14

Pedersen, Roger

From:	Stewart Schneider
Sent:	Wednesday, July 20, 2005 12:04 PM
To:	CSH@HQGWDO01.OWGWPO02; RLP1@HQGWDO01.TWGWPO01; CGJ@TWFN_DO.twf2_po; CRM@TWFN_DO.twf4_po; SXS2@TWFN_DO.twf4_po; ARJ@TWFN_DO.twf5_po
Cc:	Stephanie Coffin; Catherine Haney
Subject:	Re: Review of Proposed Rulemaking Package for Parts 19 and 20.
Attachments:	Proposed Rule Part19_20-CoverMemo 07-05-05.wpd; Proposed Rule Part19_20 SECY and FRN 07-07-05.wpd

Working group and technical support members:

Yesterday, I met with most of you to discuss the background of the proposed rulemaking to revise Parts 19 and 20. This rulemaking is commonly referred to as the RUBI rulemaking (RUBI - Reduction of Unnecessary Burden Initiative). As the recently appointed project manager, I am working toward the goal of publishing the proposed rule before the end of the year.

In addition to the hard copy package that you were provided, I am attaching the electronic version of the files. Please provide your comments to me by COB next Thursday (7/28). I will be on vacation from 7/21 through 7/27 (AM).

Thanks.

Stewart

B-14

MEMORANDUM TO: Jack R. Strosnider, Director, NMSS
Joseph R. Gray, Associate General Counsel, OGC
Carl J. Paperiello, Director, RES
Michael R. Johnson, Director, OE
Paul H. Lohaus, Director, STP
Roy P. Zimmerman, Director, NSIR
Michael T. Lesar, Chief, ADM/DAS/RDB
Brenda Jo. Shelton, Chief, OCIO/IMD/RMB
Jesse L. Funches, Chief Financial Officer, OCFO

FROM: Catherine Haney, Program Director, NRR/DRIP/RPRP

SUBJECT: OFFICE CONCURRENCE ON PROPOSED RULE - REVISION OF REPORTING OF EXPOSURE DATA, COLLECTION, AND LABELING, AND CLARIFYING DOSE DETERMINATION METHODOLOGY (TAC #MB8194)

Your review and concurrence is requested on the attached proposed Commission Paper and its attachment, a draft *Federal Register* notice (FRN) of proposed rulemaking to amend the requirements for radiation exposure related to the collection, reporting, and labeling of information and dose determination methodology in 10 CFR 19.13, 20.1003, 20.1905, 20.2104, and 20.2205.

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.

This proposed rulemaking addresses the regulatory actions suggested by the nuclear power industry to reduce unnecessary regulatory burden related to radiation protection. The following regulations would be revised by this proposed rulemaking.

- 10 CFR 19.13, "Notifications and reports to individuals," to amend the provisions to require licensees to provide annual occupational dose reports only to workers if they meet certain criteria.

CONTACT: Stewart Schneider, NRR/DRIP/RPRP
301-415-4123

- 10 CFR 20.1003, "Definitions," to change the definition of total effective dose equivalent (TEDE) to be more consistent with the technical basis for the requirements in Part 20 by clarifying that TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

- 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption from the requirements in 10 CFR 20.1904, "Labeling containers," for the labeling of certain containers within posted areas in nuclear power reactor facilities.

- 10 CFR 20.2104, "Determination of prior occupational dose," to remove the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose for an individual and add the requirement that licensees obtain the complete cumulative dose record for individuals being authorized to receive a planned special exposure.

The staff issued draft language and solicited comments from the States and public as part of our development of the proposed rule. Comments were received from two States, power reactor licensees, a fuel facility licensee, an individual, and two industry organizations (the Nuclear Energy Institute (NEI)I and the Council on Radionuclides and Radiopharmaceuticals). The language included in this proposed rulemaking did not change significantly from that provided to the States in All Agreement State Letter STP-04-002 dated January 9, 2004, or the solicitation of public comments published in the *Federal Register* on February 24, 2004 (69 FR 8350). A discussion of the major comments and the staff's disposition of the comments is provided for each of the four proposals included in the attached draft Federal Register notice of proposed rulemaking.

This request is summarized as follows:

1. Title: Revision of Requirements for Radiation Exposure: Collection, Reporting, and Labeling of Information and Clarifying the Dose Determination Methodology

2. NRR Task Leader/Contact: Stewart Schneider, DRIP/RPRP - (301) 415-4123 or E-mail address SXS4@NRC.gov

3. Cognizant Individuals: Roger Pedersen - NRR
   Charles Hinson - NRR
   Catherine Mattsen - NMSS
   Sami Sherbini - NMSS
   Andrea Jones - OSTP
   Susan Chidakel - OGC

4. Requested Action: Office Concurrence on the Proposed Rule.

5. Requested Completion Date: 20 days after the date of this memorandum.

Attachment: Draft Commission Paper and its Attachment (FRN)

Attachment: Draft Commission Paper and its Attachment (FRN)

cc: OIG

DISTRIBUTION:
see next page

ADAMS ACCESSION #
File: C:\A WP\Wpdocs NRR\RUBI RULE\Proposed Rule Package\Proposed Rule Part19_20-CoverMemo 07-05-05.wpd

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DATE	07/ /05	07/ /05	07/ /05

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RULEMAKING ISSUE
NOTATION VOTE

SECY-04-XXXX

FOR: Chairman Diaz
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING TO AMEND 10 CFR PARTS 19 AND 20: COLLECTION, REPORTING, AND LABELING REQUIREMENTS, AND CLARIFICATION OF DOSE DETERMINATION METHODOLOGY (RIN: 3150-AH40)

PURPOSE:

To obtain Commission approval to publish in the Federal Register for public comment a proposed rule to amend the requirements for radiation exposure related to the collection, reporting, and labeling of information and the dose determination methodology in 10 CFR 19.13, 20.1003, 20.1905, 20.2104, and 20.2205.

SUMMARY:

The staff has prepared a proposed rulemaking to 1) amend the provisions of 10 CFR 19.13 to require licensees to provide annual occupational dose reports only to workers if they meet certain criteria; 2) revise 10 CFR 20.1905 to add an exemption from the requirements in 10 CFR 20.1904, for the labeling of certain containers within posted areas in nuclear power reactor facilities; 3) remove the requirement in 10 CFR 20.2104 that requires licensees to attempt to obtain the records of cumulative occupational radiation doses for all employees (but add an explicit requirement to obtain a complete cumulative dose history before authorizing a planned special exposure); and 4) change the definition of total effective dose equivalent (TEDE) in 10 CFR 20.1003 to be more consistent with the technical basis for the requirements in Part 20 by clarifying that TEDE is the sum of the effective dose equivalent (for external

CONTACT: Stewart Schneider, NRR/DRIP/RPRP
301-415-4123

exposures) and the committed effective dose equivalent (for internal exposures). As a result, administrative and paperwork requirements would be reduced without adverse impact on occupational or public exposure limits. The effect of this action would allow NRC licensees to change selected procedures to reduce the administrative burdens associated with the current regulations.

