February 28, 2006

MEMORANDUM TO: Sher Bahadur, Chairman
Committee to Review Generic Requirements

FROM: R. William Borchardt, Deputy Director ***/RA/***
Office of Nuclear Reactor Regulation

SUBJECT: REQUEST TO DEFER CRGR REVIEW OF PROPOSED RULEMAKING TO AMEND 10 CFR PARTS 19, 20 AND 50, "COLLECTING AND REPORTING OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS, AND REDEFINING THE QUANTITY TOTAL EFFECTIVE DOSE EQUIVALENT

The Office of Nuclear Reactor Regulation staff has prepared a proposed rulemaking to reduce unnecessary regulatory burden in 10 CFR Parts 19, 20, and 50. This rulemaking would (1) amend the provisions of 10 CFR 19.13, "Notifications and reports to individuals," to require that licensees provide routine annual occupational dose reports to individuals only when the annual dose exceeds 1 mSv (100 mrem) or when the individual requests the report; (2) 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 by clarifying that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures); (3) revise 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption for the labeling of containers holding licensed material within posted areas in nuclear power facilities; and (4) remove the requirement in 10 CFR 20.2104, "Determination of prior occupational dose," to attempt to obtain the records of cumulative occupational radiation doses for all individuals requiring monitoring under 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose." These revisions are intended to reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

The staff is requesting to defer CRGR review of the proposed rule until after the public comment period has ended and the staff has considered any public comments received. This request is to support the schedule to issue the proposed rule for comment before the end of May 2006. In support of this request, it is noted that this rulemaking does not involve a backfit and the draft rule language was issued previously (69 FR 8350; February 24, 2004) to solicit public comment. Eight comment letters were received and they are addressed in the enclosed *Federal Register* notice. The Commission paper for the proposed rule is also enclosed for your information.

Enclosure: As stated

cc: L. Cupidon

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

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Enclosures: As stated

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DATE	12/21/2005		12/21/2005		02/24/2006		02/28/2006	

OFFICIAL RECORD COPY

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

The staff has prepared a proposed rulemaking to (1) amend the provisions of 10 CFR 19.13, “Notifications and reports to individuals,” to require that licensees provide annual occupational dose reports to individuals only when the annual dose exceeds 1 mSv (100 mrem) or when the individual requests the report (conforming changes would be made to 10 CFR 19.13(d) and 10 CFR 20.2205, “Reports to individuals of exceeding dose limits”); (2) amend the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003, “Definitions,” and 10 CFR 50.2, “Definitions,” to be consistent with current Commission policy by clarifying that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose

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equivalent (for internal exposures); (3) revise 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption for the labeling of certain containers holding licensed material within posted areas in nuclear power facilities; and (4) remove the requirement in 10 CFR 20.2104, "Determination of prior occupational dose," to attempt to obtain the records of cumulative occupational radiation doses for all individuals requiring monitoring under 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose." These revisions are intended to reduce administrative and paperwork burdens on NRC and Agreement licensees without affecting the level of protection to either the health and safety of workers and the public or the environment.

BACKGROUND:

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

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

DISCUSSION:

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

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

(1) Annual Dose Report to Workers

The first proposed change would revise 10 CFR 19.13. The staff is proposing a change to the notification requirement in 10 CFR 19.13(b) so that licensees would continue the current reporting for occupationally exposed individuals who annually exceed a dose of 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue. However, licensees would not be required to provide unsolicited annual dose reports to individuals when neither the TEDE nor the dose to any individual organ or tissue exceeds 1 mSv (100 mrem). Individuals would still be provided with their dose reports upon request. The staff selected the criterion of 1 mSv (100 mrem) because it corresponds to the

occupational dose threshold for requiring instruction to workers under 10 CFR 19.12, "Instruction to workers." NRC Form 3, "Notice to Employees," will also need to be revised to reflect the changes to the requirements for reporting doses to individuals if this rule is enacted. The proposed amendment would not change the current requirements for recordkeeping or reporting to the Commission.

Under the current provisions in 10 CFR 19.13(d) and 20.2205, licensees are required by the reference to 10 CFR 20.2206, "Reports of individual monitoring," to provide an annual dose report to each individual for whom the report was submitted to the Commission. In addition, the current provision in 10 CFR 19.13(b) requires licensees to advise each worker annually of the workers's dose. To improve regulatory efficiency, the proposed rule would remove the reference to 10 CFR 20.2206 in 10 CFR 19.13(d) and 20.2205, and the requirement to report annual dose to the individual would be consolidated into a single requirement in 10 CFR 19.13(b).

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

The second proposed change would revise the definition of TEDE in 10 CFR 20.1003 and 50.2. The purpose of this revision is to clarify and make the definition of TEDE consistent with Commission policy as discussed in Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," dated April 16, 2002, and subsequently clarified in RIS 2003-04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," dated February 13, 2003, and RIS 2004-01, "Method for Estimating Effective Dose Equivalent From External Radiation Sources Using Two Dosimeters," dated February 17, 2004. This policy allows the use of the effective dose equivalent in place of the deep dose equivalent, for exposure situations.

The proposed amendment would clarify that the TEDE is defined primarily in terms of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). In situations involving dose measurements, licensees may use the deep dose equivalent as a surrogate for the effective dose equivalent. When deep-dose equivalent is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(i), the requirement in 10 CFR 20.1201(c) to determine the deep-dose equivalent for the part of the body receiving the highest exposure will still apply. The revised definition of TEDE does not require licensees to change current procedures unless the licensee decides to use the proposed change to the definition.

(3) Labeling Containers

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

Under the proposed revision, nuclear power reactor licensees 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 accessible only to individuals who have sufficient instructions to minimize radiation exposure while handling or working in the vicinity of the containers. However, the proposed revision would require the container to be appropriately labeled under the requirements of 10 CFR 20.1904 before being removed from the posted area.

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

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

(4) Cumulative Occupational Radiation Dose

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

AGREEMENT STATE ISSUES:

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

Regarding the proposed amendment of the requirements in 10 CFR Parts 19 and 20 that licensees provide annual radiation exposure reports to individuals receiving exposures below the occupational dose limits, the State of Washington stated that the reporting threshold should be 10 percent of the dose limit. No opposing comments were received on the proposed change to clarify the definition of TEDE in 10 CFR 20.1003 and 50.2. The State of Washington commented that the proposed revision of the requirements in 10 CFR 20.1904, for the labeling

of containers within posted areas in nuclear power reactor facilities would be less confusing if the exemption was placed in Part 50. No opposing comments were received on the proposed revision of 10 CFR 20.2104 to eliminate the requirement that licensees attempt to obtain the records of cumulative occupational radiation doses for all individuals. The staff's response to these comments is presented in the enclosed *Federal Register* notice.

