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MEMORANDUM TO: Dr. John Larkins, Executive Director
Advisory Committee on Nuclear Waste

FROM: Christopher I. Grimes, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

SUBJECT: PROPOSED RULEMAKING TO AMEND 10 CFR PARTS 19, 20, AND
50: COLLECTION AND REPORTING OF OCCUPATIONAL DOSE
RECORDS, LABELING OF CONTAINERS, AND CLARIFYING THE
QUANTITY TOTAL EFFECTIVE DOSE EQUIVALENT

Attached is the draft Commission paper and *Federal Register* notice (FRN) for the proposed rulemaking to reduce unnecessary regulatory burden in 10 CFR Parts 19, 20 and 50. The proposed rulemaking is scheduled to be transmitted to the Office of the Executive Director in February 2006. We recommend that the Committee postpone its review until the staff has addressed the public comments to the proposed rule.

The staff has prepared a proposed rulemaking to (1) amend the provisions of 10 CFR 19.13(b) to require that licensees only provide routine annual occupational dose reports to individuals when their annual dose exceeds 1 mSv (100 mrem); (2) revise the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003 and 50.2 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 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(a)(2) that licensees attempt to obtain the records of cumulative occupational radiation doses for all individuals requiring monitoring under 10 CFR 20.1502. 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 subject proposed rule does not have any safety implications.

The attachments contain pre-decisional information and should not be released to the public.

Attachments: Draft Commission Paper
and FRN for Proposed Rule

cc: Jennifer Dixon-Herrity/EDO
Mary Glenn Crutchley/NRR

B-19

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cc: Jennifer Dixon-Herrity/EDO
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Distribution:

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ADAMS Accession No: ML05XXXX

*See previous concurrence.

| OFFICE | PRAB:PM | PRAB:BC | DPR: D |
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| NAME | SSchneider* | SCoffin* | CGrimes |
| DATE | 12/01/2005 | 12/05/2005 | 12/ /2005 |

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***** DRAFT - PRE-DECISIONAL INFORMATION *****

**RULEMAKING ISSUE
NOTATION VOTE**

SECY-05-XXXX

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

The staff has prepared a proposed rulemaking to (1) amend the provisions of 10 CFR 19.13, "Notifications and reports to individuals," to require that licensees only provide routine annual occupational dose reports to individuals when their annual dose exceeds 1 mSv (100 mrem) or when the individual makes a request for the report (conforming changes would be made to 10 CFR 19.13(d) and 10 CFR 20.2205, "Reports to individuals of exceeding dose limits"); (2) revise the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions," to be consistent with current Commission policy by clarifying that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures); (3) revise 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption for the labeling of containers holding licensed material within posted areas in nuclear power facilities; and (4) remove the requirement in 10 CFR 20.2104, "Determination of prior occupational dose," that requires licensees 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

Attachment 1

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

administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

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

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

DISCUSSION:

The proposed rule takes into consideration the recommendations of the Agreement States, as well as the eight comment letters received on the draft rule language. The preponderance of comments on the draft rule language supported NRC's approach.

There are four principal changes being considered as part of this proposed rulemaking. The following summarizes the main features of the proposed amendments.

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 in one year exceed a dose of 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue, but would not be required to provide unsolicited annual dose reports to individuals when their TEDE and each dose individually to organs and tissues do not exceed 1 mSv (100 mrem). The staff selected the criterion of 1 mSv (100 mrem) because it corresponds to the occupational dose threshold for requiring worker training under 10 CFR 19.12, "Instruction to workers." In addition, NRC Form 3, "Notice to Employees," would need to be revised to reflect the changes to

Attachment 1

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

reporting doses to individuals if this proposed rule is adopted as a final rule. The proposed rule does not change the current requirements for recordkeeping or for reporting to the Commission.

The proposed revision would also remove the reference to 10 CFR 20.2206, "Reports of individual monitoring," in 10 CFR 19.13(d) and 20.2205 so that the requirement for annual reporting of doses to an individual (occupational) appears only in 10 CFR 19.13(b).

Sections 19.13(d) and 20.2205 would only address the reporting of other-than-annual doses to an individual (occupational or member of the public).

2) Definition of Total Effective Dose Equivalent (TEDE)

The second proposed change would revise the definition of TEDE in 10 CFR 20.1003 and 50.2. The current definition is not consistent with the intent of the regulations in 10 CFR Part 20 as explained in Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," dated April 16, 2002, and subsequently clarified in RIS 2003-04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," dated February 13, 2003, and RIS 2004-01, "Method for Estimating Effective Dose Equivalent from External Radiation Sources Using Two Dosimeters," dated February 17, 2004. The revised definition of TEDE would be consistent with the Commission's policy.

The proposed change would clarify that the TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). It would also clarify the use of the effective dose equivalent in place of the deep-dose equivalent when TEDE is calculated. If a licensee is not using a method approved by the NRC for determining effective dose equivalent with radiation measuring devices, the deep-dose equivalent will be substituted for the effective dose equivalent when the external dose is determined by monitoring. When deep-dose equivalent is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(i), the requirement to determine the deep-dose equivalent for the part of the body receiving the highest exposure, in 10 CFR 20.1201(c), would still apply.

3) Labeling Containers

The third proposed change would revise 10 CFR 20.1905 to define an exemption to the labeling requirements in 10 CFR 20.1904, "Labeling containers," for containers holding licensed material 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." Nuclear power licensees have applied this requirement as though it meant that all of the containers in a posted area must be labeled. This conservative interpretation of the regulations has resulted in an undo burden on these licensees.

Under the proposed revision, nuclear power licensees would not be required to label containers holding licensed material that are within an area posted in accordance with 10 CFR 20.1902, "Posting requirements," if they are conspicuously marked (such as by providing a system of color coding of containers) 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. 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.

