

OMB SUPPORTING STATEMENT FOR FINAL RULE
10 CFR PARTS 19, 20, AND 50,
OCCUPATIONAL DOSE RECORDS, LABELING CONTAINERS,
AND THE TOTAL EFFECTIVE DOSE EQUIVALENT
(3150-0005, 3150-0011, 3150-0014, and 3150-0044)
REVISION

Description of the Information Collection

The Nuclear Regulatory Commission (NRC) is revising its regulations in 10 CFR Parts 19, 20, and 50, related to the reporting of annual dose to workers (19.13), the definition of the Total Effective Dose Equivalent (TEDE) (20.1003 and 50.2), the labeling of certain containers holding licensed material (20.1905), and the determination of cumulative occupational radiation dose (20.2104). Only the revisions to 10 Parts 19.13, 20.1905, and 20.2104 involve information collection requirements.

Under the current 10 CFR 19.13(b), each licensee is required to advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106. The final rule will require a licensee to provide an annual dose report to an individual when the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue, or when the individual requests a report of the individual's annual dose.

Under the current 10 CFR 20.1905, a licensee is not required to label containers holding licensed material when: the quantities or concentrations are less than those specified in 10 CFR Part 20, precautions are taken to prevent the exposure of individuals in excess of the limits in 10 CFR Part 20; packages in transport are labeled pursuant to other regulations; or equipment for which the type of equipment or the accessibility of the equipment may make labeling impractical. The final rule will provide an exemption for containers holding licensed material (other than sealed sources that are either specifically or generally licensed) that are in an area posted under the requirements of 10 CFR 20.1902 at a nuclear power facility. The final regulations will not require the licensee to label the container per the requirements of 10 CFR 20.1904 if it is conspicuously marked (such as by color coding) commensurate with the radiological hazard and accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers. The container will have to be appropriately labeled as required by 10 CFR 20.1904 before being removed from the posted area. The exemption to the labeling requirements for containers holding licensed material will not apply to non-power reactor and materials licensees or sealed sources.

Finally, under the current provisions in 10 CFR 20.2104(a)(2), licensees are required to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20.1502. The final rule will no longer require that licensees attempt to obtain the records of cumulative occupational radiation dose except for planned special exposures.

The final revisions to the above requirements are described below under the appropriate section.

A. JUSTIFICATION

The NRC Strategic Plan, Fiscal Year 2000–Fiscal Year 2005, included among NRC performance goals for nuclear reactor safety a performance goal for reducing unnecessary regulatory burden on stakeholders. The Strategic Plan defines unnecessary regulatory burden as requirements that go beyond what is necessary and sufficient to provide reasonable assurance that the public health and safety, environment, and common defense and security will be protected. The final revisions support this goal and are intended to reduce administrative and information collection burdens on licensees without affecting the level of protection for either the health and safety of workers and the public or for the environment.

1. Need for and Practical Utility of the Collection of information

10 CFR 19.13(b) currently requires that each licensee shall advise each worker annually of worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106. The final revision will require a licensee only to provide an annual dose report to an individual when the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue, or when the individual requests a report of the individual's annual dose. Licensees will no longer be required to provide unsolicited annual dose reports to those individuals whose annual dose does not exceed these limits. The criterion of 1 mSv (100 mrem) was selected because it meets the Commission's regulatory objective to provide a significant reduction in administrative and information collection burdens on licensees. In addition, it is consistent with the occupational dose threshold for requiring instruction to workers under 10 CFR 19.12, "Instruction to Workers."

Based on the information in NUREG-0713, Volume 26, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2004," (December 2005), the final change to the regulations will result in a significant reduction in administrative and information collection burdens imposed on licensees. The final amendment will not change the current requirements for recordkeeping or for reporting to the NRC.

10 CFR 20.1905 currently provides exemptions to the labeling requirements in 10 CFR 20.1904 for situations where: (1) the amount of radioactive material is small enough not to present a significant radiation hazard; (2) an attending individual takes the precautions necessary to prevent the exposure of individuals in excess of the limits in 10 CFR Part 20; (3) packages which are in transport and are labeled pursuant to the U.S. Department of Transportation regulations that provide for adequate labeling; or (4) the type of equipment or the accessibility of the equipment may make labeling impractical.

The final amendment to 10 CFR 20.1905 will add an exemption in paragraph (g) for containers holding licensed material (other than sealed sources) within licensed nuclear power facilities, providing certain conditions are met. These licensees will not be

required to label containers holding licensed material that are within an area posted under 10 CFR 20.1902, "Posting Requirements," if the containers are conspicuously marked in a manner to indicate that they may contain licensed material, commensurate with the radiological hazard, and are accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers. However, the final revision will require the container to be appropriately labeled under the requirements of 10 CFR 20.1904 before being removed from the posted area.