The staff has analyzed the proposed rule under the procedures in Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs." The staff has determined that the compatibility categories for the sections amended in this proposed rule would be the same as for the sections in the current regulations, except for the new exemption in paragraph (g) added to 10 CFR 20.1905. This exemption is classified as Compatibility Category NRC. A Compatibility Category NRC designation means the Agreement State should not adopt the requirement. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act or provisions of 10 CFR regulations.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the proposed amendments to 10 CFR Parts 19, 20, and 50 (Enclosure).

2. Certify that, based on the information currently available, the proposed rule, if adopted, is not likely to have a significant economic impact on a substantial number of small entities.

3. Note—

    a. That the proposed amendments will be published in the *Federal Register* with 75 days for public comment.

    b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

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

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

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

    f. That the proposed rule amends information collection requirements; therefore, an Office of Management and Budget information collection clearance package is required.

RESOURCES:

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

COORDINATION:

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

Luis A. Reyes
Executive Director
for Operations

Enclosure: As stated

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, and 50

RIN 3150 - AH40

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is proposing to amend its regulations related to the reporting of annual dose to workers, the definition of the quantity total effective dose equivalent (TEDE), the labeling of certain containers holding licensed material, and the determination of cumulative occupational radiation dose. The proposed rule would limit the routine reporting of annual doses to workers to those whose annual dose exceeds a specific dose threshold. The proposed rule would also amend the definition of TEDE to clarify that it is consistency with current Commission policy. The proposed rule would also modify the labeling requirements for certain containers holding licensed material within posted areas in nuclear power facilities. Finally, the proposed rule would remove the requirement to attempt to obtain cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure. These revisions would reduce administrative and paperwork 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.

DATES: Submit comments on the rule by (INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*). Submit comments on the information collection aspects of this rule by (INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*). Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.

ADDRESSES: You may submit comments by any of the one of the following methods. Please include the following number RIN 3150-AH40 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If yo do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking web site to Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White

Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publically available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/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, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 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. Public Comments in Response to the *Federal Register* Notice

IV. Agreement State Comments on the Draft Rule Language

V. Section-by-Section Analysis of Substantive Changes

VI. Agreement State Compatibility

VII. Availability of Documents

VIII. Plain Language

IX. Voluntary Consensus Standards

X. Environmental Impact: Categorical Exclusion

XI. Paperwork Reduction Act Statement

XII. Regulatory Analysis

XIII. Regulatory Flexibility Certification

XIV. Backfit Analysis

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 published a notice of a public workshop and a request for comments in the *Federal Register* (66 FR 22134; May 3, 2001). The notice indicated that the workshop would focus on three areas associated with reducing unnecessary regulatory burden: (1) risk informing portions of 10 CFR Part 50, (2) reforming outdated or paperwork oriented regulations, and (3) seeking unnecessary burden reduction in other regulatory requirements (e.g., technical specifications). The NRC also asked stakeholders to comment on the priority of the candidates for reducing unnecessary regulatory burden, to recommend what additional work should be in the scope of these initiatives, and to provide general concerns. The workshop was held on May 31, 2001.

After the workshop, the Nuclear Energy Institute (NEI) provided a comment letter dated July 2, 2001 (ADAMS No. ML011870432), which contained industry suggestions for possible burden-reduction changes to various regulations. Under the category Radiation Protection, NEI

proposed changes to 10 CFR 19.13, “Notifications and reports to individuals,” 10 CFR 20.1904, “Labeling containers,” and 10 CFR 20.2104, “Determination of prior occupational dose.”

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 NRC staff described its interactions with stakeholders regarding ways to reduce unnecessary regulatory burden and requested Commission approval of its plans to reduce burden. In its staff requirements memorandum in response to SECY-02-0081, dated June 25, 2002, the Commission approved the proposal to reduce unnecessary regulatory burden on power reactor licensees by developing proposed rulemakings from short-term, limited-scope initiatives without preparing formal rulemaking plans.

This proposed rule addresses the regulatory changes that NEI suggested under the Radiation Protection category. The NRC has determined that the regulations suggested for revision by NEI currently impose an undue regulatory burden on licensees. Additional changes NEI proposed to other areas of the Commission’s regulations have been or are being assessed separately by the NRC.

The NRC also proposes to revise 10 CFR 20.1003, “Definitions,” and 10 CFR 50.2, “Definitions,” to specify the use of effective dose equivalent in place of the deep-dose equivalent in the definition of total effective dose equivalent (TEDE). This revision is consistent with current Commission policy.

As part of the development of this rule, the NRC prepared draft rule language. The NRC solicited 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. The NRC also solicited public comment on the draft rule language (69 FR 8350; February 24, 2004). The NRC considered the comments received during the development of this proposed rule.

II. Discussion

Four principal amendments are being considered as part of this proposed rule.

A. Annual Dose Report to Workers

The first proposed amendment would revise 10 CFR 19.13, "Notifications and reports to individuals," and 10 CFR 20.2205, "Reports to individuals of exceeding dose limits." Section 19.13 currently requires that licensees: (1) report radiation exposure data to the worker; (2) advise each worker annually of the worker's dose; (3) furnish exposure reports at the request of former worker's; (4) provide the worker a copy of the worker's exposure report when the report is provided to the Commission; and (5) provide at the request of a worker who is terminating employment the worker's exposure report for the current year. With respect to 10 CFR 20.2205, this section requires that licensees provide a copy of an individual's exposure report to the individual when a copy is submitted to the Commission, whether that individual was exposed occupationally or as a member of the public.

Section 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," requires licensees to provide monitoring for individuals likely to receive, from sources external to the body, an annual dose that exceeds ten percent of the limits in 10 CFR 20.1201(a). Licensees conservatively determine who should be monitored under 10 CFR 20.1502 because there is uncertainty about who is likely to exceed this criterion and because this is a prospective determination. As a result of this conservatism many of the individuals monitored under 10 CFR 20.1502 receive very low doses. The current regulations at 10 CFR 20.2206, "Reports of individual monitoring," requires all records of monitoring under 10 CFR 20.1502 to be reported to the Commission for all licensees in the seven categories

listed in 10 CFR 20.2206(a). In addition, under 10 CFR 19.13(d) and 20.2205, these records of low doses must be reported to individuals. Further, 10 CFR 19.13(b) requires licensees to annually report doses to workers and to generate numerous reports of doses far below the regulatory limits in 10 CFR 20.1201(a) to individuals.

The NRC is proposing a change to the notification requirement in 10 CFR 19.13(b) so that licensees would continue the current reporting for occupationally exposed individuals who annually exceed a dose of 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue. However, licensees would not be required to provide unsolicited annual dose reports to individuals when neither the TEDE nor the dose to any individual organ or tissue exceeds 1 mSv (100 mrem). Individuals would still be provided with their dose reports upon request. This criterion would be applicable to the whole body, to the lens of the eye, to the skin of the whole body, and to the skin of the extremities. The criterion of 1 mSv (100 mrem) was selected because it corresponds to the occupational dose threshold for requiring instruction to workers under 10 CFR 19.12, “Instruction to workers.”