It is the staff's position that the exemption to labeling requirements under 10 CFR 20.1905 is not appropriate for materials licensees because of the many types and large quantities typically found in containers at facilities such as hospitals and universities. The staff is also not proposing to make this exemption applicable to non-power reactor licensees because the operations at these facilities are non-routine and must be dealt with on a case-by-case basis. Activated materials having high levels of radioactivity are frequently taken out of these reactors and moved around in the posted areas.

Sealed sources such as those used for calibration or check sources would not be included in the proposed revision to 10 CFR 20.1905 because these sources are either specifically or generally licensed, and therefore it would not be appropriate to remove their labels.

4) Cumulative Occupational Radiation Dose

The fourth proposed change would revise the requirement in 10 CFR 20.2104(a)(2) that licensees attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring pursuant to 10 CFR 20.1502. Records pertaining to an individual's lifetime dose are not needed by a licensee to evaluate the occupational dose received during the current monitoring year. Lifetime dose is only needed when a licensee makes the determination to authorize 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 prior to permitting an individual to participate in a planned special exposure to ascertain the exposure history of an individual's prior lifetime doses as required by 10 CFR 20.2104(b).

AGREEMENT STATE ISSUES:

Prior to public availability of the draft rule language through the *Federal Register* (69 FR 8350; February 24, 2004), the staff solicited comments from the Agreement States, 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 of Illinois and Washington.

Regarding the proposed amendment of the requirements in 10 CFR Parts 19 and 20 for licensees to provide annual radiation exposure reports to individuals receiving exposures below the occupational dose limits, the State of Washington indicated that the reporting threshold should be ten percent of the dose limit. On the proposed change to the definition of TEDE in 10 CFR 20.1003 and 50.2, no opposing comments were received on the approach to clarify the definition. On the proposed revision of 10 CFR 20.1904, for the labeling of containers within posted areas in nuclear power reactor facilities, the State of Washington commented that it would be less confusing if the exemption was included in Part 50. Finally, 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 can be found in the attached *Federal Register* notice.

The staff has analyzed the proposed rule in accordance with the procedures established within 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 (g) added to 10 CFR 20.1905. This exemption is classified as Compatibility Category NRC. A Compatibility Category "NRC" designation means the Agreement State is not required for purposes of compatibility to 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. The State should not adopt these program elements.

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. The Committee has no objection to the staff's proposal to issue this proposed rule for public comment.

The Advisory Committee on Nuclear Waste elected not to review the proposed rule requirements. The Committee 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 the final stage.

RESOURCES:

The resources needed to complete this rulemaking are 0.8 FTE, approximately 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 performed through the normal inspection process.

RECOMMENDATIONS:

That the Commission:

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

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.

Note:

1. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
2. 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).
3. 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.
4. That the appropriate Congressional committees will be informed of this action.
5. 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.
6. That an Office of Management and Budget information collection clearance package is required.

Luis A. Reyes
Executive Director
for Operations

Attachment: As stated

DRAFT LAST REVISED ON 12/07/05

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, and 50

RIN 3150 - AH40

**Collection and Reporting of Occupational Dose Records,
Labeling of Containers, and Clarifying 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 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. 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 clarify the definition of TEDE to ensure consistency with current Commission policy. Further, the proposed rule would modify the labeling requirements for containers holding licensed material within posted areas in nuclear power facilities. Finally, the proposed rule would remove the requirement to attempt to obtain lifetime exposure records for workers unless such individuals are being authorized to receive a planned special exposure. These revisions are intended to reduce administrative and paperwork burdens on NRC

Attachment 2

licensees without affecting the level of protection to the health and safety of workers and the public.

DATES: Submit comments on the rule by **(INSERT DATE 75 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER)**. Submit comments specific to the information collections 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 on the rule by any one of the following methods:

Submit comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 AM and 4:15 PM on Federal Workdays.

You may also provide comments via the NRC's interactive rulemaking Website at <http://ruleforum.llnl.gov>. This site provides the capacity to upload comments as files (any format) if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: CAG@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.

***** DRAFT - PRE-DECISIONAL INFORMATION *****

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Discussion
- III. Public Comments on the Draft Rule Language
- 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. Public Protection Notification
- XIII. Regulatory Analysis
- XIV. Regulatory Flexibility Certification
- XV. Backfit Analysis

I. Background

The NRC Strategic Plan, Fiscal Year 2000-Fiscal Year 2005, included 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.

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To further this goal, the NRC published a notice of public workshop and request for comments in the *Federal Register* on May 3, 2001, (66 FR 22134) and sponsored a workshop on May 31, 2001. The Nuclear Energy Institute (NEI) provided a comment letter, dated July 2, 2001 (ADAMS No. ML011870432), that contained industry suggestions for possible changes to various categories of the 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." This proposed rulemaking addresses the regulatory changes suggested by NEI under the category of "Radiation Protection." The NRC's assessment is that the regulations suggested for revision by NEI impose an undo regulatory burden on licensees. Additional changes proposed by NEI to other areas of the Commission's regulations have been or are being assessed by the NRC separately.

The NRC is also proposing as part of this action to revise 10 CFR 20.1003, "Definitions," and 10 CFR 50.2, "Definitions," to clarify the use of the 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.

The NRC solicited comments from the Agreement States, 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 has considered the comments received during the development of this proposed rulemaking.

II. Discussion

There are four principal changes being considered as part of this proposed rulemaking.

A. Annual Dose Report to Workers

The first change being proposed would revise 10 CFR 19.13, "Notifications and reports to individuals," and 20.2205, "Reports to individuals of exceeding dose limits." Section 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," requires licensees to provide monitoring for individuals likely to receive in one year from sources external to the body, a dose in excess of ten percent of the limits in 10 CFR 20.1201(a). Because there is uncertainty as to who is likely to exceed this criterion, licensees conservatively determine who should be monitored under 10 CFR 20.1502, especially because this is a prospective determination. This conservatism results in many of the individuals monitored under 10 CFR 20.1502 receiving very low doses. The current regulations in 10 CFR 20.2206, "Reports of individual monitoring," requires all records of monitoring per 10 CFR 20.1502 to be reported to the Commission. In addition, according to 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. This regulatory requirement results in licensees generating numerous reports to individuals of doses far below the regulatory limits in 10 CFR 20.1201(a).