10 CFR 20.2104(a)(2) currently requires licensees to attempt to obtain records of prior occupational exposures prior to authorizing entry into restricted or controlled areas by individuals for whom personal monitoring is required. The final revision will remove the requirement that licensees attempt to obtain the records of cumulative occupational radiation dose. Since the revision to 10 CFR Part 20 (56 FR 23391; May 21, 1991), cumulative lifetime dose is no longer used in Part 20, except for cases involving planned special exposures. That revision made it unnecessary for licensees to attempt to obtain lifetime exposures for workers who are not participating in a planned special exposure program.

The final amendment will result in a burden reduction for the third party collection to obtain records of cumulative dose which is contained in 10 CFR 20.2104 and is covered in a separate OMB clearance for NRC Form 4 (OMB clearance number 3150-0005).

NRC Form 4 Cumulative Occupational Dose History

NRC Form 4 is used to record the summary of an individual's cumulative occupational radiation dose up to and including the current year to ensure that the dose does not exceed regulatory limits. NRC Form 4 is a cumulative summary of the information found on NRC Form 5, "Occupational Dose Record for a Monitoring Period," submitted annually by the licensees for whom monitoring was provided. The final revision to 10 CFR 20.2104, will reduce the burden by removing the requirement that licensees attempt to obtain cumulative exposure records for workers unless these individuals are being authorized to receive a planned special exposure.

2. Agency Use of the Information

10 CFR 19.13(b) requires licensees to provide dose information to workers to protect their health and safety. Nothing is submitted to the NRC.

The NRC uses the labeling required by 10 CFR 20.1905(e) to ensure that doses to workers do not exceed the limits in 10 CFR Part 20, are as low as reasonably achievable, and that radioactive materials are stored and handled properly in a way that will adequately protect the health and safety of workers.

It has been determined that the use of NRC Form 4 is needed only to ascertain the exposure history of an individual's prior lifetime dose before a licensee permits an individual to participate in a planned special exposure. In this case, the NRC uses the

information to ensure that licensees are complying with the appropriate regulations and their license conditions in order to protect the health and safety of workers.

3. Reduction of Burden Through Information Technology

There are no legal objections to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. A licensee is at liberty to utilize advanced technology to reduce the burden of recordkeeping and reporting. None of the regulations being revised, currently or after this revision, involve the filing of submissions to the NRC. Notifications and requests pursuant to 10 CFR Part 19 must be made in writing. Most radiation record information pursuant to 10 CFR Part 20 is stored electronically.

The NRC Form 4 is not required to be submitted to the NRC. It is provided to the radiation workers listing their exposure history. The NRC supplied software, Radiation Exposure Management Information Transmittal (REMIT) is available at no cost to licensees. The NRC provides technical support to users of the REMIT software which allows licensees to generate the NRC Form 4. In addition, the NRC has an automated dose history request form on the Radiation Exposure and Information Reporting System (REIRS) Web site (www.reirs.com) to allow individuals and organizations to request a dose history using NRC Form 4 for individuals monitored at NRC facilities. The automated request form allows the user to request and receive the report electronically.

4. Effort to Identify Duplication and Use Similar Information

There is no duplication of requirements. The NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

Many of the materials licensees affected by the final changes to 10 CFR 19.13(b) and 20.2104(a)(2) are small entities or businesses as those terms are used in the Regulatory Flexibility Act. However, the final changes will result in a reduction in burden for all licensees.

The final change to 10 CFR 19.13(b) will reduce burden because licenses will not be required to provide annual dose reports (NRC Form 5) to individuals whose annual dose does not exceed 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue in the preceding year. About 70 and 80 percent of the individuals monitored by materials and nuclear power reactor licensees, respectively, receive an annual dose that is less than 1 mSv (100 mrem). Individuals whose annual dose does not exceed these limits will still be provided with their dose reports upon request. The NRC expects that about 90 percent of such individuals will not request a dose report.

Under the final amendment to 10 CFR 20.2104(a)(2), NRC Form 4 will no longer be needed to record the summary of an individual's cumulative occupational radiation dose. This change will reduce burden because licensees will not need to generate an NRC Form 4 to assess an individual's annual radiation dose. The NRC Form 4 will only need to be generated in the rare case to support a licensee's decision to permit an individual to participate in a planned special exposure. To date, NRC Form 4 has only been used in the former case; licensees have yet to request the NRC to authorize a planned special exposure.

