not applicable under 10 CFR 50.54(f) because the final revisions reduce the administrative and information collection burdens on licensees without affecting the level of protection to either the health and safety of workers and the public or the environment and does not request information from licensees.

(xi) **For each proposed power reactor backfit analyzed pursuant to 10 CFR 50.109(a)(2) (i.e., backfits other than either adequate protection or compliance backfits), an assessment of how the proposed action relates to the Commission's Safety Goal Policy Statement.**

The Commission has determined that the backfit rule does not apply to this final rule because these amendments do not involve any provision that imposes backfits as defined in 10 CFR Chapter I. The final revisions do not impose new requirements on NRC licensees. These revisions either maintain without substantive change existing requirements or reduce current regulatory requirements. Therefore, a backfit analysis is not required for this final rule.