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 in one year exceed a dose of 1 millisievert (mSv) (100 millirem (mrem)) TEDE or 1 mSv (100 mrem) to any individual organ or tissue, but would not be required to provide unsolicited annual dose

reports to individuals when their TEDE and each dose individually to organs and tissues do not exceed 1 mSv (100 mrem). Individuals would still be provided with their dose reports if they request them. This criterion would be applicable to the whole body, to the lens of the eye, to 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 worker training under 10 CFR 19.12, "Instruction to workers." In addition, NRC Form 3, "Notice to Employees," would need to be revised to reflect the changes to reporting doses to individuals if this proposed rule is adopted as a final rule. The proposed rule does not change the current requirements for recordkeeping or for reporting to the NRC.

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 skin of the whole body or extremities (i.e., 1 mSv (100 mrem), 3 mSv (300 mrem), and 10 mSv (1000 rem), respectively). The NRC has re-evaluated this approach and determined that using the requirement for instructions to workers in 10 CFR 19.12 as the basis for the reporting threshold is preferable. Because licensees are required to provide instructions when an individual is likely to receive in a year an 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 a single reporting threshold instead of three different ones and it gives essentially the same reduction in burden.

Under 10 CFR 20.2206, seven categories of licensees are required to submit to the NRC an annual report of radiation exposure for each monitored individual. Each year, the NRC publishes a NUREG report that summarizes this occupational radiation exposure data. The

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latest publication, NUREG-0713, Volume 25, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2003," (October 2004) indicates that 75 percent (i.e., 90,817 individuals) of the 121,265 monitored individuals received a TEDE that did not exceed 1 mSv (100 mrem). Further, 58,185 (i.e., 64 percent) of the 90,817 individuals received no measurable exposure. Based on this information, the proposed requirement to not provide routine annual reports to individuals of their occupational radiation exposure when the dose does not exceed 1 mSv (100 mrem) would result in a significant reduction in burden for licensees. The revised requirement would reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

This proposed rulemaking would also remove the reference to 10 CFR 20.2206 in 10 CFR 19.13(d) and 20.2205 so that the requirement for annual reporting of doses to an individual (occupational) appears only in 10 CFR 19.13(b). Sections 19.13(d) and 20.2205 would only address the reporting of other-than-annual doses to an individual (occupational or member of the public).

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

The second proposed change would revise the definition of TEDE in 10 CFR 20.1003, "Definitions," and 50.2, "Definitions." 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.

The proposed change would clarify that the TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition is permissive; it does not require licensees to change current procedures. If a licensee is not using a method approved by the NRC for determining effective dose equivalent when the external dose is determined with a radiation measuring device, the deep-dose equivalent will be substituted for the effective dose equivalent (for external exposures), consistent with the current practice. When deep-dose equivalent is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(I), the requirement to determine the deep-dose equivalent for the part of the body receiving the highest exposure, in 10 CFR 20.1201(c), would still apply.

C. Labeling Containers

The third proposed change would revise 10 CFR 20.1905, “Exemptions to labeling requirements,” to define an exemption to the labeling requirements in 10 CFR 20.1904 for containers holding licensed material 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.” These licensees would not be required to label containers holding licensed material that are within an area posted in accordance with 10 CFR 20.1902, “Posting requirements,” if they 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. 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.

In the *Federal Register* notice that solicited public comment on the draft rule language (69 FR 8350; February 24, 2004), the NRC indicated that this proposed change would revise 10 CFR 20.1905 or alternatively add a new regulation to 10 CFR Part 50. The NRC proposes that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it logically fits with the other exemptions in this section. In that *Federal Register* notice, the NRC also asked if there are categories of materials licensees to which this exemption might be applied, where adequate controls for radioactive materials stored within these 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 facilities, the group that initially requested it (see Section I, "Background," above), and not to materials or non-power reactor licensees.

Nuclear power licensees have applied the requirements of 10 CFR 20.1904 as though it meant that all of the containers in a posted area must be labeled. This conservative interpretation of the regulations has resulted in an undue burden on these licensees. At nuclear power facilities, containers within a posted area are accessible only to individuals who have had training per 10 CFR 19.12 and who have been assigned a radiation work permit to control their activities. The proposed revision to 10 CFR 20.1905, would require that containers be conspicuously marked commensurate with the radiological hazard without the detailed labeling information such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment

as required under 10 CFR 20.1905. It would be expected that the conspicuous markings on the containers 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 a color-coding system to indicate high, medium, or low levels of activity or hazard. Containers such as fifty-five gallon steel drums holding contaminated gloves and booties could be marked with a color that represents low levels of activity or the low potential for airborne contamination. Specific instructions on handling of marked containers would be provided prior to workers having access to such containers.

The proposed revision to 10 CFR 20.2104(a)(2) would reduce administrative and paperwork burdens on nuclear power licensees without affecting the level of protection to the health and safety of workers and the public.

It is the Commission's position that the exemption to labeling requirements under 10 CFR 20.1905 is not appropriate for materials licensees because of the many types and large quantities typically found in containers at facilities such as hospitals and universities. The Commission is also not proposing to make this exemption applicable to non-power reactor licensees because the operations at these facilities are non-routine and must be dealt with on a case-by-case basis. Activated materials having high levels of radioactivity are frequently taken out of these reactors and moved around in the posted areas.

This proposed rule excludes sealed sources from the revision to the exemption to labeling requirements, which is in contrast to that contained in the draft rule language. The Commission finds 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 either specifically or generally licensed, and therefore it would not be appropriate to remove their labels.