BACKGROUND:

The NRC Strategic Plan, Fiscal Year 2000-Fiscal Year 2005, included, among NRC performance goals for nuclear reactor safety, that of reducing unnecessary regulatory burden on stakeholders. In order to further this goal, the staff conducted a public workshop and solicited public comments from stakeholders.

In SECY-02-0081, "Staff Activities Related to the NRC Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees, dated May 13, 2002, the staff described its interactions with stakeholders regarding ways to reduce unnecessary regulatory burden, and requested Commission approval of its plans to meet this goal.

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

As part of the development of the proposed rule, the staff drafted proposed rule language. The staff requested comments from the States on the draft rule language in All Agreement State Letter STP-04-002 dated January 9, 2004. Comments were received from the 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 power reactor licensees, a fuel facility licensee, and industry groups (i.e., 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 substantive 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 change being proposed affects 10 CFR 19.13 and 20.2205. The staff is proposing a change to the notification requirement in § 19.13(b) so that licensees would continue the current reporting for adult workers who receive more than two percent of the limits specified in 10 CFR 20.1201 (this would generally translate to exceeding a TEDE of 1 millisievert (mSv) (100 millirem (mrem)) dose in one year but would not be required to provide unsolicited annual dose reports to workers who receive less than two percent of those limits. The staff's initial criterion of 1 mSv (100 mrem) was selected because it corresponds to the annual public dose limit in 10 CFR 20.1301, "Dose limits for individual members of the public," and is also the threshold for requiring employee training pursuant to 10 CFR 19.12, "Instruction to workers." In addition, licensees would still provide an annual dose report for workers who are younger than 18 years of age, or have declared themself pregnant. The number of workers in those categories is small. This continued small burden is justified given the radiosensitivity and lower dose limits.

In addition, because the requirement to report annually the doses to workers would be consolidated in the proposed revision to section 19.13, conforming changes would need to be made to section 20.2205.

2) Labeling Containers

The second change being proposed would revise 10 CFR 20.1905 to include an exemption from labeling containers in accordance with10 CFR 20.1904 for certain containers within facilities licensed under Parts 50 or 52. The exempted containers would need to satisfy such conditions as being located within an area posted in accordance with 10 CFR 20.1902, being conspicuously marked, and being accessible only to trained individuals.

3) Cumulative Occupational Radiation Dose

The third proposed change revises 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. The staff is proposing to change 10 CFR 20.2104 to require that licensees obtain the records of cumulative occupational radiation dose only for those individuals being authorized to receive a planned special exposure. The information on occupational doses in years other than the current year is not used except in performing evaluations required by 10 CFR 20.1206, "Planned special exposures."

4) Definition of Total Effective Dose Equivalent (TEDE)

The fourth change proposed by the staff is to revise the definition of TEDE in 10 CFR 20.1003 to be more consistent with the technical basis for the requirements in Part 20 (e.g., the recommendations of the International Commission on Radiological Protection (ICRP)). The proposed change resolves a source of possible confusion in the current regulation by clarifying that the TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). 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 (DDE) will be substituted for the effective dose equivalent (for external exposures). When DDE is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(I), the requirement to determine the DDE for the part of the body receiving the highest exposure, in 10 CFR 20.1201(c), will still apply.

AGREEMENT STATE ISSUES:

Prior to publication of the draft rule language in the Federal Register (69 FR 8350; February 24, 2004), the staff solicited comments from the States in All Agreement State Letter STP-04-002 dated, January 9, 2004. We received comments from the States of Illinois and Washington on this letter.

Regarding the proposed amendment of the requirements in 10 CFR Parts 19 and 20 for licensees to provide annual radiation exposure reports to workers receiving exposures below the existing regulatory limits, the State of Washington indicated that the reporting threshold should be ten percent of the dose limit. On the proposed revision of 10 CFR 20.1904, for the labeling of certain 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. Regarding the proposed revision of 10 CFR 20.2104 to require that licensees obtain the records of cumulative occupational radiation doses only for those individuals being authorized to receive a planned special exposure, the State of Illinois indicated that the change is appropriate. Finally, regarding the change to the definition of TEDE in 10 CFR 20.1003, the State of Washington agreed that the revised definition is technically valid and more consistent with the ICRP recommendations. The staff's resolution of 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 D. A

Compatibility Category "D" designation means the Agreement State is not required for purposes of compatibility to adopt the requirement.

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 has no objection to issuing the rule.
The Advisory Committee on Reactor Safeguards elected not to review the proposed rule requirements.
The Committee to Review Generic Requirements has been informed of the staff's intention to publish this rule and has no objection.
The Committee to Review Generic Requirements has deferred its review of the rule until the final stage.

RESOURCES:

The staff estimates that the resources needed to complete this rulemaking is 1.2 FTE, approximately 0.6 FTE in FY 2005 and FY 2006. Inspection of licensee implementation will be performed through the normal inspection process.

RECOMMENDATIONS:

That the Commission:

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

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 an Environmental Assessment with a finding of no significant environmental impact and a Regulatory Analysis.

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

RECOMMENDATIONS:

That the Commission:

Approve for publication in the Federal Register the proposed amendments to 10 CFR Parts 19 and 20 (Attachment).
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.
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6. That an Office of Management and Budget information collection clearance package is required.

Luis A. Reyes
Executive Director
for Operations

Attachment: As stated

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[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19 and 20

RIN 3150 - AH40

Collection, Reporting, and Labeling Requirements, and Clarification of Dose Determination Methodology

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for radiation exposure related to the collection, reporting, and labeling of information and the dose determination methodology. The proposed rule would require annual occupational dose reports under certain circumstances and limit the scope of the records to be obtained pertaining to cumulative radiation dose to an individual. The proposed rule would also modify labeling requirements for certain containers in nuclear power facilities. Finally, the proposed rule would change the definition of total effective dose equivalent (TEDE) to be more consistent with the technical basis for the requirements in 10 CFR Part 20, "Standards for Protection Against Radiation." As a result, administrative and paperwork requirements would be reduced without adverse impact on occupational or public exposure limits. The effect of this action would allow NRC licensees to change selected procedures to reduce the administrative burdens associated with the current regulations.

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 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*)**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number RIN 3150-AH40 in the subject line of your comments. Comments on rulemakings submitted in writing or electronic form will be made available to the public in their entirety on the NRC rulemaking website. Personal information will not be removed from your comments.

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

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

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

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

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publically available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@nrc.gov.

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

SUPPLEMENTARY INFORMATION:

XII. Regulatory Flexibility Certification

XIII. Backfit Analysis

I. Background

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

To further this goal, the NRC published a notice of pubic workshop and request for comments in the *Federal Register* on May 3, 2001, (66 FR 22134) and sponsored a workshop on May 31, 2001. In response to this workshop, the NRC received one comment letter. This letter from the Nuclear Energy institute (NEI) dated July 2, 2001, (ADAMS No. ML011870432) provided a consolidated industry list of suggested burden-reduction issues 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."