6. Consequences to Federal Program Activities if the Collection is not Conducted or is Conducted Less Frequently

Under the final revision to 10 CFR 19.13(b), licensees will provide annual dose reports to individuals on a less frequent basis. However, there will be no consequences to Federal program or policy activities because the final action will not change the current requirements for recordkeeping or reporting to the NRC.

Under the final revision to 10 CFR 20.1905, containers holding licensed material (other than sealed sources that are either specifically or generally licensed) within posted areas in nuclear power facilities will not be required to meet the labeling requirements in 10 CFR 20.1904, if the containers are conspicuously marked (to indicate that they may contain licensed material) commensurate with the radiological hazard and are accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers. The final container marking system will reduce licensee administrative and information collection burdens, but serve the same health and safety functions as the current labeling requirements. Therefore, the final amendment will not affect the level of protection for either the health and safety of workers and the public or for the environment.

Under the final revision to 10 CFR 20.2104(a)(2), NRC Form 4 will only be generated in the rare case to support a licensee's decision to permit an individual to participate in a planned special exposure. There will be no consequences to Federal program activities as a result of the final action. The final amendment will not affect the level of protection for either the health and safety of workers and the public or for the environment.

7. Circumstances Which Justify Variation from OMB Guidelines

Records associated with NRC Form 4 and Form 5 must be retained for the life of the NRC license in order to determine a worker's prior occupational radiation dose, as required pursuant to 10 CFR 20.2104, to permit an individual to receive a planned special exposure.

8. Consultation Outside the NRC

The NRC has closely coordinated this effort with the nuclear industry and held a public workshop (May 31, 2001) on issues pertinent to this rulemaking. As part of the development of this rule, the NRC prepared draft rule language and solicited comments from the Agreement States and Minnesota and Pennsylvania (two Agreement State

candidates) on the draft rule language in All Agreement State Letter STP-04-002, dated January 9, 2004. The NRC also solicited public comment on the draft rule language (69 FR 8350; February 24, 2004). The NRC staff has considered comments on the draft rule language that were submitted by three power reactor licensees, a fuel facility licensee, an individual, an alliance of six nuclear power plants (Strategic Teaming and Resource Sharing (STARS)), Nuclear Energy Institute, Council on Radionuclides and Radiopharmaceuticals, and the Agreement States Illinois and Washington. Opportunity for additional public comment was published in the *Federal Register* notice for the proposed rule (71 FR 55382; September 22, 2006). The NRC staff has considered the 16 comment letters on the proposed rule proposed rule language that were submitted by a number of individuals; industry organizations; and power reactor, uranium recovery, and fuel facility licensees.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

This information is subject to the Privacy Act of 1974 and is only available through the NRC's Privacy Act System of Records, NRC-27, REIRS. Pursuant to 10 CFR 20.2106(d), information on doses to named individuals is protected under the Privacy Act.

11. Justification for Sensitive Questions

NRC Forms 4 and 5 specify the use of the individual's name, social security number or other identification, date of birth, and sex. This information is necessary to ensure the proper identification of the individual.

12. Estimate of Annualized Burden and Burden Hour Cost

There are approximately 4,621 NRC licensees in the United States, subject to the requirements contained in 10 Parts 19 and 20. Of these 4,621 licensees, approximately 227 licensees are required to report to the NRC under 10 CFR 20.2206, "Reports of Individual Monitoring." The following discussions contain burden estimates for those 227 licensees using data in NUREG-0713, Volume 26, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2004" (December 2005). The 227 licensees consist of 104 nuclear power reactor licensees and 123 materials licensees. In addition, burden estimates are provided for the remaining 4,394 licensees that are not required to report to the NRC in accordance with 10 CFR 20.2206.

Section 19.13(b) Annual Reports to Current Employees (3150-0044)

The final revision to 10 CFR 19.13(b) is estimated to reduce the burden by 10,882 hours. The burden for preparing the exposure record and giving the report to the individual is estimated as 5 minutes per individual in the clearance package for 10 CFR Part 19. It is estimated that 72 percent of the workers at nuclear power reactor licensees and 63