In the draft rule language previously published by the NRC (69 FR 8350; February 24, 2004), the proposed threshold for reporting was two percent of the dose limits in 10 CFR 1201(a). Use of a two-percent criterion would result in a different reporting threshold for doses to the whole body, to the lens of the eye, and to the skin of the whole body or to the skin of any extremity (i.e., 1 mSv (100 mrem), 3 mSv (300 mrem), and 10 mSv (1000 rem), respectively). The NRC determined that it is preferable to use the requirement for instructions to workers in 10 CFR 19.12 as the basis for the reporting threshold. Because licensees are required to provide instructions when an individual is likely to receive an annual occupational dose in excess of 1 mSv (100 mrem), only one threshold for providing reports would apply to all of the occupational dose limits in 10 CFR 20.1201(a). This approach is simpler because there is one reporting threshold instead of three and results in the same reduction in burden.

Under 10 CFR 20.2206, seven categories of licensees are required to submit an annual report of radiation exposure for each monitored individual to the NRC. Each year, the NRC publishes a NUREG report that summarizes this occupational radiation exposure data. The latest publication, 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). Further, 61,725 of the monitored individuals received no measurable exposure.

On the basis of this information, the proposed requirement would result in a significant reduction in administrative and paperwork burdens on licensees. The proposed amendment would not change the current requirements for recordkeeping or for reporting to the NRC. Therefore, the proposed amendment would not affect the level of protection to either the health and safety of workers and the public or the environment.

Under the current provisions in 10 CFR 19.13(d) and 20.2205, licensees are required by the reference to 10 CFR 20.2206 to provide an annual dose report to each individual for whom the report was submitted to the Commission. In addition, the current provision in 10 CFR 19.13(b) requires licensees to advise each worker annually of the workers's dose. To improve regulatory efficiency, the proposed rule would remove the reference to 10 CFR 20.2206 in 10 CFR 19.13(d) and 20.2205, and the requirement to report annual dose to the individual would be consolidated into a single requirement in 10 CFR 19.13(b).

NRC Form 3, "Notice to Employees," will also need to be revised to reflect the changes to the requirements for reporting doses to individuals if this rule is enacted.

B. Definition of Total Effective Dose Equivalent (TEDE)

The second proposed amendment would revise the definition of TEDE in 10 CFR 20.1003, “Definitions,” and 50.2, “Definitions.” The TEDE is currently defined as the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

The purpose of this revision is to clarify and make the definition of TEDE consistent with Commission policy as discussed in Regulatory Issue Summary (RIS) 2002-06, “Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays,” dated April 16, 2002, and subsequently clarified in RIS 2003-04, “Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments,” dated February 13, 2003, and RIS 2004-01, “Method for Estimating Effective Dose Equivalent From External Radiation Sources Using Two Dosimeters,” dated February 17, 2004. This policy allows the use of the effective dose equivalent in place of the deep dose equivalent, for exposure situations.

The proposed amendment would clarify that the TEDE is defined primarily in terms of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). In situations involving dose measurements, licensees may use the deep dose equivalent as a surrogate for the effective dose equivalent. When deep-dose equivalent is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(i), the requirement in 10 CFR 20.1201(c) to determine the deep-dose equivalent for the part of the body receiving the highest exposure will still apply. The revised definition of TEDE does not require licensees to change current procedures unless the licensee decides to use the proposed change to the definition. The proposed amendment would not

affect the level of protection to either the health and safety of workers and the public or the environment.

C. Labeling Containers

The third proposed amendment would revise 10 CFR 20.1905, “Exemptions to labeling requirements.” Section 20.1905 currently provides exemptions to the labeling requirements in 10 CFR 20.1904 for situations where: (1) the amount of radioactive material is small enough not to present a significant radiation hazard; (2) packages are labeled pursuant to other regulations (i.e., U.S. Department of Transportation) that provide for adequate labeling; or (3) equipment for which the type of equipment or the type of accessibility of the equipment may make labeling impractical.

The NRC is proposing to amend 10 CFR 20.1905 to add an exemption for containers holding licensed material (other than sealed sources that are either specifically or generally licensed) within nuclear power facilities licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” or 10 CFR Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants,” providing certain conditions are met. 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 accessible only to individuals who have sufficient instructions to minimize radiation exposure while handling or working in the vicinity of the containers. However, the proposed revision would require the container to be appropriately labeled under the requirements of 10 CFR 20.1904 before being removed from the posted area.

In the *Federal Register* document that solicited public comment on the draft rule language (69 FR 8350; February 24, 2004), the NRC indicated that this proposed change would either revise 10 CFR 20.1905 or add a new requirement to 10 CFR Part 50. The NRC proposes that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it fits logically with the other exemptions in that section. In the February 24, 2004, *Federal Register* document, the NRC also asked whether there were categories of materials licensees to which this exemption might be applied and whether adequate controls for radioactive materials stored within these licensees' facilities could be provided by the conditions being considered for the exemption. No categories of materials licensees responded to this question. The NRC is proposing that this exemption would apply only to nuclear power reactor licensees, not to materials or non-power reactor licensees.

Some nuclear power reactor licensees have interpreted 10 CFR 20.1904 to mean that all containers in a posted area whether they contain licensed material or not must be labeled because every container has the potential for internal contamination. This conservative interpretation of the regulations has put an undue burden on these licensees. The proposed revision to 10 CFR 20.1905 would require containers to be conspicuously marked commensurate with the radiological hazard. This would exempt 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 currently under 10 CFR 20.1905. The conspicuous markings on the containers would 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 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. Specific instructions on handling of marked containers would be provided before workers were given access to these containers.

The proposed container marking system would reduce licensee administrative and paperwork burdens, but serve the same health and safety functions as the current labeling requirements. Therefore, the proposed amendment would not affect the level of protection to either the health and safety of workers and the public or the environment.

The NRC has determined that the exemption to labeling requirements under 10 CFR 20.1905 is not appropriate for materials licensees because of the many types of radioactive material in containers at facilities such as hospitals and universities. Also, the NRC does not propose to make this exemption applicable to non-power reactor licensees because the operations at these facilities are not routine and must be addressed on a case-by-case basis. Highly radioactive materials are frequently taken out of these reactors and potentially present a significant health and safety concern.

This proposed rule excludes sealed sources from the revision to the exemption to labeling requirements. This exclusion is being added to the draft rule language (69 FR 8350; February 24, 2004). The NRC has determined that sealed sources such as those used for calibration or check sources should not be included in the proposed revision to 10 CFR 20.1905 because these sources are usually either specifically or generally licensed and should be managed, used, and stored appropriately. Therefore the proposed amendment would not permit removal of their labels.

D. Cumulative Occupational Radiation Dose

The fourth proposed amendment would remove the provision in 10 CFR 20.2104 (a)(2) that requires licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20.1502. After the 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.(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.