D. Cumulative Occupational Radiation Dose

The fourth proposed change would remove the requirement in paragraph (a)(2) of 10 CFR 20.2104, "Determination of prior occupational dose," for licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20.1502. Since the major revision to 10 CFR Part 20 (56 FR 23391; May 21, 1991), 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) in the current 10 CFR Part 20 essentially accomplishes the same goal as the previous dose limit of 0.03 Sv (3 rems) per quarter constrained by the then age dependent lifetime dose limit. The proposed revision would not change the criterion under 10 CFR 20.1206, "Planned special exposures," which requires licensees prior to permitting an individual to participate in a planned special exposure to ascertain the exposure history of an individual's prior lifetime doses as required by 10 CFR 20.2104(b).

The proposed revision to 10 CFR 20.2104(a)(2) would reduce administrative and paperwork burdens on NRC licensees without affecting the level of protection to the health and safety of workers and the public.

III. Public Comments on the Draft Rule Language

The February 24, 2004, notice of the draft rule language (69 FR 8350) solicited public comment on a number of specific questions concerning 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 are discussed below arranged 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," of this document.

A. Annual Dose Report to Workers

All of the commenters supported the intent of the proposed revision to 10 CFR 19.13 to not require licensees to provide unsolicited annual dose reports to workers who receive less than a threshold dose value in that monitoring year. However, one industry commenter disagreed with the NRC's selected threshold value. Two other industry commenters raised a concern about implementation.

Comment. One industry commenter questioned the use of two percent of the annual dose limit as the threshold and proposed using the same criteria established in 10 CFR 20.1502 for monitoring individuals (i.e., ten percent of the dose limits or 5 mSv (500 mrem)).

Response. The NRC is no longer proposing to use two percent of the annual dose limits in 10 CFR 20.1201(a) as the threshold for not requiring licensees to provide unsolicited annual dose reports to occupationally exposed individuals. Use of such a system could be difficult to implement because each of the occupational dose limits for adults in 10 CFR 20.1201(a) would have a unique reporting threshold. Instead, the NRC is now proposing a simpler approach that gives essentially the same reduction in burden. Under this approach, there would be one reporting threshold based on the requirement in 10 CFR 19.12 that licensees provide instruction

to all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). The reporting threshold of 1 mSv (100 mrem) would apply to whole-body exposures or doses to any organ or tissue specified in 10 CFR 20.1201(a). The NRC position is 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. The proposed rule does not change the current requirements for recordkeeping or for reporting to the NRC.

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 the specific licensee's facility, and is not applicable to the cumulative annual dose received from work activities at all (multiple) licensee facilities during the year.

Response. To comply with the regulations in 10 CFR 19.13(b), nuclear power licensees have generally adhered to the practice that for one power station they provide a single NRC Form 5, "Occupational Dose Record for a Monitoring Period," to an individual who works at one or more units at the station. Under the proposed rule, a licensee would be required to provide an annual dose report to an individual only when any dose recorded on the Form 5 exceeds the reporting threshold of 1 mSv (100 mrem). In cases where a nuclear utility has two or more power stations, it is general practice that an individual who works at two or more different stations is provided with a separate Form 5 for each station at which the individual works. For this situation, the licensee would be required to provide to an individual only those reports (Form 5s) for which the recorded dose exceeds the reporting threshold of 1 mSv (100 rem).

Comment. In the *Federal Register* notice of draft rule language (69 FR 8350; February 24, 2004), the NRC solicited specific response on whether the proposed changes would result in cost savings to licensees and, if so, to provide an estimate of the savings. The

NRC also requested that stakeholders provide the costs associated with implementing this possible change. One commenter representing the nuclear power industry indicated that 10 CFR Part 50 licensees have estimated a cost savings of \$1 K to more than \$5 K per year due to burden reduction associated with the proposed change. Another commenter representing an alliance of six nuclear power utilities estimated the savings to be over \$1 K per plant per year. Still another reactor-industry commenter stated that the estimated cost savings are approximately \$5 K per site per year in administrative, supplies, and management time with a total estimated savings of \$85 K to \$125 K for their fleet of nuclear power plants and would not require significant costs to implement. Lastly, a commenter representing manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides indicated that for a manufacturing licensee, with 300 employees who are monitored for radiation exposure and where the data is managed electronically, savings due to the NRC proposal may be only \$100 per year. This commenter further stated that a licensee where the data is managed manually may 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 (see Section XIII in this document) uses a \$3 K cost-savings value, the midpoint of the values provided by the first commenter, to estimate the annual savings per nuclear power plant. While the commenter representing materials licensees stated that the estimated savings may be only \$100 per year, that was based on the use of an electronic data management system. Thus for all other licensees, an estimated savings of \$10 per individual is used by the NRC because it is assumed that these licensees do not have an electronic data management system.

B. Definition of the Total Effective Dose Equivalent

The seven industry commenters agreed with the proposed revision to the definition of total effective dose equivalent in 10 CFR 20.1003.

C. Labeling Containers

In the *Federal Register* notice of draft rule language (69 FR 8350; February 24, 2004), the NRC solicited specific response on whether to revise 10 CFR 20.1905 or alternatively 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.

Regarding the first issue, five industry commenters supported the proposed exemption to the labeling requirements in 10 CFR 20.1904. Three commenters favored revising 10 CFR 20.1905 and two commenters preferred adding a new regulation to 10 CFR Part 50. The NRC has decided to propose that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it logically fits with the other exemptions in this section.

With respect to the second issue, the NRC received no comments from materials licensees on this issue. The NRC is proposing that this exemption would apply only to nuclear power facilities, the group that initially requested it (see Background above), and not to materials or non-power reactor licensees. The Commission's position is that the exemption to labeling requirements is not appropriate for materials licensees because of the many types and large quantities typically found in containers at facilities such as hospitals and universities. The Commission is also not proposing to make this exemption applicable to non-power reactor licensees because the operations at these facilities are non-routine and must be dealt with on a

case-by-case basis. Activated materials having high levels of radioactivity are frequently taken out of these reactors and moved around in the posted areas.