percent of the workers at material licensees, respectively, will not request the report or will not receive an exposure that will trigger receiving the report. The rule change will result in a burden reduction as follows. For nuclear power reactor licensees (monitored reportable workers to the NRC under 10 CFR 20.2206) there is a burden reduction of 6,588 hours (104 reactor licensees x 1,060 workers/licensee x 5 minutes (0.083 hours) x 0.72). For materials licensees (monitored workers reportable to the NRC under 10 CFR 20.2206) there is a burden reduction of 618 hours (123 materials licensees x 96 workers/licensee x 5 minutes (0.083 hours) x 0.63). And for materials licensees not reporting to the NRC per 10 CFR 20.2206, there is a burden reduction of 3,676 hours (4,394 materials licensees x 16 workers/licensee x 5 minutes (0.083 hours) x 0.63). The total reduction in burden is 10,882 hours (6,588 hours + 618 hours + 3,676 hours). Thus, the reduction in burden per licensee is 235 hours (10,882 hours ÷ 4,621 licensees). The results for this assessment are shown in Table 1, "Annual Third Party Collection Burden Reduction Collection Reduction Associated with 10 CFR 19.13(b) (3150-0044)."

Section 20.1905 Exemptions to Labeling Requirements (3150-0014)

Section 20.1904 requires specific labeling of containers that contain licensed material. The new exemption under 10 CFR 20.1905(g) will allow containers within a posted area in power reactors to be color coded, rather than specifically labeled. The final change is expected to result in a burden reduction to power reactor licensees of approximately 300 hours annually per reactor. However, because 10 CFR 20.1904 in the renewal package considered this labeling requirement as standard labeling, no burden reduction is being taken for this rule provision.

NRC Form 4 Cumulative Occupational Dose History (3150-0005)

The final revision to 10 CFR 20.2104(a)(2) is estimated to reduce the burden by 9,969 hours. This burden reduction is captured against NRC Form 4, Cumulative Occupational Exposure History (3150-0005). The burden for maintaining the exposure records and for licensees to request previous exposure records is in the NRC Form 4 clearance package as 30 minutes per individual. The final revision will only require a licensee to maintain an NRC Form 4 for a planned special exposure. It is estimated that 99 percent of the NRC Form 4s will not be needed because the NRC Form 4 will only be used to authorize a planned special exposure. For nuclear power reactor licensees (monitored reportable workers to the NRC under 10 CFR 20.2206) there is a burden reduction of 8,751 hours (104 reactor licensees x 170 workers/licensee x 30 minutes x 0.99). For all materials licensees (monitored reportable workers to the NRC under 10 CFR 20.2206) there is a burden reduction of 1,218 hours (123 materials licensees x 20 workers/licensee x 30 minutes x 0.99). The total reduction in burden is 9,969 hours (8,751 hours + 1,218 hours). Thus, the reduction in burden per licensee is 44 hours (9,969 hours ÷ 227 licensees). The results for this assessment are shown in Table 2, "Annual Third Party Collection Burden Reduction Collection Reduction Associated with NRC Form 4 (3150-0005)."

13. Estimate of Other Additional Cost

None.

14. Estimated Annualized Cost to the Federal Government

Although the final rule will reduce the burden entailed during NRC inspections because of a slight reduction in the number of records inspected, overall it is negligible and is captured in the routine inspection effort in associated clearance packages.

15. Reasons for Change in Burden or Cost

The final rule provisions will reduce the burden for Part 19 by 10,882 hours from 35,674 hours to 24,792 hours by requiring that dose reports be provided only to individuals exceeding specified limits or who request the reports and also reduce the burden for NRC Form 4 by 9,969 hours from 12,176 hours to 2,207 hours by eliminating the need to provide cumulative occupational dose history reports except for planned special exposures.

16. Publication for Statistical Use

The collected information is not published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the *Code of Federal Regulations* to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable. Statistical methods are not used in this collection of information.

TABLE 1 – ANNUAL THIRD PARTY COLLECTION BURDEN REDUCTION ASSOCIATED WITH 10 CFR 19.13(b) (3150-0044)

Number of Recordkeepers		Burden Hours per Recordkeeper	Total Annual Burden Hours	Cost @ \$65/Hour
Reactors	104	-63	-6,588	-\$426,270
Materials (licensees reporting to NRC per § 20.2206)	123	-5	-618	-\$40,170
Materials (licensees <u>not</u> reporting to NRC per § 20.2206)	4,394	-0.84	-3,676	-\$238,940
Totals	4,621		-10,882	-\$707,330

TABLE 2– ANNUAL THIRD PARTY COLLECTION BURDEN REDUCTION ASSOCIATED WITH NRC FORM 4 (3150-0005)

Number of Recordkeepers		Burden Hours per Recordkeeper	Total Annual Burden Hours	Cost @ \$258/Hour
Reactors	104	-84	-8,751	-\$2,257,758
Materials	123	-9.9	-1,218	-\$314,244
Totals	227		-9,969	-\$2,572,002