The proposed amendment would 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 proposed amendment to 10 CFR 20.2104(a)(2) would result in a significant reduction in administrative and paperwork burdens on licensees and would not affect the level of protection to either the health and safety of workers and the public or the environment. This is because the requirements to determine an individual's dose during the current year or cumulative dose prior to permitting a planned special exposure would not be amended.

In 10 CFR 20.2104, paragraphs (c) and (d) would also be revised to correct the omission of a reference to paragraph (b) in this section regarding planned special exposures. The reference to paragraph (c) is based on Regulatory Guide 8.35, "Planned Special Exposures" (June 1992), which directs licensees to obtain complete records of the worker's current and previously accumulated occupational dose by following the provisions of

10 CFR 20.2104(c).

III. Public Comments in Response to the *Federal Register* Notice

The February 24, 2004, *Federal Register* document (69 FR 8350) presenting the draft rule language solicited public comment on a number of questions about the proposed language. The Commission received eight comment letters. Comment letters were received from utility representatives, power reactor licensees, a fuel facility licensee, an industry organization representing material licensees, and a member of the public. The majority of comment letters supported NRC's approach. The significant comments discussed below are by subject. No changes to the draft rule language were made as a result of the comment letters. Agreement State comments are addressed separately in Section IV, "Agreement State Comments on the Draft Rule Language."

A. Annual Dose Report to Workers

All of the commenters supported the intent of the proposed revision to 10 CFR 19.13 not to require that licensees provide unsolicited annual dose reports to workers who receive less than a threshold dose in a monitoring year. However, one industry commenter disagreed with the NRC's proposed threshold value and believed it should be linked to the monitoring threshold for occupational exposure.

Comment. One industry commenter stated that 10 CFR 1502 only requires licensees to monitor worker external exposure when there is reasonable expectation that the worker could exceed 5 mSv (500 mrem) in a year and recommended that licensees should not therefore be required to inform workers unless their annual exposure exceeds ten percent (i.e., 5 mSv

(500 mrem)) of the limits. This commenter requested that NRC explain why licensees who monitor employees that receive less than 5 mSv (500 mrem) should receive reports when others who are similarly exposed are not monitored and cannot, therefore, receive reports.

Response. The NRC disagrees with part of this comment for the following reasons. 10 CFR Part 20 specifies two independent requirements related to the monitoring of workers. Section 20.1502 requires that each licensee monitor occupational exposure for all individuals likely to receive in a year a dose in excess of ten percent of the limits in 10 CFR 20.1201(a). Section 20.2206 requires licensees to submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 10 CFR 20.1502 during that year. Therefore, according to the current regulations a report must be filed for all individuals for whom monitoring was required regardless of the magnitude of the dose received. Section 19.13(d) also requires that a report be provided to the individual whenever a report is provided to the Commission. While the commenter's suggested threshold of 5 mSv (500 mrem) per year is a possible option, the occupational exposure data in NUREG-0713, Volume 25, suggests that raising the threshold from the proposed value of 1 mSv (100 mrem) would not reduce significantly administrative and paperwork burdens on licensees.

Comment. Another commenter representing the nuclear power industry suggested that NRC clarify that the applicability of the criterion is limited to the occupational dose received from work activities at a specific facility, and is not applicable to the cumulative annual dose received from work activities at all (multiple) licensee facilities during the year.

Response. Nuclear power reactor licensees generally provide a separate occupational dose record (Form 5) to an individual for each facility reflecting the dose received at that facility. Under the proposed regulations, the licensee would be required to provide only those reports

(Form 5s) to an individual whose recorded dose exceeded the reporting threshold of 1 mSv (100 rem).

Comment. The NRC also solicited comment on whether the proposed changes would result in cost savings to licensees and, if so, how much. The NRC also requested that stakeholders estimate the costs of implementing this possible change. One commenter representing the nuclear power industry stated that 10 CFR Part 50 licensees have estimated a cost savings of $1,000 to more than $5,000 per year due to the proposed change. Another commenter representing an alliance of six nuclear power utilities estimated the savings to be over $1,000 per plant per year. Still another reactor industry commenter estimated that the cost savings would be approximately $5,000 per site per year in administrative, supplies, and management time with a total estimated savings of $85,000 to $125,000 for the licensee's fleet of nuclear power plants and that implementation costs would be insignificant. Lastly, a commenter representing manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides stated that a manufacturing licensee who monitors 300 employees for radiation exposure and who manages the data electronically, might save only $100 per year, but that a licensee who manages the data manually might realize substantially larger cost savings from the changes under consideration.

Response. The savings estimates provided by the three commenters from the nuclear power industry are generally consistent. The regulatory analysis in Section XIII of this document uses a $3,000 cost-savings value, the midpoint of the values provided by the first commenter, to estimate the annual savings per nuclear power plant. The estimate that the savings might be only $100 per year for material licensees was based on the use of an electronic data management system. For all other licensees, NRC used an estimated savings of $10 per individual, assuming that these licensees do not have an electronic data management system.

B. Definition of Total Effective Dose Equivalent (TEDE)

Seven commenters addressed this issue and all agreed with the proposed revision to the definition of TEDE in 10 CFR 20.1003.

C. Labeling Containers

In the *Federal Register* document presenting the draft rule language (69 FR 8350; February 24, 2004), the NRC solicited comments on whether to revise 10 CFR 20.1905 or to add a new regulation to 10 CFR Part 50, and whether there are categories of material licensees to which the labeling exemption might be applied.

Five industry commenters supported the proposed exemption to the labeling requirements. Three commenters favored revising 10 CFR 20.1905. Two commenters preferred adding a new regulation to 10 CFR Part 50. As discussed in Section II of this document, the NRC proposes that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it fits logically with the other exemptions in this section.

The NRC received no comments from materials licensees that addressed the labeling exemption. As discussed in Section II of this document, the NRC proposes that this exemption would apply only to nuclear power facilities, the group that initially requested it, not to materials or non-power reactor licensees.

Comment. An industry commenter suggested that the rule should require the labeling of containers of radioactive material before they are removed from a restricted area instead of a posted area, and that container markings should be required only when the container was in an area not otherwise adequately posted and controlled.

Response. The NRC has determined that the previously published draft language pertaining to this requirement is appropriate for the control of containers. Also, the NRC has determined that the proposed language affords significant relief to the licensees and maintains necessary controls on radioactive materials to protect workers from preventable contaminations or exposures. The proposed revision would also require the container to be appropriately labeled under the requirements of 10 CFR 20.1904 before being removed from the posted area.