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's position is that the language pertaining to this requirement, as previously published in draft form, is appropriate for the control of containers. While the requirements proposed by the NRC do not provide as much regulatory relief as compared to this industry suggestion, the NRC's position is that the proposed draft language affords significant relief to the licensees while maintaining 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. In the *Federal Register* notice of draft rule language (69 FR 8350; February 24, 2004), the NRC solicited specific response on whether the proposed changes would result in cost savings to licensees and, if so, to provide an estimate of the savings. One commenter representing the nuclear power industry indicated that 10 CFR Part 50 licensees have estimated a cost savings of \$10 K to more than \$50 K per year due to burden reduction associated with the proposed change. A second commenter representing an alliance of six nuclear power utilities estimated the savings to be \$50 K per year in technician and supervisory person-hours. A third commenter stated that licensees would realize a savings of about \$25 K per year due to a reduction in the use of radioactive material labels and staff needed to ensure tagging 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 (see Section XIII in this document) uses a \$30 K 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

All of the industry commenters agreed with the intent of the proposed revision to 10 CFR 20.2104 to not require licensees to obtain the records of cumulative dose for all workers who require monitoring. However, another stakeholder had a comment on this revision.

Comment. A member of the public expressed concern that the proposed rule change would give workers the impression that lifetime dose is not important.

Response. The Commission has previously adopted a fixed annual dose limit as opposed to a separate lifetime dose limit when it revised 10 CFR Part 20 (56 FR 23360; May 21, 1991). In the *Federal Register* notice for that revision, the Commission stated, "If the magnitude of the annual dose is limited, there is a *de facto* limitation of the lifetime dose that can be received." The proposed revision to 10 CFR 20.2104 for occupationally exposed individuals is consistent with that regulatory action. By deleting the requirement to obtain the records of cumulative occupational radiation dose in 10 CFR 20.2104(a)(2), this action confirms that the individual's cumulative lifetime dose is not necessary to demonstrate compliance with the annual dose limits in the current Part 20. The proposed revision would not change the criterion under 10 CFR 20.1206, "Planned special exposures," which requires licensees prior to permitting an individual to participate in a planned special exposure to ascertain the exposure history of an individual's prior lifetime doses as required by 10 CFR 20.2104(b).

Comment. In the *Federal Register* notice of draft rule language (69 FR 8350; February 24, 2004), the NRC solicited specific response on whether the proposed changes would result in cost savings to licensees and, if so, to provide an estimate of the savings. One commenter representing the nuclear power industry indicated that 10 CFR Part 50 licensees have estimated a cost savings of \$2 K to more than \$15 K per year due to burden reduction associated with the proposed change. Another commenter representing an alliance of six nuclear power utilities estimated that the savings could be as much as \$100 K per plant per year. Lastly, a commenter representing manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides noted that in the manufacturing industry, most new hires do not have prior dose records. This commenter also provided as an example, one manufacturer with 250 radiation workers having made only three requests for records in 2003. The estimated savings was \$30 per year for the three requests.

Response. The regulatory analysis (see Section XIII in this document) uses an \$8.5 K cost-savings value, the midpoint of the values provided by the first commenter to estimate the annual savings per nuclear power plant. The estimate of \$100 K per year provided by the second commenter was not used because it represented the savings for a few operating plants and is much higher than the savings provided by the first commenter for the entire nuclear power industry. For all other licensees, a savings of \$10 per individual is used by the NRC. 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, Minnesota, and Pennsylvania (two Agreement State candidates) in All Agreement State Letter STP-04-002, dated January 9, 2004. Comments were received from the Agreement States of Illinois and

Washington on this letter. 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 of the 5 mSv (500 mrem) occupational dose limit for adults and not two percent of this dose limit.

Response. The NRC is no longer proposing to use two percent of the annual dose limits in 10 CFR 20.1201(a) as the threshold for not requiring licensees to provide unsolicited annual dose reports to occupationally exposed individuals. Use of such a system could be difficult to implement because each of the occupational dose limits for adults in 10 CFR 20.1201(a) would have a unique reporting threshold. Instead, the NRC is now proposing a simpler approach that gives essentially the same reduction in burden. Under this approach, there would be one reporting threshold based on the requirement in 10 CFR 19.12 that licensees provide instruction to all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). The reporting threshold of 1 mSv (100 mrem) would apply to whole-body exposures or doses to any organ or tissue specified in 10 CFR 20.1201(a). The NRC position is 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. The proposed rule does not change the current requirements for recordkeeping or for reporting to the NRC.

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 preparing, sending and tracking these reports, and the monies required to produce and distribute these reports. Further, the State of Washington stated that the actual cost savings

cannot easily be quantified, as it is dependent on the number individual monitored, and the method used to inform the individuals of their dose.

Response. The NRC agrees that it is not easy to estimate the savings to licensees by 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 making use of the estimates for savings provided by other commenters in the regulatory analysis (see Section XIII in 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 Part 50.

Response. The NRC has decided to propose that the new exemption to labeling requirements be contained in 10 CFR 20.1905 because it logically fits with the other exemptions in this section.

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

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

IV. 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

Section 19.13, “Notifications and reports to individuals,” would be revised to consolidate and amend the Commission’s requirement to report occupational doses to individuals on an annual basis. The current requirement appears in 10 CFR 19.13(b), 19.13(d) and 20.2205. Section 19.13(b) would be revised to consolidate the requirement to report annually the occupational doses to individuals and not require a license to provide unsolicited annual dose reports to individuals when their TEDE and each dose individually to the organs and tissues specified in 10 CFR 20.1201(a) do not exceed 1 mSv (100 mrem). Also, 10 CFR 19.13(d) would be revised by deleting the reference to 10 CFR 20.2206 so that 10 CFR 19.13(d) only addresses the reporting of other-than-annual occupational doses to an individual.

Because the requirement to report annually the occupational doses to individuals would be consolidated in the proposed revision to 10 CFR 19.13(b), conforming changes would be made to 10 CFR 20.2205. Changes to 10 CFR 20.2205 are discussed below in this section.