The NRC staff reported to the Commission on its interactions with stakeholders regarding ways to reduce unnecessary regulatory burden in SECY-02-0081, "Staff Activities Related to the NRC Goal of Reducing Unnecessary Regulatory Burden on Power Reactor Licensees," dated May 13, 2002. In that document, the NRC staff requested approval of its plans to meet this goal. By a Staff Requirements Memorandum (SRM) dated June 25, 2002,

the Commission approved, subject to certain qualifications,[1] the NRC 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.

The NRC considered the comments from industry and other stakeholders provided in response to the earlier cited notice of public workshop and request for comments. This proposed rulemaking addresses those regulatory changes suggested by NEI under the category of "Radiation Protection" as described above and the resulting conforming changes to 10 CFR 20.1905, "Exemptions to labeling requirements" and 10 CFR 20.2205, "Reports to individuals of exceeding dose limits. The NRC's assessment is that the regulations suggested for revision by NEI impose a regulatory burden on licensees beyond what is necessary to protect workers and the public. Additional changes proposed by NEI to other areas of the Commission's regulations have been or are being assessed by the NRC under different regulatory actions.

Another component of this action to reduce unnecessary regulatory burden, is the NRC's proposal to change 10 CFR 20.1003, "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).[2]

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[1] Among other things, the Commission directed the NRC staff not to pursue certain regulatory changes and directed the staff to provide certain additional information and establish a method for measuring the results of its efforts.

[2] See Regulatory Issue Summary (RIS) 2004-01, "Method for Estimating Effective Dose Equivalent from External Radiation Sources Using Two Dosimeters," dated February 17, 2004, and RIS 2003-04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," dated February 13, 2003.

As part of the development of the proposed rule, the NRC solicited comments from the States on the draft rule language in All Agreement State Letter STP-04-002 dated January 9, 2004, (ML040090486). Comments were received from the States of Illinois and Washington. The draft rule language was referenced in the *Federal Register* (69 FR 8350; February 24, 2004) to solicit public comment. The Commission received eight public comment letters. Based on the comments received, the language included in this proposed rulemaking did not change significantly from that provided to the States in All Agreement State Letter STP-04-002, or that published in the *Federal Register* on February 24, 2004.

II. Discussion

There are four substantive changes being considered as part of this proposed rulemaking. The February 2004 notice solicited public comment on a number of specific questions on the draft rule language. 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 preponderance of the public comments on the proposed rule language supported NRC's approach. The following summarizes the comments received and NRC's resolution. State comments are addressed separately in Section V, "Agreement State Issues," of the **SUPPLEMENTARY INFORMATION** of this document.

Annual dose report to workers

The first change being proposed affects 10 CFR 19.13 and 20.2205. In accordance with 10 CFR 19.13(b), licensees are currently required to advise workers annually of received doses as shown in records maintained by the licensee pursuant to 10 CFR 20.2106(a). That regulation requires maintaining records of doses received by individuals for whom monitoring was required under 10 CFR 20.1502(a), which requires monitoring of occupational radiation exposure for adult workers likely to receive a dose in excess of 10 percent of the limits specified in 10 CFR 20.1201. Licensees make this determination prospectively so that many of the workers monitored by licensees actually receive no measurable exposure or only a small fraction of the doses specified in 10 CFR 20.1201. As a result, the recordkeeping and reporting requirements have applied unnecessarily to a large number of workers, thereby increasing administrative costs to licensees.

The NRC is proposing a change to the notification requirement in § 19.13(b) so that licensees would continue the current reporting for adult workers who receive more than two percent of the limits specified in 10 CFR 20.1201 (this would generally translate to exceeding a TEDE of 1 millisievert (mSv) (100 millirem (mrem)) dose in one year) but would not be required to provide unsolicited annual dose reports to workers who receive less than two percent of those limits. The NRC's initial criterion of 1 mSv (100 mrem) was selected because it corresponds to the annual public dose limit in 10 CFR 20.1301, "Dose limits for individual members of the public," and is also the threshold for requiring employee training pursuant to 10 CFR 19.12, "Instruction to workers." Further, the NRC is proposing to consolidate the reporting requirements to individuals involved in radiological accidents, overexposures, and planned special exposure into 10 CFR 20.2205.

The publication of the draft rule language in the February 2004 *Federal Register* notice did not address minors subject to the dose limits in 10 CFR 20.1207, "Occupational dose limits to minors," and declared pregnant women subject to the dose limits of 10 CFR 20.1208, "Dose equivalent to an embryo/fetus." Accordingly, the draft rule language in 10 CFR 19.13 has been revised to include these conditions. Licensees would still provide an annual dose report for workers who are younger than 18 years of age, or have declared themself pregnant. The number of workers in those categories is small. This continued small burden is justified given the radiosensitivity and lower dose limits.

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)). It is the NRC's position that setting the criteria at 1 mSv (100 mrem), consistent with the annual dose limit for members of the public and employee training requirements, reasonably balances reducing unnecessary regulatory burden and the need to keep individual workers informed of their occupational dose.

Another industry commenter suggested that NRC clarify that the applicability of the criterion is limited to the occupational dose received from work activities at the specific license's facility, and is not applicable to the cumulative annual dose received from work activities at all (multiple) licensee facilities during the year. The NRC's position is that the threshold is to be applied to a dosimetry program whether it covers a single facility or multiple facilities owned by the licensee. Licensees need not consider radiation exposure from employment by a prior licensee when applying this criterion in that monitoring year.

In response to the published draft rule language, industry provided comments on worker training as it relates to the notification and reporting requirements. While one commenter stated

that individual workers should receive training on their right to request an annual report of their occupational exposure, two commenters suggested that existing regulations adequately address this issue. The NRC's position is that the regulations at 10 CFR 19.12(a)(6) provide adequate requirements for the training of workers regarding their right to request reports about their occupational exposure. However, NRC Form 3, "Notice to Employees," would need to be revised to reflect the reporting threshold to be established if this proposed rule is adopted as a final rule.

The language used in this proposed rule has been revised from that previously published in draft for comment. Reference to 10 CFR 20.1502(a) has been added to the proposed rule language to clarify the conditions requiring individual monitoring of dose. Also, the requirement to provide reports to minors and declared pregnant women has been added as discussed above.

Labeling containers

The second change under consideration would revise 10 CFR 20.1905, "Exemptions to labeling requirements," to include an exemption from labeling containers in accordance with10 CFR 20.1904 for certain containers within 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. The exempted containers would need to satisfy such conditions as being located within an area posted in accordance with 10 CFR 20.1902, being conspicuously marked, and being accessible only to trained individuals.