Comment. The NRC solicited comments on whether the proposed changes would result in cost savings to licensees and, if so, how much. One commenter representing the nuclear power industry stated that 10 CFR Part 50 licensees have estimated a cost savings of $10,000 to more than $50,000 per year from the proposed change. A second commenter representing an alliance of six nuclear power utilities estimated the savings to be $50,000 per year in technician and supervisory person-hours. A third commenter stated that licensees would realize a savings of about $25,000 per year due to a reduction in the use of radioactive material labels and staff needed to ensure staging areas within the radiological controlled area have appropriate labels.

Response. The savings estimates provided by the three commenters from the nuclear power industry are generally consistent. The regulatory analysis in Section XIII of this document uses a $30,000 cost-savings value, the midpoint of the values provided by the first commenter, to estimate the annual savings per nuclear power plant.

D. Cumulative Occupational Radiation Dose

Comment. All industry commenters agreed with the intent of the proposed revision to 10 CFR 20.2104 not to require licensees to obtain the records of cumulative dose for all

workers who require monitoring. However, a member of the public expressed concern that the proposed rule change would give workers the impression that lifetime dose is not important.

Response. As explained above in the Section II of this document, the cumulative lifetime dose is not used in the Commission's regulations to restrict an individual's annual occupational exposure but it is used in special circumstances such as a planned special exposure. The proposed rule would not change the requirement in 10 CFR 20.1206 to ascertain an individual's cumulative lifetime dose prior to permitting the individual to participate in a planned special exposure.

Comment. The NRC also solicited comment on whether the proposed changes would result in cost savings to licensees and, if so, how much. One commenter representing the nuclear power industry indicated that 10 CFR Part 50 licensees have estimated a cost savings of $2,000 to more than $15,000 per year from the proposed change. Another commenter representing an alliance of six nuclear power utilities estimated that the savings could be as much as $100,000 per plant per year. Lastly, a commenter representing manufacturers and distributors of radiopaharmaceuticals, radioactive sources, and research radionuclides noted that most recently hired employees in the manufacturing industry do not have prior dose records. As an example, this commenter also mentioned that one manufacturer with 250 radiation workers made only three requests for records in 2003. The estimated savings was $30 per year for the three requests.

Response. The regulatory analysis in Section XIII of this document uses an $8,500 cost-savings value, the midpoint of the values provided by the first commenter, to estimate the annual savings per nuclear power plant. The second commenter's estimate of $100,000 per year was not used because it represented the savings for a few operating plants and is much higher than the savings estimated by the first commenter for the entire nuclear power industry.

The NRC uses a savings of $10 per individual for all other licensees. This is consistent with the information provided by the commenter representing materials licensees.

IV. Agreement State Comments on the Draft Rule Language

The NRC solicited comments from the Agreement States and Minnesota and Pennsylvania (two Agreement State candidates) in All Agreement State Letter STP-04-002, dated January 9, 2004. Comments on this letter were received from the Agreement States Illinois and Washington. No changes to the draft rule language were made as a result of the Agreement State comments.

Comment. The State of Washington commented that the proposed reporting threshold for providing annual dose reports to workers under 10 CFR 19.13(b) should be ten percent (5 mSv (500 mrem)) of the occupational dose limit for adults, not two percent of this dose limit.

Response. While the commenter's suggested threshold of 5 mSv (500 mrem) per year is a possible option, the occupational exposure data in NUREG-0713, Volume 25, suggests that raising the threshold from the proposed value of 1 mSv (100 mrem) would not reduce significantly administrative and paperwork burdens on licensees. The NRC has determined that the proposed threshold of 1 mSv (100 mrem) reasonably balances reducing unnecessary regulatory burden and the need to keep individuals informed of their occupational dose.

Comment. The State of Washington suggested that facilities providing dosimetry to all individuals would most likely see a cost savings from the reduced administrative person-hours needed to prepare, send and track these reports and the lower cost to produce and distribute these reports. The State of Washington also stated that the actual cost savings cannot easily be quantified, being dependent on the number of monitored individuals and the method used to inform these individuals of their dose.

Response. The NRC agrees that it is difficult to estimate the savings to licensees from not having to prepare and distribute annual dose reports when the dose to an individual does not exceed 1 mSv (100 mrem). However, the NRC is using other commenters' estimates of savings in the regulatory analysis (see Section XIII of this document).

Comment. The State of Washington commented that the exemption to labeling requirements for containers holding radioactive material in a posted area in a nuclear power facility should be in 10 CFR Part 50.

Response. As discussed in Section II of this document, the NRC proposes that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it fits logically with the other exemptions in this section.

Comment. The State of Washington commented that quantifying the actual cost savings from not having to obtain prior dose records depends on the number of individuals for whom prior dose histories were required and the processes used to obtain the information.

Response. The NRC agrees that it is difficult to estimate the savings to licensees from not having to attempt to obtain the lifetime dose records for individuals. However, the NRC is using other commenters' estimates for savings in the regulatory analysis (see Section XIII of this document).

V. Section-by-Section Analysis of Substantive Changes

The Commission is proposing to amend 10 CFR 19.13, 20.1003, 20.1905, 20.2104, 20.2205, and 50.02.

Section 19.13—Notifications and reports to individuals.

Paragraph (b) would be 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. 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) would be 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) would be 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). This definition would also be amended to specify 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) would be 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 regulations would not require the licensee to label the container if it

is conspicuously marked (such as by color coding) commensurate with the radiological hazard, accessible only to individuals who have sufficient instructions to minimize radiation exposure while handling or working in the vicinity of the containers, and appropriately labeled as required by 10 CFR 20.1904 before being removed from the posted area. The exemption to the labeling requirements for containers holding licensed material would not apply to non-power reactor and materials licensees, or sealed sources.

Section 20.2104—Determination of prior occupational dose.

Paragraph (a)(2) would be removed to delete the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose. Paragraphs (a) and (a)(1) would then be combined and designated as paragraph (a). Paragraphs (c) and (d) would also be 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 would be 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 50.2, the definition of <u>total effective dose equivalent</u> (TEDE) would be 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). This definition would also be

amended to specify that when the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC.

VI. 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 proposed rule would be a matter of compatibility between NRC and the Agreement States, that provides consistency between Agreement State and NRC requirements. The NRC analyzed the proposed rule under 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://www.hsrd.ornl.gov/nrc/home.html). The NRC has determined that the compatibility categories for the sections amended in this proposed rule would be the same as for the sections in the current regulations, except for the new exemption (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 revision to 10 CFR 20.1003 is 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 is not required to 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 CFR provisions.

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.

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

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. (Provide the name, address, and telephone number of the NRC staff contact.)

Document	PDR	RuleForum	ADAMS	NRC Staff
Comments received	X	X		X
NEI comment letter, July 2, 2001	X	X	ML011870432	
NRC Strategic Plan FY 2000-2005	X	X		
Agreement State Letter STP-04-002	X	X	ML040090486	X
Form 3, “Notice to Employees”	X	X		X
NUREG-0713, Vol. 26	X	X		X
NUREG-1350, Vol. 17	X	X		X
NUREG/BR-0184	X			X
NUREG/BR-0058	X			X
56 FR 23391; May 21, 1991	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 Website at http://www.nrc.gov/reading-rm.html.