Section 20.1003 – Definitions

In 10 CFR 20.1003, “Definitions,” 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 shall 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, “Exemptions to labeling requirements,” to provide an exemption for containers holding licensed material that are within 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 providing a system of color coding of containers) 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. The regulations would require that the container be appropriately labeled, in accordance with 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

In 10 CFR 20.2104, “Determination of prior occupational dose,” the current paragraph (a)(2) would be removed that requires licensees to 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 correct an omission of reference to paragraph (b) in this section regarding planned special exposures.

The reference to paragraph ©) is substantiated by 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 using the provisions of 10 CFR 20.2104©).

Section 20.2205 – Reports to individuals of exceeding dose limits

Section 20.2205, "Reports to individuals of exceeding dose limits," would be revised to remove the reference to 10 CFR 20.2206. The deletion of the reference to 10 CFR 20.2206 was made so that (1) the requirement for annual reporting of doses to an occupationally exposed individual appears only in 10 CFR 19.13(b) and (2) the requirement for reporting other-than-annual doses to an individual (occupational or member of the public) appears only in 10 CFR 20.2205. The revised 10 CFR 20.2205 would continue to require a licensee, under the provisions of 10 CFR 20.2203 and 20.2204, to provide an individual (occupational or member of the public) with a copy of any report to the Commission pertaining to radiological incidents, exposures in excess of the regulatory limits, and planned special exposures.

Section 50.2 – Definitions

In 10 CFR 50.2, "Definitions," 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 shall be

used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC.

V. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The NRC analyzed the proposed rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at <http://www.hsrdo.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 terms necessary for a common understanding of radiation protection principles. Compatibility Category "A" designated Agreement State requirements should be essentially identical to that of NRC.

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 for purposes of compatibility to 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. The State should not adopt these program elements.

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 for purposes of compatibility to adopt the requirement.

VI. Availability of Documents

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

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

Rulemaking Website (Web). 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 | X | |
| Agreement State Letter STP-04-002 | X | X | X | X |
| Form 3, "Notice to Employees | X | X | X | X |
| NUREG-0713, Vol. 25 | X | X | | X |
| NUREG/BR-0184 | X | | | X |
| NUREG/BR-0058 | X | | | X |
| 56 FR 23391; May 21, 1991 | X | X | | |
| 66 FR 22134; May 3, 2001 | X | X | | X |
| 69 FR 8350; February 24, 2004 | X | X | | X |

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

VIII. Plain Language

The Presidential memorandum "Plain Language in Government Writing" published June 10, 1998 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. The NRC is revising specific requirements related to the collection, reporting, and labeling of information and dose determination methodology. The NRC is proposing to revise specific requirements related to the reporting of dose to workers, the definition of the quantity total effective dose equivalent, the labeling of containers holding licensed material, and the attempt to determine lifetime 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 categorically excluded and do not require environmental review. 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 policy 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).

X. 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 number(s) 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 attempt to determine 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 to 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](mailto:John_A.Asalone@omb.eop.gov) or comment by telephone at (202) 395-4650.

XI. 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 that is provided as a part of 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

This rule would amend certain requirements for notification of workers, revise the definition of total effective dose equivalent, amend certain 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 licensees without affecting the level of protection to the health and safety of workers and the public.

2. Identification of Regulatory Alternatives

This regulatory analysis evaluates the values and impacts 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, "Discussion," in 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 serves as the baseline against which the proposed rule alternative (described below) is measured.

2.2 Proposed Rule Alternative

Under the proposed rule alternative, the NRC would revise its regulations for the reporting of dose to workers, the definition of the quantity TEDE, the labeling of containers holding licensed material, and the attempt to obtain the records of cumulative occupational radiation dose in 10 CFR Parts 19, 20, and 50 to be consistent with current Commission policy and to reduce administrative and paperwork burdens on NRC and Agreement State licensees. Because this action was undertaken as an easing of burden, the rulemaking process is the only regulatory option appropriate to effect the proposed changes.

3. Analysis of Values and Impacts

3.1 Identification of Affected Attributes

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

Industry Implementation. This attribute would be affected by three of the four principal revisions. They are 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. Licensees would incur costs to implement the proposed changes due to procedural revisions to accommodate the changes.

Industry Operation. This attribute would be affected by three of the four principal revisions. Licensees would incur 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 (except sealed sources) holding licensed material 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 costs to complete this regulatory action.

Regulatory Efficiency. All four of the principal revisions would enhance regulatory efficiency. 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.

3.2 Methodology

Incremental values and impacts associated with the proposed regulatory action were analyzed relative to the baseline described in Section 2.1 above. The values (savings) include any desirable changes in the affected attributes, while the impacts (costs) include any undesirable changes in the affected attributes.

In accordance with Office of Management and Budget guidance and NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004, the results of the analysis are presented using both 3 percent 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. The seven categories are: 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. (There are currently no NRC licensees involved in low-level waste disposal 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 25, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2003," (October 2004)). To simplify the analysis, the seven categories of

licensees are consolidated into two groups. The first group contains only commercial nuclear power reactor licensees (hereafter referred to as "nuclear power licenses") and the second group contains all of the other licensee categories listed above (hereafter referred to as "REIRS material licenses").

The seven categories of licensees specified in 10 CFR 20.2206 are not inclusive of all NRC licensees. The majority of NRC licensees (e.g., hospitals, medical facilities, universities, radiological services, disposal, etc) are not required by the Commission's regulations to submit annual radiation exposure reports for monitored individuals. These licensees (hereafter referred to as "non-REIRS materials licenses") comprise 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 individuals monitored nor 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 and that 68 percent of these individuals receive a dose that does not exceed 1 mSv (100 mrem).

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

- From NUREG-0713, the number of nuclear power licenses is 104 (NRC licensees only).
- From NUREG-0713, the number of REIRS materials licenses is 119 (NRC licensees only).
- Based on professional judgement, the NRC assumes that the ratio of Agreement State licenses to NRC licenses is 4.
- 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 (October, 2003) indicates a total of 4,517 materials licenses. Correcting for the 119 REIRS

materials licenses in the database and accounting for Agreement State licenses, the total number of both Agreement State and NRC licenses is estimated to be 22,000 licenses $[(4 \times (4,517 - 119)) + (4,517 - 119), \text{rounded}]$.