In the *Federal Register* notice that referenced the draft rule language, NRC indicated that this proposed change would revise 10 CFR 20.1905 or alternatively add a new regulation to 10 CFR Part 50. Two comments were received on this issue. One commenter favored the creation of a new exemption in 10 CFR 20.1905; while the other commenter favored placing the exemption in 10 CFR Part 50. It is the NRC's position that it would be more appropriate to add a new exemption to 10 CFR 20.1905 (applicable only to nuclear power reactor licensees), which specifically established exemptions from the container labeling requirements.

A third industry comment suggested that the rule should require the labeling of containers 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. 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 industry suggestions, 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.

In response to the specific question in the February 2004 *Federal Register* notice, on whether there are categories of material licensees to which this exemption might be applied, no comments were received. The NRC position is that the proposed change will continue to apply only to Part 50 licensees because these licensees showed specific interest by requesting this action in the NEI letter dated July 2, 2001. For additional information on the NEI letter, refer to Background in the **SUPPLEMENTARY INFORMATION** in this document.

The language used in this proposed rule is nearly the same as that previously published in draft for comment. One minor change to the draft rule language was made by removing the term "labeling" to be consistent with the terminology in 10 CFR 20.1904 and 20.1905.

Cumulative occupational radiation dose

This proposed change revises the requirement in 10 CFR 20.2104(a)(2), "Determination of prior occupational dose," for licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring pursuant to 10 CFR 20.1502. The information on occupational doses in years other than the current year is not used except in performing evaluations required by 10 CFR 20.1206, "Planned special exposures." Requirements related to obtaining information, performing evaluations, maintaining records, and making reports to individuals and the NRC about planned special exposures are codified in 10 CFR 20.1206, "Planned special exposures," and 20.2104(b). The NRC is proposing to change 10 CFR 20.2104 to require that licensees obtain the records of cumulative occupational radiation dose only for those individuals being authorized to receive a planned special exposure.

The industry comments received on this proposed amendment, supported the change to the language in 10 CFR 20.2104. Another commenter, a member of the public, expressed concern that the proposed rule change would give workers the impression that lifetime dose is not important. 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).

The language used in this proposed rule is the same as that previously published in draft for comment.

Definition of total effective dose equivalent

The fourth change proposed by the NRC is to revise the definition of TEDE in 10 CFR 20.1003 to be more consistent with the technical basis for the requirements in Part 20 (e.g., the recommendations of the International Commission on Radiological Protection (ICRP)) and thus resolve an apparent conflict between the definitions of TEDE and the whole-body weighting factor in Part 20. The proposed change resolves this source of possible confusion in the current regulation by clarifying that the TEDE is the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). 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 (DDE) will be substituted for the effective dose equivalent (for external exposures). When DDE is used to determine compliance with the TEDE limit in 10 CFR 20.1201(a)(1)(I), the requirement to determine the DDE for the part of the body receiving the highest exposure, in 10 CFR 20.1201(c), will still apply. RIS 2003-04 and RIS 2004-01 provide a discussion of the regulatory basis, and approved methods, for using the effective dose equivalent from external exposures in complying with the regulatory requirements, and limits, on TEDE.

Only industry comments were received on this issue and they favored the proposed change. The language used in this proposed rule is the same as that previously published in draft for comment.

III. Section-by-Section Analysis

Section 19.13, "Notifications and reports to individuals," would be revised to consolidate and amend the Commission's requirements for notifying workers of occupational doses. The

current requirement to report radiation doses to individuals on an annual basis appears in 10 CFR sections 19.13(b), 19.13(d) and 20.2205. Paragraph (b) would be revised to consolidate these requirements and to require that licensees make available to workers information regarding their doses as shown in records maintained by the licensee pursuant to 10 CFR 20.2106, and provide annual dose reports to workers who are monitored pursuant to 10 CFR 20.1201(a) if a worker's occupational dose exceeds two percent of the dose limits in section 20.1201(a), if the individual is a minor subject to the dose limit in section 20.1207, if the individual is a declared pregnant woman subject to the dose limit in section 20.1208(a) or if the individual makes a request for a report of his or her annual dose. Paragraph 19.13(d) would be removed to delete the requirement that licensees provide individuals with reports when they are required pursuant to sections 20.2202, 20.2203, 20.2204 or 20.2206 to report to the Commission exposures of individuals to radiation or radioactive material.

In section 20.1003, "Definitions," the definition of total effective dose equivalent (TEDE) would be revised to be more consistent with the technical basis for the requirements in Part 20 (e.g., the recommendations of the ICRP) by clarifying 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.

A new paragraph (g) would be added to section 20.1905, "Exemptions to labeling requirements," that provides an exemption to the labeling requirements for containers holding licensed material that are within an area posted pursuant to the requirements of section 20.1902 at a nuclear power plant. The regulations would not require the licensee to label the container if

it is conspicuously marked commensurate with the radiological hazard, accessible only to individuals handling or working in the vicinity of the containers who have sufficient instructions to minimize radiation exposure, and appropriately labeled pursuant to section 20.1904 before being removed from the posted area.

In Section 20.2104, "Determination of prior occupational dose," the current paragraph (a)(2) would be deleted that requires licensees to attempt to obtain the records of cumulative occupational radiation dose. Then paragraphs (a) and (a)(1) would be combined and renumbered. Paragraph (a)(2) would be revised to require licensees to obtain the complete cumulative dose record for individuals being authorized to receive a planned special exposure.

Section 20.2205, "Reports to individuals of exceeding dose limits," would be revised to delete the reference to section 20.2206 and add a reference to section 20.2202. Also, the title of this section would be revised to delete the term "of exceeding dose limits." The deletion of the reference to section 20.2206 was to facilitate the consolidation of the requirement to report annually the doses to workers in the proposed revision to section 19.13. Reference to section 20.2202 was added to (and section 19.13(d) deleted) to consolidate the reporting requirements to individuals involved in radiological incidents, overexposures, and planned special exposures. The title was revised because planned special exposure may not involve doses to individuals exceeding the dose limits.

IV. Agreement State Issues

Prior to publication of the draft rule language in the *Federal Register*, the NRC solicited comments from the States in All Agreement State Letter STP-04-002 dated, January 9, 2004. Comments were received from the States of Illinois and Washington on this letter.

Regarding the proposed amendment of the requirements in 10 CFR Parts 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," and 20 on providing annual radiation exposure reports to workers receiving exposures below the existing regulatory limits, the State of Washington indicated that the reporting threshold should be ten percent of the 5 mSv (500 mrem), occupational dose limit for adults. As explained above, it is the NRC's position that setting the criteria at 1 mSv (100 mrem) (two percent of the occupational dose limit) consistent with the annual dose limit for members of the public and employee training requirements, reasonably balances reducing unnecessary regulatory burden and the need to keep individual workers informed of their occupational dose.

Regarding the proposed revision of 10 CFR 20.1904, for the labeling of certain 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. As explained above, it is the NRC's position that the exemption better fits with the other exemptions listed in 10 CFR 20.1905.

Regarding the proposed revision of 10 CFR 20.2104 to require that licensees obtain the records of cumulative occupational radiation doses only for those individuals being authorized to receive a planned special exposure, the State of Illinois indicated that the change is appropriate.