VIII. Plain Language

The Presidential memorandum “Plain Language in Government Writing” published June 10, 1998 (63 FR 31883), directed that the Government’s documents be in clear and accessible language. The NRC requests comments on the proposed rule specifically with

respect to the clarity and reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of this notice.

IX. 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 proposed rule, the NRC is proposing to revise requirements for the reporting of annual dose to workers, the definition of the quantity total effective dose equivalent (TEDE), the labeling of certain containers holding licensed material, and the determination of cumulative occupational radiation dose. This proposed regulatory action does not constitute the establishment of a standard that contains generally applicable requirements.

X. Environmental Impact: Categorical Exclusion

The NRC has determined that the proposed amendments to 10 CFR Parts 19, 20, and 50 are the type 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 proposed 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 proposed amendment to the definition of TEDE in 10 CFR 20.1003 and 50.2 comes under the categorical exclusion in 10 CFR 51.22(c)(2) because this revision is of a minor nature and does not substantially modify

existing regulations. For the proposed 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 proposed 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).

XI. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements contained in Form 5 and 10 CFR Parts 19 and 20 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collection requirements have been submitted to the Office of Management and Budget for review and approval. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0006, 3150-0044, and 3150-0014.

Type of submission, new or revision:	Revision
The title of the information collection	10 CFR Parts 19 and 20, Collection and Reporting of Occupational Dose Records, Labeling of Containers, and Clarifying the Quantity Total Effective Dose Equivalent
The form number if applicable:	Form 5
How often the collection is required:	Occasionally, annually
Who will be required or asked to report:	Nuclear power licensees and other NRC licensees
An estimate of the number of annual responses:	XXXX

The estimated number of annual respondents: XXXX

An estimate of the total number of hours needed annually to complete the requirement or request: XXXX hours

Abstract: The U.S. Nuclear Regulatory Commission is proposing to revise several administrative requirements related to the reporting of dose to workers, the definition of the quantity total effective dose equivalent (TEDE), the labeling of containers holding licensed material, and the determination of lifetime dose. (There are no information collection requirements related to the proposed revision of TEDE.) These revisions are intended to reduce administrative and paperwork requirements on NRC licensees without affecting the level of protection of the health and safety of workers and the public.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice and are also available at the rule forum site, http://ruleforum.llnl.gov.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER) to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV and to the Desk Officer, John A. Asalone, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014, 3150-0044), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to John_A._Asalone@omb.eop.gov or comment by telephone at (202) 395-4650.

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.

XII. Regulatory Analysis

The NRC has prepared a regulatory analysis on this proposed regulation and has included it in this *Federal Register* notice. The analysis examines the costs and benefits of the alternatives considered by the NRC.

1. Statement of the Problem and Objective

The NRC has determined that the regulations proposed for revision in 10 CFR 19.13, 20.1003, 20.1905, 20.2104, and 50.2 currently impose an undue regulatory burden on licensees. This proposed rule would amend certain requirements for notification of workers, revise the definition of total effective dose equivalent, amend certain container labeling requirements, and remove the requirement to attempt to obtain the records of cumulative occupational radiation dose. These revisions are intended to reduce administrative and paperwork 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.

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 retains the current regulations as described in Section II of this document. Licensees would continue to be required to: (1) provide annual dose reports to all monitored individuals, (2) determine the total effective dose equivalent (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 proposed alternative. The no-action alternative would not accomplish the stated objective.

2.2 Proposed Rule Alternative

Under the proposed rule alternative, the NRC would revise its regulations in 10 CFR Parts 19, 20, and 50 for: (1) reporting dose to workers, (2) defining TEDE, (3) labeling of certain containers holding licensed material, and (4) requiring that licensees attempting to obtain the records of cumulative occupational radiation dose for all individuals. This alternative would make the regulations consistent with current Commission policy and to reduce administrative and paperwork burdens on NRC and Agreement State licensees. Because this action was undertaken to ease burden, the rulemaking process is the only regulatory option appropriate to make the proposed changes effective.

3. Analysis of Values and Impacts of Proposed Rulemaking

3.1 Identification of Affected Attributes

The attributes that the proposed 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 would be 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 the proposed changes, licensees would incur the costs of revising procedures.

Industry Operation. This attribute would be affected by three of the four principal revisions. Licensees would 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 would incur costs to make minor revisions to Form 3, “Notice to Employees,” to account for the proposed changes to the reporting of annual dose to workers. The NRC would also incur the costs of completing this regulatory action.

Regulatory Efficiency. All four of the principal revisions would enhance regulatory efficiency. The revisions are intended to reduce administrative and paperwork 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.

3.2 Methodology

The incremental savings and costs of the proposed regulatory action were 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 3 and 7 percent real discount rates.

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.) For these licensees, the value-impact analysis uses the latest 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)). 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 licenses) and the second group contains all of the other licensee categories listed above (REIRS material licenses).

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 licenses) 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 licenses and is assumed to be applicable to non-REIRS materials licenses.

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

- Based on NUREG-0713, the number of nuclear power reactor licenses is 104 (NRC licenses only).
- Based on NUREG-0713, the number of REIRS materials licenses is 123 (NRC licenses only).
- Based on NUREG-1350, Volume 17, “NRC Information Digest: 2005 - 2006 Edition,” (July 2005), there are approximately 17,298 Agreement State licenses.
- The number of non-REIRS materials licenses (Agreement State and NRC licenses) was estimated as follows. A review of the NRC Licensing Tracking System database in October 2005 indicated that a total of 4,517 materials licenses are administered by the NRC. Correcting for the 123 REIRS materials licenses in the database and accounting for Agreement State licenses, the total number of Agreement State and NRC licenses

designated as non-REIRS materials licenses is approximately 21,692 licenses (17,298 Agreement State licenses + 4,517 NRC materials licenses - 123 REIRS material licenses).

- 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).
- The NRC estimates that procedural revisions would require about 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 each of the proposed changes.
- For nuclear power reactor licenses, it is assumed that the average life remaining for power reactor facilities is 49 years. For 3 and 7 percent 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 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 licenses.

In implementing the proposed regulatory action, nuclear power reactor licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $2,000 per nuclear power plant (20 hours x $100/hour) and $210,000 for the nuclear power industry (104 licenses x $2,000/license).

With respect to industry operation, there would be the savings of not having to provide unsolicited annual dose reports to workers when their doses do not exceed 1 mSv (100 mrem). Based on public comment, the NRC estimates the annual savings to be $3,000 per nuclear power plant and $310,000 for the nuclear power industry ($3,000 x 104 licenses). For a discounted flow of funds at a 3 percent 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 discounted flow of funds at a 7 percent 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.