- From NUREG-0713, the number of individuals working for nuclear power licensees is 109,990.
- From NUREG-0713, the number of individuals working for REIRS materials licensees is 11,275.
- Based on professional judgement, the NRC assumes that to be 500,000 individuals work for non-REIRS materials licensees (Agreement State and NRC licensees).
- For non-REIRS and REIRS materials licensees, there would be a range of hours from 2 to 20 hours to revise procedures depending on the number of workers at each facility. This analysis uses 10 hours as the average time to revise procedures for each of the proposed changes.
- For nuclear power licenses, it is assumed that the average life remaining for power reactor facilities is 49 years. Thus for 3 and 7 percent discount rates, the analysis uses factors of 25.50 and 13.77, respectively, following the guidance in NUREG/BR-0184.
- For all other licenses, it is assumed that the average life remaining for these facilities is 20 years. Thus 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 licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by nuclear power licensees to revise procedures. The NRC estimates that procedural revisions would require about 20 hours 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 K per nuclear power plant (i.e., 20 hours x \$100/hour) and \$208 K for the nuclear power industry (i.e., 104 licenses x \$2 K/license).

Regarding industry operation, there would be a savings by 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 K per nuclear power plant and \$310 K for the nuclear power industry (i.e., \$3 K 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 K and \$8,000 K, 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 \$40 K and \$4,300 K, respectively.

REIRS materials licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by REIRS materials licensees to revise procedures. The NRC estimates that procedural revisions would require about 10 hours for each of the 119 REIRS materials licenses. Assuming a staff rate of \$100 per hour, the one-time cost of implementing the proposed action would be \$1 K per license (i.e., 10 hours x \$100/hour) and \$120 K for all licenses in this category (i.e., 119 licenses x \$1 K/license).

Regarding industry operation, the following analysis was done. Using the 2003 data in NUREG-0713, it was determined that 7,630 workers had an annual dose that did not exceed 1 mSv (100 mrem). Assuming these workers are equally distributed among the 119 licenses in this group, there are about 64 workers per license. For this analysis, the NRC estimates a savings of \$10 per worker not receiving a dose report. Thus, the estimated annual savings is \$640 per license (i.e., 64 workers/license x \$10/worker) and \$77 K for all licenses in this category (i.e., \$640/license x 119 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 \$9 K and \$1,100 K, 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 K and \$800 K, respectively.

Non-REIRS materials licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by non-REIRS materials licensees to revise procedures. The NRC estimates that procedural revisions would require about 10 hours for each of the 22,000 non-REIRS materials licenses.

Assuming a staff rate of \$100 per hour, the one-time cost of implementing the proposed action would be \$1 K per license (i.e., 10 hours x \$100/hour) and \$22,000 K for all licenses in this category (i.e., 22,000 licenses x \$1 K/license).

Regarding industry operation, the following analysis was done. The analysis assumes 500,000 workers, 22,000 non-REIRS licenses, 23 workers per license, and a savings of \$10 for each worker not receiving a dose report. In addition, a factor of 68 percent is used to estimate the fraction of workers who would not receive a dose report because of the proposed rule. 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. Thus, 16 workers per license are assumed not to receive an annual dose report. The estimated annual savings is \$160 per license (i.e., 16 workers/license x \$10/worker) and \$3,500 K for all licenses in this category (i.e., \$160/license x 22,000 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 K and \$52,400 K, 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 \$2 K and \$37,300 K, respectively.

3.3.2 Definition of Total Effective Dose Equivalent

There are minimal values and impacts associated with the proposed revision to the definition of TEDE. The proposed revision would make it clear to all NRC and Agreement State licensees that their current practice of calculating TEDE is consistent with Commission policy. By clarifying that licensees are operating within the regulatory requirements, this revision would eliminate the need for licensees to repeatedly request guidance from the NRC and, in some cases, having to request a license amendment to incorporate clarification of 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 licensees. These licensees would incur one-time implementation costs to revise procedures. The NRC estimates that procedural revisions would require about 20 hours 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 K per license (i.e., 20 hours x \$100/hour) and \$208 K for the nuclear power industry (i.e., 104 licenses x \$2 K/license).

Regarding industry operation, the following analysis was done. Based on public comment, the NRC estimates an annual savings of \$30 K 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 \$3,120 K (i.e., 104 licenses x \$30 K/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 K and \$79,600 K, 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 \$400 K, and \$43,000 K, respectively.

3.3.4 Cumulative Occupational Radiation Dose

Nuclear power licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by nuclear power licensees to revise procedures. The NRC estimates that procedural revisions would require about 20 hours 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 K per nuclear power plant (i.e., 20 hours x \$100/hour) and \$208 K for the nuclear power industry (i.e., 104 licenses x \$2 K/license).

Regarding industry operation, there would be a savings by not having to obtain the records of cumulative occupational radiation dose for a worker. Based on public comment, the NRC estimates the annual savings to be \$8.5 K per nuclear power plant and \$890 K for the nuclear power industry (i.e., \$8.5 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 K and \$22,500 K, 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 K and \$12,200 K, respectively.

REIRS materials licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by REIRS materials licensees to revise procedures. The NRC estimates that procedural revisions would require about 10 hours for each of the 119 REIRS materials licenses. Assuming a staff rate of \$100 per hour, the one-time cost of implementing the proposed action would be \$1 K per license (i.e., 20 hours x \$100/hour) and \$120 K for all licenses in this category (i.e., 119 licenses x \$1 K/license).

Regarding industry operation, the following analysis was done. Using the 2003 data in NUREG-0713, the number of individuals working for REIRS materials licensees is 11,275. Assuming these workers are equally distributed among the 119 licenses in this group, there are about 95 workers per license. For this analysis, the NRC estimates that 20 percent of all workers would be affected and a savings of \$10 per worker for not having to obtain records of prior dose. Thus, the estimated annual savings is \$190 per license (i.e., 95 workers/license x \$10/worker x 0.2) and \$23 K for all licenses in this category (i.e., \$190/license x 119 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 \$3 K and \$340 K, 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 \$2 K and \$240 K, respectively.