Finally, regarding the change to the definition of TEDE in 10 CFR 20.1003, the State of Washington agreed that the revised definition is technically valid and more consistent with the ICRP recommendations.

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.hsrd.ornl.gov/nrc/home.html). The NRC has determined that the Compatibility Categories for the sections amended in this proposed rule would be the same as for the sections in the current regulations, except for the new exemption (g) added to § 20.1905.

The revision to § 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 revisions to §§ 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 § 20.2104(a) and the new exemption (g) added to § 20.1905 are 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. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in these proposed revisions to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this document. 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 the preamble.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. The NRC is revising specific requirements related to the collection, reporting, and labeling of information and dose determination methodology. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination reads as follows:

This action endorses existing requirements and establishes regulations that reduce regulatory burdens for nuclear reactor licensees. The proposed changes may also affect some other NRC and Agreement State licensees but to a lesser degree than expected for the power reactor licensees. This action stems from the Commission's ongoing effort to reduce paperwork requirements and eliminate obsolete regulations. The proposed rule would reduce the regulatory burdens for radiation exposure on present and future licensees by eliminating the need to collect, report, and label certain information and clarifying the dose determination methodology.

The proposed action relates to the collection, reporting, and labeling of information and dose determination methodology, and would not, therefore, significantly increase the probability or consequences of an accident. No changes are being made in the types or quantities of radiological effluents that may be released and there is no significant increase in public radiation exposure since there is no change to facility operations that could create a new or affect a previously analyzed accident or release path. With regard to non-radiological impacts, no changes are being made to non-radiological effluent releases and there are no changes in

activities that would adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with the proposed action.

The primary alternative to this action would be the no action alternative. The no action alternative would continue to impose unwarranted regulatory burdens for which there would be no safety, risk, or environmental benefit.

The NRC has sent a copy of this proposed rule to every State Liaison Officer and requested their comments on this environmental assessment.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC is seeking public participation. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

IX. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The annual savings to industry for these information collections is estimated to be 13,700 hours and $100,000.

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 F52), 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, (3150-0011), Office of

Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to John_A._Asalone@omb.eop.gov or comment by telephone at (202) 395-4650.

X. 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.

XI. Regulatory Analysis

The Commission has prepared a draft 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 Commission and considers the following potentially affected attributes: Occupational health; Industry implementation; Industry operation; NRC implementation; and NRC operation. The following four changes, which are discussed in the **SUPPLEMENTARY INFORMATION** in this document, are considered in connection with each of these attributes.

(1) 10 CFR 19.13, "Notifications and reports to individuals," and related regulations in 10 CFR Part 20, "Standards for protection against radiation," to modify the requirements for licensees providing annual radiation exposure reports to workers receiving exposures below the existing regulatory limits.

(2) 10 CFR 20.1003, "Definitions," to change the definition of total effective dose equivalent (TEDE) to be more consistent with the technical basis for the requirements in Part 20 as discussed in RIS 2004-01 and RIS 2003-04.

(3) 10 CFR 20.1905, "Exemptions to labeling requirements," to add an exemption from 10 CFR 20.1904, "Labeling containers," for certain containers within posted areas in nuclear power reactor facilities.

(4) 10 CFR 20.2104, "Determination of prior occupational dose," to require that licensees obtain the records of cumulative occupational radiation doses only for those individuals being authorized to receive a planned special exposure.

1. Statement of the Problem and Objective

The objective of the rulemaking activity is to revise requirements for licensees to reduce unnecessary regulatory burden while maintaining requirements needed to protect workers and the public from exposure to radioactive materials and by clarifying the dose determination methodology. The specific changes in this proposed rulemaking were identified as part of a broader initiative to reduce unnecessary regulatory burden as specified in the NRC Strategic Plan for fiscal years 2000 through 2005. This initiative is also consistent with the goal of ensuring that NRC actions are effective, efficient, realistic, and timely as described in the NRC Strategic Plan for fiscal years 2004 through 2009. This proposed rulemaking improves NRC regulation

by adding needed requirements (or clarifications as in the proposed definition of TEDE) and eliminating unnecessary requirements.

2. Identification and Preliminary Analysis of Alternative Approaches

The NRC's assessment identified two alternatives related to the requirements. The first option would be not to undertake the rulemaking. The second option involves the changes described in this proposed rulemaking.

(A) No Action Alternative

Under the no action alternative, the NRC would not move forward with the proposed rule, and the current regulations would remain in place. This option will be used as the baseline in evaluating the benefits of the proposed rulemaking.

(B) Proposed Rule Alternative

Under the proposed rule alternative, the NRC would amend its regulations in 10 CFR 19.13, 20.1003, 20.1905, 20.2104, and 20.2205. The rulemaking option was considered relative to the following goals of the NRC: ensuring protection of public health and safety and the environment; ensuring the secure use and management of radioactive materials; ensuring

openness in the regulatory process; ensure that NRC activities are effective, efficient, realistic, and timely; and ensuring excellence in agency management.

The proposed rulemaking involves changes to administrative or procedural requirements for radiation exposure related to collecting, reporting, and labeling of information and the dose determination methodology, and has no direct bearing on facility designs or operating practices. The proposed rulemaking is therefore neutral in terms of the NRC goals of maintaining safety and securing radioactive materials. The proposed rulemaking maintains the current reports which are provided to the NRC and available in the public domain. The proposed rulemaking is therefore neutral in terms of the goal to ensure openness in the regulatory process. The proposed rulemaking was initiated to achieve the goal stated in NRC's strategic plan for fiscal years 2000 through 2005 to reduce unnecessary regulatory burdens. In terms of the current NRC strategic plan, the proposed changes relate to the goal of ensuring that NRC actions are effective, efficient, realistic, and timely. Specifically, the proposed rulemaking is intended to modify requirements related to collecting, reporting and labeling of information and the dose determination methodology to more efficiently achieve the agency's mission. The proposed rulemaking does not change the NRC's internal processes or responsibilities and, therefore, is neutral in terms of the NRC goal of ensuring excellence in agency management. Additional information is provided in the following value-impact assessment.

3. Value-Impact Assessment

The proposed rulemaking involves a change to an NRC administrative process and would not affect attributes related to public health, property, or environmental considerations. The potentially affected attributes are discussed below:

3.1 Occupational Health

3.1.1 Annual Exposure Report

The proposed change is limited to the requirements to provide an annual report of occupational dose to workers whose dose is a fraction of the regulatory limits. The proposed regulations are not expected to change the number of workers exposed to radiation or change the dose incurred by workers, individually or collectively, and would, therefore, not adversely affect the health of the workers involved in NRC licensed activities.

3.1.2 Labeling Containers

The proposed change is limited to the requirements to label certain containers within areas posted inside nuclear power plants. The provisions for using the added exemption include the need to mark containers posing a radiological hazard and limit accessability to trained individuals. These provisions are intended to ensure that the proposed regulation does not change the number of workers exposed to radiation or change the dose incurred by workers, individually or collectively, and to avoid adversely affecting the health of the workers at nuclear power plants.