For this analysis, the NRC estimates it would take 5 minutes (0.083 hour) for a licensee to provide each worker with an annual dose report. Assuming an average of 1,060 workers per nuclear power plant, the annual burden reduction from implementing the proposed action is

estimated to be 88 hours per nuclear power plant (1,060 workers x 0.083 hour) and the total industry impact is 9,200 hours (88 hours/license x 104 licenses).

REIRS materials licenses.

In implementing the proposed regulatory action, REIRS materials licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 10 hours to revise the procedures for each of the 123 REIRS materials licenses. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $1,000 per license (10 hours x $100/hour) and $120,000 for all licenses in this category (123 licenses x $1,000/license).

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 licenses in this group, about 67 workers per license would not receive an annual dose report. The NRC estimates a savings of $10 per worker not receiving a dose report. Thus, the estimated annual savings is $670 per license (67 workers/license x $10/worker) and $82,000 for all licenses in this category ($670/license x 123 licenses). For a discounted flow of funds at a 3 percent rate, the estimated savings per license and for all licenses in this category are $10,000 ($670 x 14.9) and $1.2 million ($82,000 x 14.9), respectively. For a discounted flow of funds at a 7 percent rate, the estimated savings per license and for all licenses in this category are $7,100 ($670 x 10.6) and $870,000 ($82,000 x 10.6), respectively.

For this analysis, the NRC estimates it would take 5 minutes (0.083 hour) for a licensee to provide each worker with an annual dose report. Assuming an average of 67 workers per license, the annual burden reduction from implementing the proposed action is estimated to be

6 hours per license (67 workers x 0.083 hour) and 740 hours for all licenses in this category (6 hours/license x 123 licenses).

Non-REIRS materials licenses.

In implementing the proposed regulatory action, non-REIRS materials licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 10 hours to revise the procedures for each of the 21,692 non-REIRS materials licenses. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $1,000 per license (10 hours x $100/hour) and $22 million for all licenses in this category (21,692 licenses x $1,000/license).

With respect to industry operation, the NRC assumes 500,000 monitored workers, 21,692 non-REIRS licenses, 23 workers per license, 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 would not receive an annual dose report. Thus, 16 workers per license are assumed not to receive an annual dose report. The estimated annual savings is $160 per license (16 workers/license x $10/worker) and $3.5 million for all licenses in this category ($160/license x 21,692 licenses). For a discounted flow of funds at a 3 percent rate, the estimated savings per license and for all licenses in this category are $2,400 ($160 x 14.9) and $52 million ($3.5 million x 14.9), respectively. For a discounted flow of funds at a 7 percent rate, the estimated savings per license and for all licenses in this category are $1,700 ($160 x 10.6) and $37 million ($3.5 million x 10.6), respectively.

For this analysis, the NRC estimates it would take 5 minutes (0.083 hour) for a licensee to provide each worker with an annual dose report. Assuming an average of 16 workers per

license, the annual burden reduction from implementing the proposed action is estimated to be 1.3 hours per license (16 workers x 0.083 hour) and 28,000 hours for all licenses in this category (1.3 hours/license x 21,692 licenses). For NRC licenses only, the total annual burden reduction is estimated to be 5,700 hours (1.3 hours/license x 4,394 NRC licenses).

3.3.2 Definition of Total Effective Dose Equivalent

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

3.3.3 Labeling Containers

The proposed revision to 10 CFR 20.1905, “Exemptions to labeling requirements,” would apply only to nuclear power reactor licensees. These licensees would incur one-time implementation costs to revise procedures. The NRC estimates it would take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $2,000 per license (20 hours x $100/hour) and $210,000 for the nuclear power industry (104 licenses x $2,000/license).

With respect to industry operation, based on public comments, the NRC estimates an annual savings of $30,000 per nuclear power plant if the proposed exemption to the labeling

containers is granted. For the entire nuclear power industry, the NRC estimates a savings of $3.1 million (104 licenses x $30,000/license). For a discounted flow of funds at a 3 percent 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 discounted flow of funds at a 7 percent 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.

Using an annual savings of $30,000 per nuclear power plant and a staff rate of $100 per hour, the annual burden reduction from implementing the proposed action is estimated to be 300 hours per plant ($30,000/license ÷ $100/hour) and the total industry impact is 31,000 hours (300 hours/license x 104 licenses).

3.3.4 Cumulative Occupational Radiation Dose

Nuclear power reactor licenses.

In implementing the proposed regulatory action, nuclear power reactor licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 20 hours to revise the procedures for each of the 104 nuclear power plants. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $2,000 per nuclear power plant (20 hours x $100/hour) and $210,000 for the nuclear power industry (104 licenses x $2,000/license).

With respect to industry operation, there would be a savings from not having to obtain the records of cumulative occupational radiation dose for a worker. Based on public comments, the NRC estimates the annual savings to be $8,500 per nuclear power plant and $880,000 for

the nuclear power industry ($8,500 x 104 licenses). For a discounted flow of funds at a 3 percent rate, the estimated savings per nuclear power plant and for the nuclear power industry are $220,000 ($8,500 x 25.50) and $22 million ($880,000 x 25.50), respectively. For a discounted flow of funds at a 7 percent rate, the estimated savings per nuclear power plant and for the nuclear power industry are $120,000 ($$8,500 x 13.77) and $12 million ($880,000 x 13.77), respectively.

Using an annual savings of $8,500 per nuclear power plant and a staff rate of $100 per hour, the annual burden reduction from implementing the proposed action is estimated to be 85 hours per plant ($8,500/license ÷ $100/hour) and the total industry impact is 8,800 hours (85 hours/license x 104 licenses).

REIRS materials licenses.

In implementing the proposed regulatory action, REIRS materials licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 10 hours to revise the procedures for each of the 123 REIRS materials licenses. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $1,000 per license (10 hours x $100/hour) and $120,000 for all licenses in this category (123 licenses x $1,000/license).

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 licenses in this group, there are about 98 workers per license. For this analysis, the NRC estimates that 20 percent of all workers would be affected, saving $15 per worker by not being required to obtain records of prior dose. Thus, the estimated annual savings is $300 per license (98 workers/license x $15/worker x 0.2) and

$37,000 for all licenses in this category ($300/license x 123 licenses). For a discounted flow of funds at a 3 percent rate, the estimated savings per license and for all licenses in this category are $4,500 ($300 x 14.9) and $550,000 ($37,000 x 14.9), respectively. For a discounted flow of funds at a 7 percent rate, the estimated savings per licensee and for all licenses in this category are $3,200 ($300 x 10.6) and $390,000 ($37,000 x 10.6), respectively.

Using an annual savings of $300 per license and a staff rate of $100 per hour, the annual burden reduction from implementing the proposed action is estimated to be 3 hours per license ($300/license ÷ $100/hour) and 370 hours for all licenses in this category (3 hours/license x 123 licenses).

Non-REIRS materials licenses.