Non-REIRS materials licenses.

In implementing the proposed regulatory action, a one-time cost would be incurred by non-REIRS materials licensees to revise procedures. The NRC estimates that procedural

revisions would require about 10 hours for each of the 22,000 non-REIRS materials licenses. Assuming a staff rate of \$100 per hour, the one-time cost of implementing the proposed action would be \$1 K per license (i.e., 10 hours x \$100/hour) and \$22,000 K for all licenses in this category (i.e., 22,000 licenses x \$1 K/license).

Regarding industry operation, the following analysis was done. The analysis assumes 500,000 individuals working under 22,000 non-REIRS licenses and an even distribution of workers per license (i.e., 23 workers/license) . For this analysis, the NRC also assumes that 20 percent of all workers would be affected and estimates a savings of \$10 per worker for not having to obtain records of prior dose. Thus, the estimated annual savings is \$50 per license (i.e., 23 workers/license x \$10/worker x 0.2) and \$1,000 K for all licenses in this category (i.e., \$46/license x 22,000 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 \$7 K and \$15,100 K, 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 \$5 K and \$10,700 K, respectively.

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 in 10 CFR 19.13(b).

The one-time cost for this task is estimated to be \$32 K (320 staff-hours at \$100 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 cumulative occupational radiation dose for an individual.

Cost of the Regulatory Action.

The NRC would incur 0.8 Full Time Equivalent (FTE) of staff time to complete this rulemaking from the end of proposed rule publication. The cost for this action is estimated to be \$126 K (0.8 FTE at \$157 K 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) (\$K) | Operating Savings (Costs) | |
| | | | Using 7% Discount Rate (\$K) | Using 3% Discount Rate (\$K) |
| 1) Annual Exposure Reports | Nuclear Power | (208) | 4,300 | 8,000 |
| | REIRS materials | (120) | 800 | 1,100 |
| | Non-REIRS materials | (22,000) | 37,300 | 52,400 |

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| Table 1. Summary of Industry Implementation and Operating Savings (Costs) | | | | |
|---|---------------------|--------------------------------------|------------------------------|------------------------------|
| Proposed Regulatory Action | License Category | Implementation Savings (Costs) (\$K) | Operating Savings (Costs) | |
| | | | Using 7% Discount Rate (\$K) | Using 3% Discount Rate (\$K) |
| 2) TEDE | Nuclear Power | n/a | minimal | minimal |
| | REIRS materials | n/a | minimal | minimal |
| | Non-REIRS materials | n/a | minimal | minimal |
| 3) Labeling Containers | Nuclear Power | (208) | 43,000 | 79,600 |
| | REIRS materials | n/a | n/a | n/a |
| | Non-REIRS materials | n/a | n/a | n/a |
| 4) Prior Occupational Dose | Nuclear Power | (208) | 12,200 | 22,500 |
| | REIRS materials | (120) | 240 | 340 |
| | Non-REIRS materials | (22,000) | 10,700 | 15,100 |
| SUBTOTALS | Nuclear Power | (624) | 59,500 | 110,100 |
| | REIRS materials | (240) | 1,040 | 1,440 |
| | Non-REIRS materials | (44,000) | 48,000 | 67,540 |
| TOTAL | | (44,900) | 108,500 | 179,100 |

The total implementation cost to the NRC for the proposed regulatory action is \$158 K.

Operating costs to the NRC associated with the proposed action are assumed to be minimal.

The net present value of the proposed action is \$224,000 K at a 3 percent discount rate (i.e., NRC and industry implementation (\$158 K + 44,900 K) + industry operation \$179,100 K). Whereas, the net present value of the proposed action is \$154,600 K at a 7 percent discount rate (i.e., NRC and industry implementation (\$158 K + 44,900 K) + industry operation \$108,500 K).

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5. Decision Rationale

The net present value of this proposed action is \$224,000 K and \$154,600 K for 3 and 7 percent discount rates, respectively. These savings are obtained by reducing administrative and paperwork requirements on licensees. The NRC recommends proceeding with the proposed rulemaking because the changes improve the effectiveness of NRC regulations and reduce unnecessary regulatory burden without affecting the level of protection to the health and safety of workers and the public.

6. Implementation Schedule

Following 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, which would become effective 30 days after its publication in the *Federal Register*.

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

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 included in the proposed rule would cover all 22,000 licensees regulated by the NRC and Agreement States, the changes are such that 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 it is cost effective to do so. The NRC has determined, therefore, that the changes do not have a significant economic impact on those 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" set forth in the Regulatory Flexibility Act, or the Size Standards established by the NRC (10 CFR 2.810).

XIV. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, 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. The proposed revisions do not impose new requirements on NRC licensees. These revisions either maintain without substantive change existing requirements or reduce current regulatory requirements.

List of Subjects

10 CFR Part 19

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

10 CFR Part 20

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

10 CFR Part 50

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

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

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

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

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as

amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

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

§ 19.13 Notifications and reports to individuals.

* * * * *

(b) Each licensee shall make available to workers information regarding their dose as shown in records maintained by the licensee under the provisions of § 20.2106 of 10 CFR Part 20. On an annual basis, the licensee shall provide a report to each individual monitored in accordance with § 20.1502 of 10 CFR Part 20, 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 makes a request for a report of the individual's annual dose.

* * * * *

(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 therein. This report must be transmitted at a time not 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:

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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 shall 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.

* * * * *

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(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 Part 50 or 52 of this chapter, not including non-power reactors, that are within an area posted in accordance with the requirements in § 20.1902 if they 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, in accordance with § 20.1904, before being removed from the posted area.

* * * * *

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

§ 20.2104 Determination of prior occupational dose.

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

* * * * *

©) 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. 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 the provisions of §§ 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 therein. This report must be transmitted at a time 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 shall 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 , 2005.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook, Secretary of the Commission.