3.1.3 Prior Occupational Dose

The information on occupational doses in years other than the current year is used only in performing evaluations required by 10 CFR 20.1206. The proposed rule does not affect the regulatory limits established for radiation dose. Thus, the proposed regulation will not result in a change to the number of workers exposed to radiation or change the dose incurred by workers, individually or collectively, and would not adversely affect the health of the workers involved in NRC licensed activities.

3.1.4 TEDE

The proposed change in the definition of TEDE is intended to clarify the regulations and does not affect the regulatory limits established for radiation dose. The proposal would not change the number of workers exposed to radiation or change the dose incurred by workers, individually or collectively, and would not adversely affect the health of the workers involved in NRC licensed activities.

3.2 *Industry Implementation*

3.2.1 Annual Exposure Report

Industry implementation of the proposed changes would involve some changes to procedures, labeling, and training. The NRC's position is that preparing revisions to procedures and training could be included in the ongoing support of those programs and, therefore, have minimal additional costs to licensees for nuclear power plants. Comments from nuclear power plant licensees provided in response to the solicitation of comments on draft language for this proposed rulemaking confirmed that the implementation of the changes would not involve significant costs. For this analysis, the NRC estimates that the changing of procedures and training modules would require approximately 40 hours for each of the approximately 70 reactor sites or 2800 person-hours for the nuclear power industry. Assuming an NRC-staff rate of $88 per hour, the one-time cost of implementing the proposed rule would be $250,000 for the nuclear power industry.

The implementation costs for the materials licensees will vary because of differences in the sizes of work forces and the diversity of licensed activities. This analysis assesses the likely costs for licensees as they are categorized in Volume 24 of NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power

Reactors and Other Facilities 2002," (October 2003) as (1) fuel cycle facilities, (2) independent spent fuel storage installations (ISFSIs), (3) low-level waste disposal facilities, (4) manufacturing and distribution facilities, and (5) industrial radiography licensees. For this analysis, fuel cycle facilities and ISFSIs are combined into one group based on the similarity in their procedures and programs for monitoring and reporting information to individuals. Likewise, the analysis assumes comparable implementation costs for low-level waste disposal (Agreement State licensees), manufacturing and distribution licensees, and industrial radiography licensees. These categories have a greater range of monitored individuals and more varied programs in terms of procedures and programs.

The implementation costs related to the proposed changes for annual radiation exposure reports for fuel cycle facilities and ISFSIs are expected to be similar to power reactor licensees. Comparable numbers of employees and similar procedures and controls translate into comparable costs to implement the proposed change. The 10 facilities referred to in NUREG-0713 would therefore have an implementation cost of approximately $35,000 (40 staff-hours at $88 per hour for 10 licenses).

The implementation costs for the second grouping (consisting of low-level waste disposal, manufacturing and distribution, and industrial radiography) will depend on the number of monitored individuals and the programs and procedures used by each licensee. The average number of monitored individuals in this group is about 40 per license and the number of licenses (NRC and Agreement States) is estimated to be several hundred. Estimating the implementation costs for this diverse group of licensees is further complicated by the fact that licensees need not change their programs and procedures to adopt the reduced reporting requirement in the proposed

rule. It is possible that licensees will maintain their current practices since the proposed change is a relaxation of requirements and compliance with current requirements would also satisfy the proposed regulation. Licensees would not be expected to change their procedures and practices unless they determined it was cost effective to do so. The implementation cost for an individual licensee would be expected to range from zero for those licensees maintaining the status quo to approximately $3,500 (40 staff-hours times $88 per hour) for those licensees adopting the revised reporting requirement. Assuming the higher cost estimate, only those licensees with large numbers of employees would likely implement the changes allowed by the proposed rulemaking. Using data from NUREG-0713 and increasing the number to account for Agreement State licensees, the NRC estimates the number of licensees in this grouping likely to implement the change to be 20. The total implementation cost would, therefore, range from zero if few licensees implemented the change to approximately $70,000 if the larger licensees adopted the reduced reporting requirement.

3.2.2 Labeling Containers

This proposed change is only applicable to nuclear power plant licensees. Industry implementation of the proposed changes would involve some changes to procedures, labeling, and training. It is the NRC's position that preparing revisions to procedures and training could largely be included in the ongoing support of those programs and, therefore, have minimal additional costs to licensees for nuclear power plants. In addition, the rulemaking adds an exemption for the labeling requirements in 10 CFR 20.1904 but licensees are not required to adopt it and may continue their current practices. Licensees choosing not to adopt the exemption would not incur implementation costs associated with the proposed rule. The NRC estimates that most licensees will choose to use the exemption and that the related changes to procedures and training modules would require approximately 80 hours for each of the approximately 70 reactor sites or 5600 person-hours for the nuclear power industry. Assuming an NRC-staff rate of $88 per hour, the one-time cost of implementing the proposed rule would be $500,000 for the nuclear power industry.

3.2.3 Prior Occupational Dose

Industry implementation of the proposed changes would involve some changes to procedures, labeling, and training. The NRC's position is that preparing revisions to procedures and training could be included into the ongoing support of those programs and, therefore, have minimal additional costs to licensees for nuclear power plants. Accounting for the changes as a separate activity, the NRC estimates that the changing of procedures and training modules would require approximately 40 hours for each of the approximately 70 reactor sites or 2800 person-hours for the nuclear power industry. Assuming an NRC-staff rate of $88 per hour, the one-time cost of implementing the proposed rule would be $250,000 for the nuclear power industry.

The implementation costs related to the proposed changes for annual radiation exposure reports for fuel cycle facilities and ISFSIs is expected to be similar to power reactor licensees. The 10 facilities referred to in NUREG-0713 would therefore have an implementation cost of approximately $35,000 (40 staff-hours at $88 per hour for 10 licenses).

The implementation costs for the second grouping (consisting of low-level waste disposal, manufacturing and distribution, and industrial radiography) varies depending on the licensee and its related programs and procedures. In most cases, the implementation cost is less than for power reactors and fuel cycle facilities since the effort involved in developing and processing a procedure change is less for the smaller organizations. The licensee could wait to implement the proposed rule until it needs, under the current rule, to obtain an individual's collective radiation dose. The related procedure changes could likely be made using fewer resources than would be needed to perform the data collection for a single employee under the existing rule. The licensee could also choose to comply with the existing requirements instead of changing procedures to adopt the proposed changes. NUREG-0713 explains that 99 percent of the transient work force monitored for radiation exposure is associated with the nuclear power industry. The NRC assumes that the cost to this group of licensees is related to the number of transient employees and, therefore, would be approximately $25,000 (one percent of the nuclear power industry implementation cost of $250,000 multiplied by 10 to account for the larger number of licensees).