In implementing the proposed regulatory action, non-REIRS materials licensees would incur a one-time cost to revise procedures. The NRC estimates it would take 10 hours to revise the procedures for each of the 21,692 non-REIRS materials licenses. Assuming a staff rate of $100 per hour, the one-time cost of implementing the proposed action would be $1,000 per license (10 hours x $100/hour) and $22 million for all licenses in this category (21,692 licenses x $1,000/license).

With respect to industry operation, the analysis assumes 500,000 individuals working under 21,692 non-REIRS licenses and an even distribution of workers per license (23 workers/license) . The NRC also assumes that 20 percent of all workers would be affected and estimates a savings of $15 per worker by not being required to obtain records of prior dose. Thus, the estimated annual savings is $70 per license (23 workers/license x $15/worker x 0.2) and $1.5 million for all licenses in this category ($70/license x 21,692 licenses). For a discounted flow of funds at a 3 percent rate, the estimated savings per license and for all

licenses in this category are $1,000 ($70 x 14.9) and $22 million ($1.5 million x 14.9), respectively. For a discounted flow of funds at a 7 percent rate, the estimated savings per license and for all licenses in this category are $740 ($70 x 10.6) and $16 million ($1.5 million x 10.6), respectively.

Using an annual savings of $70 per license and a staff rate of $100 per hour, the annual burden reduction from implementing the proposed action is estimated to be 0.7 hour per license ($70/license ÷ $100/hour) and 15,200 hours for all licenses in this category (0.7 hour/license x 21,692 licenses). For NRC licenses only, the total annual burden reduction is estimated to be 3,100 hours (0.7 hour/license x 4,394 NRC licenses).

3.3.5 NRC Implementation

Annual dose report to workers.

The NRC would incur costs to make minor revisions to Form 3, “Notice to Employees,” to account for the proposed 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 $28,000 (320 staff-hours at $88 per hour).

Other Proposed Revisions.

The NRC would incur no implementation costs due to the proposed revisions to the definition of TEDE, the labeling of containers holding licensed material, or the attempt to obtain the records of an individual’s cumulative occupational radiation dose.

Cost of the Regulatory Action.

The NRC would incur 0.8 full time equivalent (FTE) of staff time to complete this rulemaking after publishing the proposed rule. The cost for this action is estimated to be $126,000 (0.8 FTE at $157,000 per FTE).

4. Presentation of Results

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)

Proposed Regulatory Action	License Category	Implementation Savings (Costs) ($1,000)	Operating Savings (Costs)	
			Using 7 Percent Discount Rate ($1,000)	Using 3 Percent Discount Rate ($1,000)
Annual Exposure Reports	Nuclear power reactor	(210)	4,300	8,000
	REIRS materials	(120)	870	1,200
	Non-REIRS materials	(22,000)	37,000	52,000
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	(210)	43,000	79,000
	REIRS materials	n/a	n/a	n/a
	Non-REIRS materials	n/a	n/a	n/a
Prior Occupational Dose	Nuclear power reactor	(210)	12,000	22,000
	REIRS materials	(120)	390	550
	Non-REIRS materials	(22,000)	16,000	22,000
SUBTOTALS	Nuclear power reactor	(630)	59,300	109,000

Table 1. Summary of Industry Implementation and Operating Savings (Costs)				
Proposed Regulatory Action	License Category	Implementation Savings (Costs) ($1,000)	Operating Savings (Costs)	
			Using 7 Percent Discount Rate ($1,000)	Using 3 Percent Discount Rate ($1,000)
	REIRS materials	(240)	1,260	1,750
	Non-REIRS materials	(44,000)	53,000	74,000
TOTAL (rounded)		(45,000)	114,000	185,000

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

Table 2. Summary of Annual Burden Reduction per License and Industry			
Proposed Regulatory Action	License Category	Annual Burden Reduction (hours)	
		License	Industry
Annual Exposure Reports	Nuclear power reactor	88	9,200
	REIRS materials	6	740
	Non-REIRS materials	1.3	28,000
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	300	31,000
	REIRS materials	n/a	n/a
	Non-REIRS materials	n/a	n/a
Prior Occupational Dose	Nuclear power reactor	85	8,800
	REIRS materials	3	370
	Non-REIRS materials	0.7	15,200
SUBTOTALS	Nuclear power reactor	473	49,000
	REIRS materials	9	1,100
	Non-REIRS materials	2	43,200

Table 2. Summary of Annual Burden Reduction per License and Industry			
Proposed Regulatory Action	License Category	Annual Burden Reduction (hours)	
		License	Industry
TOTAL (rounded)		500	93,000

The total implementation cost to the NRC for the proposed regulatory action is $154,000. The NRC operating costs for the proposed action are assumed to be minimal.

The net present value of the proposed action is $230 million at a 3 percent discount rate (NRC and industry implementation ($154,000 + $45 million) + industry operation ($185 million)). The net present value of the proposed action is $159 million at a 7 percent discount rate (NRC and industry implementation ($154,000 + $45 million) + industry operation $114 million)). In addition, the total industry reduction in annual burden from implementing the proposed action is estimated to be 93,000 hours.

Several comments were received on the costs and benefits of the draft rule language (69 FR 8350; February 24, 2004) and are included in Section III of this document. These comments were considered in the development of this regulatory analysis.

5. Decision Rationale

The net present value of this proposed action is $230 million and $159 million for 3 and 7 percent discount rates, respectively. The total industry reduction in annual burden from implementing the proposed action is estimated to be 93,000 hours. These savings are obtained by reducing administrative and paperwork requirements on licensees. The NRC recommends proceeding with the proposed rule because the changes improve the effectiveness of NRC

regulations and reduce unnecessary regulatory burden without affecting the level of protection to either the health and safety of workers and the public or the environment

6. Implementation Schedule

After the publication of the proposed rule in the *Federal Register* and the consideration and resolution of the public comments, a final rule would be published, that would become effective 30 days after publication.

The Commission requests public comments on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading of this document.

XIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this proposed rule, if adopted, would 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 proposed rule pertain to all 21,692 licensees regulated by the NRC and Agreement States, the licensees, including the affected small entities, could continue their current practices and remain in compliance with the proposed regulation. Licensees would be expected to incur the costs of changing their procedures only if they determine that the changes are cost effective, therefore, the NRC has determined that the changes would not have a significant economic impact on licensees defined as small entities. The change related to labeling containers would affect 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.

XIV. Backfit Analysis

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

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:

<u>§ 19.13 Notifications and reports to individuals.</u>

* * * * *

(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 their 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). 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.

* * * * *

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

§ 20.1905 Exemptions to labeling requirements.

* * * * *

(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 instructions 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.

6. In § 20.2104, the introductory text of paragraphs (a) and (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; and

* * * * *

(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.

* * * * *

7. 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

8. 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).

9. 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). 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.

* * * * *

Dated at Rockville, Maryland, this day of , 2006.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.