3.2.4 TEDE

Industry implementation of the proposed changes would involve some changes to procedures and training. The NRC's position is that preparing revisions to procedures and training could be included into the ongoing maintenance of those programs and, therefore, have minimal additional costs to licensees for nuclear power plants. This is especially true when considering the possible implementation of this proposed change along with one or more of the other changes included in this proposed rulemaking. Revising the actual estimation of TEDE using effective dose equivalent in accordance with an NRC approved dosimetry method would be part of other licensees' initiatives in their radiation protection program and, while possibly aided by this proposed rulemaking, would not be caused by the proposed changes. Considering the likely implementation of this clarifying change to the regulations coincident with the other changes in this proposed rulemaking, the NRC estimates that the implementation cost of 10 hours for each of the approximately 70 reactor sites or 700 person-hours for the nuclear power industry. Assuming a staff rate of $88 per hour, the one-time cost of implementing the proposed rule would be $62,000 for the nuclear power industry.

Other NRC licensees may also need to revise their procedures and training to reflect the changes in the definition of TEDE in NRC regulations. As stated above for licensees of nuclear power plants, it is the NRC's position that preparing revisions to procedures and training could be included into the ongoing support of those programs and, therefore, have minimal additional costs to other NRC licensees. In some cases, the proposed clarification of the TEDE definition may better align NRC regulations with licensees' current procedures and practices developed using previous interpretations of the rules or following interactions with the appropriate regulatory bodies.

3.3 Industry Operation

3.3.1 Annual Exposure Report

In its solicitation for comments on draft language associated with this proposed rulemaking, the NRC requested that commenters provide an estimate of the burden reduction that would result if the rulemaking was pursued. The nuclear power industry estimates were between $1000 to $5000 per site per year or approximately $70,000 to $350,000 per year for the nuclear power industry. Using an estimate of $100,000 per year in savings for the value impact assessment, and using data reported in NUREG-0713, this savings translates to $0.85 per monitored individual receiving less than 1 mSv (100 mrem). At an assumed discount rate of three percent and an average of remaining license term of 37 years, the total savings (in present dollars) is $2,217,000. An assumed discount rate of seven percent over the same period results in an estimated savings of $1,312,000.

Using the data reported in NUREG-0713, Volume 25, "Occupational Radia approximately 6000 individuals at fuel cycle facilities and ISFSIs received an annual dose of less than 1 mSv (100 mrem) during. Under the proposed rulemaking, the licensees would not be required to automatically provide reports to these workers and would, therefore, avoid the associated costs. Assuming a comparable savings as calculated for power reactor licensees ($0.85 per report), the savings for this group of licensees is $5,000 per year. This value is consistent with the comments from a fuel cycle facility licensee responding to the publication of draft language stating that minimal cost savings resulted from the proposed change. For an operating term consistent with power reactors (37 years), the lifetime savings are $111,000 for an assumed discount rate of three percent and $66,000 for an assumed discount rate of seven percent.

The impact of the proposed change regarding annual exposure reports for the second grouping (consisting of low-level waste disposal, manufacturing and distribution, and industrial radiography) will depend on the number of monitored individuals and the programs and procedures used by each licensee. Those licensees choosing to maintain their current procedures for providing an annual report to all monitored individuals would not realize savings from the proposed rule. Licensees adopting the reduced reporting requirements could achieve some modest savings. The NRC estimates that this change would be adopted by only the approximately 20 licensees in this category that employ large numbers of employees. This results in a number of potentially eliminated reports to individuals that is comparable to that of the fuel cycle facilities discussed above. Assuming similar savings per report eliminated, the lifetime savings for this group of licensees would likewise be in the range of $66,000 to $111,000 for an assumed discount rate of three and seven percent, respectively.

3.3.2 Labeling Containers

Comments provided in response to the notice on draft language that preceded this proposed rulemaking indicated estimated savings for nuclear power plant licensees of $10,000 to $50,000 per site per year or approximately $700,000 to $3.5 million (M) per year for the industry. The NRC will use an estimate of $1M per year in savings for the value impact assessment. At an assumed discount rate of three percent and an average of remaining license term of 37 years, the total savings (in present dollars) is $22,170,000. An assumed discount rate of seven percent over the same period results in an estimated savings of $13,120,000. This proposed change is applicable only to power reactor licensees.

3.3.3 Prior Occupational Dose

Comments provided in response to the notice on draft language that preceded this proposed rulemaking included estimated savings for nuclear power plant licensees of $2,000 to $100,000 per site per year or approximately $140,000 to $7M per year for the industry. The NRC will use an estimate of $200,000 per year in savings for the value impact assessment for the nuclear power industry. At an assumed discount rate of three percent and an average of remaining license term of 37 years, the total savings (in present dollars) is $4,434,000. An assumed discount rate of seven percent over the same period results in an estimated savings of $2,624,000.

Specific estimates were not provided for other types of NRC licensees in the comments received following the notices providing draft language before this proposed rulemaking. The cost savings associated with the proposed change on obtaining prior cumulative radiation dose is dependent on the number of individuals being added to a radiation protection program through hiring new employees or using contract workers. Both of the previous groupings of materials licensees have smaller work forces and bring in new employees less frequently than do the power reactor licensees. The NRC assumes the proposed rule will result in no or minimal reductions in the operating costs for both groups of materials licensees. NUREG-0713 explains that 99 percent of the transient work force is associated with the nuclear power industry. The NRC will assume that the savings to the non-power reactor licensees is proportional to the number of transient employees and therefore would be in the range of $26,000 (seven percent discount rate) to $44,000 (three percent discount rate).

3.3.4 TEDE

The changes associated with this proposed rulemaking provide clarification to the regulations. There is an apparent conflict between the definitions of TEDE and the

whole-body weighting factor in Part 20. Adopting the proposed revision to the definition of TEDE would avoid licensees from having to request an exemption, which some have felt necessary to clarify their compliance with the regulatory requirements. For the purpose of this assessment, the clarification of the TEDE definition is assumed to result in a savings of 200 hours per year for the nuclear power industry (NRC assumes 2 hours per year per licensee). At an assumed $88 per staff hour, a discount rate of three percent, and an average of remaining license term of 37 years, the total savings (in present dollars) is $390,000. An assumed discount rate of seven percent over the same period results in an estimated savings of $231,000.

Other NRC licensees may also realize some savings from the clarification of the NRC regulations. As shown above for licensees of nuclear power plants, the NRC's position is that the savings associated with this change are small and are comparable to the likewise small implementation costs.

3.4 NRC Implementation

Implementation of the proposed rulemaking would require minor changes to existing documents such as NRC Form 3. The proposed rulemaking may also require minor changes to NRC procedures and guidance documents. The NRC estimates that preparing the various documents and guidance would require approximately 250 staff-hours or $22,000 (assuming a conversion factor of $88 per staff-hour). The NRC will incur additional costs for publishing and distribution of revised forms, which may be completed by spending less than $28,000. The one-time NRC cost of implementing the proposed rule is, therefore, estimated to be $50,000.

3.5 NRC Operation

Following its implementation, the proposed rulemaking would not affect routine NRC operations. The change to clarify the definition of TEDE may result in some savings by reducing the number of licensing actions and interactions with licensees caused by the current language. These savings are relatively small and so the NRC assumes the proposed rulemaking is neutral in terms of assessing the effect on NRC operations.

The results of the NRC's value-impact assessment are summarized in the following table:

Summary of Industry Implementation and Operating Costs (Savings)				
	Licensee	Implementation Costs (Savings) ($K)	Operating Costs (Savings)	
			Using 7% Discount Rate ($K)	Using 3% Discount Rate ($K)
1) Annual Exposure Reports	Power Reactors	250	(2,217)	(1,312)
	Fuel Cycle/ISFSIs	35	(111)	(66)
	Industrial, etc. (note 1)	70	(111)	(66)
2) Labeling Containers	Power Reactors	500	(22,170)	(13,120)
	Fuel Cycle/ISFSIs	n/a	n/a	n/a
	Industrial, etc.	n/a	n/a	n/a
3) Prior Occupational Dose	Power Reactors	250	(4,434)	(2,624)
	Fuel Cycle/ISFSIs	35	(44)	(26)
	Industrial, etc. (note 1)	25		
4) TEDE	Power Reactors	62	(390)	(231)
	Fuel Cycle/ISFSIs	minimal	minimal	minimal

Summary of Industry Implementation and Operating Costs (Savings)				
	Licensee	Implementation Costs (Savings) ($K)	Operating Costs (Savings)	
			Using 7% Discount Rate ($K)	Using 3% Discount Rate ($K)
	Industrial, etc. (note 1)	minimal	minimal	minimal
SUBTOTALS	Power Reactors	1,062	(29,211)	(17,287)
	Fuel Cycle/ISFSIs	70	(266)	(158)
	Industrial, etc. (note 1)	95		
TOTAL (note 2)		1,227	(29,477)	(17,445)

note 1: It is difficult to estimate the implementation costs and potential savings for the diverse groups of materials licensees. In general, the NRC believes the costs and savings to be minor and the nature of the changes allows licensees to continue current practices if they determine it is not cost beneficial to make the administrative changes needed to adopt the relaxed requirements.

note 2: The addition of the NRC implementation cost of $50K results in a total implementation cost of $1,207K

In summary, the implementation cost of the proposed rule would be relatively small for both the nuclear industry and the NRC. Implementation costs for the nuclear power industry are estimated to range from minimal to as much as $1M if each change was to be implemented as an independent activity. Estimating the costs for materials licensees is difficult but the NRC believes the costs to be small. In addition, licensees could generally maintain their current procedures and practices under the proposed rule and pursue changes only if found to be cost beneficial. The cost savings associated with the proposed rule would largely benefit the licensees for nuclear power plants and are expected to be in the range of $17M to $29M. Other NRC licensees may realize marginal cost savings from the proposed changes.

4. Presentation of Results

As described in the NRC's value-impact assessment, the savings associated with each of the proposed changes exceed the expected implementation costs for the nuclear power industry. When combined, the proposed changes are expected to cost less than $1M for the nuclear power industry to implement and would result in long term savings for those licensees of between $17M and $29M. The proposed changes are expected to be slightly beneficial or neutral for other NRC and Agreement State licensees. The changes are such that licensees may continue with current practices if they determine that it is not cost effective to revise procedures to adopt the reduced collection, reporting and labeling of information.

An additional benefit from the proposed changes is that they improve the clarity of NRC regulations. This is especially true for the proposed changes to the TEDE definition. Issues related to the definition of TEDE required the NRC to issue a RIS to explain the regulations. The proposed change clarifies the existing regulation.

5. Decision Rationale

The nuclear power industry could save approximately $23M from the proposed changes over the remaining license terms for the operating plants. Although only marginal savings might be realized by some materials licensees, the proposed rulemaking does not introduce significant costs or administrative burdens for those licensees. The savings are obtained by reducing administrative and paperwork requirements that could be achieved without affecting the regulatory requirements that are intended to limit the exposure of workers or the public to radiation. The NRC recommends proceeding with the proposed rulemaking because the changes improve the effectiveness of NRC regulations, and reduce unnecessary regulatory burden, while not adversely affecting the agency's other performance goals. This proposed rulemaking is part of the NRC initiative to reduce unnecessary regulatory burden as described in SECY-02-0081 and in the performance goals for the agency's Strategic Plan for fiscal years 2000 through 2005. The proposed rulemaking is also consistent with the goals and effectiveness strategies in the NRC Strategic Plan for fiscal years 2004 through 2009.

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*.

XII. 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).

XIII. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule because these amendments do not impose new requirements on NRC licensees. The proposed amendments either maintain without substantive change existing requirements or reduce current regulatory requirements. Therefore, the NRC has not prepared a backfit analysis for this rulemaking.

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.

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 and 20.

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, paragraph (b) is revised to read as follows and paragraph (d) is removed and reserved:

§19.13 Notifications and reports to individuals.

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(b) Each licensee shall make available to workers information regarding their dose as shown in records maintained by the licensee pursuant to the provisions of §20.2106 of 10CCFR part 20. On an annual basis, the licensee shall provide a report to each individual monitored pursuant to §20.1502(a) of 10 CFR part 20, the dose received in that monitoring year, if:

(1) The individual's occupational dose exceeds 2 percent of the dose limits in §20.1201(a) of 10CCFR part 20;

(2) The individual is a minor subject to the dose limit in §20.1207 of 10 CFR part 20;

(3) The individual is a declared pregnant woman subject to the dose limit in §20.1208(a) of 10 CFR part 20; or

(4) The individual makes a request for a report of the individual's annual dose.

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§19.13(d) Reserved

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PART 20 — STANDARDS FOR PROTECTION AGAINST RADIATION

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

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

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

§ 20.1003 Definitions.

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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.

3. In §20.1905, paragraph (g) is added to read as follows:

§20.1905 Exemptions to labeling requirements.

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(g) Containers holding licensed material that are within an area posted pursuant to the requirements in 10 CFR 20.1902 at a nuclear power plant if they are:

(1) Conspicuously marked (such as by providing a system of color coding or tagging 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, pursuant to 10 CFR 20.1904, before being removed from the posted area.

4. In §20.2104, paragraph (a) is revised to read as follows:

§20.2104 Determination of prior occupational dose.

(a) (1) For each individual who is likely to receive in a year, an occupational dose requiring monitoring pursuant to § 20.1502, the licensee shall determine the occupational radiation dose received during the current year; and

(2) For any individual being authorized to receive a planned special exposure, the licensee shall obtain the records of cumulative occupational radiation dose.

5. Section 20.2205 is revised to read as follows:

§20.2205 Reports to individuals.

When a specific licensee is required, pursuant to the provisions of §§ 20.2202, 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.

Dated at Rockville, Maryland, this day of , 2005.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook, Secretary of the Commission.