SUPPORTING STATEMENT FOR
INFORMATION COLLECTIONS CONTAINED IN
REFORMING AND MODERNIZING THE NRC'S RADIATION PROTECTION FRAMEWORK
PROPOSED RULE

10 CFR PARTS 20, 34, 35, 50, 53, and 72

3150-0014, 3150-0007, 3150-0010, 3150-0011, 3150-0274, and 3150-0132

(RIN 3150-AL47)

NEW

DESCRIPTION OF INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern its standards for protection against radiation. This effort is consistent with, and implements direction in, the recently issued Executive Order (E.O.) 14300, "Ordering the Reform of the Nuclear Regulatory Commission." The revisions to the NRC's Standards for Protection Against Radiation reflect the agency's reconsideration of its use of the linear no-threshold (LNT) model for assessing health effects from radiation exposure and its application of the "as low as is reasonably achievable" (ALARA) principle that is predicated on LNT. The proposed rule would reflect the NRC's experience and other developments in the field of radiation protection since the NRC's last major revisions to these standards in 1991.

The proposed rule covers a wide range of topics, including the following that would result in recordkeeping and reporting requirements:

- Instructions to workers,
- Radiation protection requirements,
- Industrial radiography,
- Medical use of byproduct material,
- Source material licensing, and
- Storage and transportation of radioactive material.

This supporting statement includes burden associated with revised information collection in Part 20, Part 34, Part 35, Part 50, Part 53, and Part 72.

Part 20:
The proposed rule, under Part 20, "Standards for Protection Against Radiations," would include conforming changes related to the removal of the term "as low as reasonably achievable" from the regulations. The proposed rule would also:

- Introduce a new section, 10 CFR 20.1010, "Alternative dosimetry methods," to provide a licensee or applicant a path to obtain NRC authorization to use an alternative dosimetry method not incorporated by reference in this part.
- Introduce a new section, 10 CFR 20.1205, "Planned occupational dose limit extension," which allows a licensee to authorize an adult worker to receive occupational doses in excess of the limits specified in this part, provided that certain conditions are satisfied.
- Revise 10 CFR 20.1301, "Dose limits for individual members of the public," so that a licensee or applicant may request prior NRC authorization for an annual dose limit in

excess of 0.1 rem (1 mSv) for members of the public who have access to controlled areas, provided that dose is appropriately managed.
- Remove a requirement under 10 CFR 20.1302, “Compliance with dose limits for individual members of the public,” for approval by Commission to adjust the effluent concentration values.
- Revise 10 CFR 20.1703, “Use of individual respiratory protection equipment,” to allow the use of respiratory protection equipment that has not been tested or certified by the National Institute for Occupational Safety and Health (NIOSH) but has previously been approved for use by the NRC, without an application, provided that the licensee maintains appropriate records.
- Revise 10 CFR 20.1705, “Application for use of higher assigned protection factors,” to allow the use of higher assigned protection factors, that have previously been approved for use by the Commission, without an application, provided that the licensee maintains appropriate records.
- Revise 10 CFR 20.2105, “Records of planned occupational dose limit extensions and planned special exposures,” to require maintenance of records when using the provisions of new 10 CFR 20.1205 for planned occupational dose limit extensions.
- Revise 10 CFR 20.2107, “Records of dose to individual members of the public,” to require retention of records of the justification for the dose received by a caregiver for 3 years after the final date of the allowed exposure.
- Revise 10 CFR 20.2203, “Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits,” to add exceptions to reportable events listed in this section.

Part 34:
The proposed rule, under Part 34, “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations,” would remove specific duties and authorities of the Radiation Safety Officer for industrial radiography under 10 CFR 34.42(c). The proposed rule would also remove the definition of ALARA to conform with changes related to the removal of the term “as low as reasonably achievable” from the regulations.

Part 35:
The proposed rule, under Part 35, “Medical Use of Byproduct Material,” would update the conditions for release of patients administered byproduct material to better enable licensees to use byproduct material as per E.O. 14300. Specifically, the NRC staff have proposed the introduction and definition of an administration regimen, over which any public doses would be assessed. Additionally, the NRC staff is proposing the introduction of the “caregiver” definition for members of the public who provide the released patient with support or comfort for non-commercial gains following the administration of byproduct material. The proposed changes would increase the dose limit to a consenting caregiver to 50 mSv (5 rem) per patient administration regimen, provided the caregiver and patient (or the patient’s parent/guardian) has received instruction on methods to manage exposure. Finally, under the proposed changes, the licensee would need only to maintain records of the procedure, and not individual records for each patient released. These procedures are necessary to provide high confidence that patients are being released in accordance with the regulations. Additionally, the NRC staff have proposed deletion of requirements that licensees maintain records of instructions provided to patients who are breast-feeding a child. The proposed changes would increase flexibility for licensees to release patients while ensuring adequate protection of public health and safety.

Part 50:
The proposed rule, under Part 50, “Domestic Licensing of Production and Utilization Facilities,” would include conforming changes related to the removal of the term “as low as reasonably achievable” from the regulations. The proposed rule would modify 10 CFR 50.36a to change the requirements for reports on quantities of principal radionuclides released to the environment. The regulations currently require an annual report to be submitted in accordance with 10 CFR 50.4, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The proposed regulations would modify this requirement and require, instead, that this annual report, or reports, be developed and maintained as records as specified in 10 CFR 50.71(c). In addition, the proposed rule would create a new Section VI under Appendix I to Part 50 to provide an acceptable alternative for establishing specifications under 10 CFR 50.36a to maintain adequate control of releases of radioactive materials to unrestricted areas during normal conditions, including anticipated operational occurrences.

Part 53:
This rulemaking would amend Part 53, “Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants,” to include conforming changes related to the removal of the term “as low as reasonably achievable” from the regulations. In addition, the proposed rule would also modify 10 CFR 53.1645(a) to change the requirements for radiation exposure reports. The regulations currently require operating license (OL) and combined operating license (COL) holders, after the Commission has made the finding under 10 CFR 53.1452(g), to submit annual radiological reports. The proposed regulations would modify this requirement and require, instead, that those OL and COL holders must develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the surveillance and monitoring program required by 10 CFR 53.850(a) and 53.850(b) during the previous 12 months. The time between the development of the reports must be no longer than 12 months.

Part 72:
This rulemaking would amend Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste,” to include conforming changes to remove the term “as low as reasonably achievable” from the regulations. In addition, the proposed rule would also modify 10 CFR 72.44(d)(3) to change the requirements for reports on quantities of principal radionuclides released to the environment. The regulations currently require an annual report to be submitted in accordance with 10 CFR 72.4, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The proposed regulations would modify this requirement and require, instead, that this annual report, or reports, be developed and maintained as records until termination of the license.

Affected Entities

Part 20:
For the purposes of this supporting statement, the NRC estimates that there would be 162 Part 20 respondents (18 NRC and 144 Agreement State) affected during the three-year period covered by this clearance (2027-2029). Several reporting requirements are being made to be not required if appropriate records are maintained. This results in a decrease in reporting burden and a slight increase in recordkeeping burden for these respondents. This results in the elimination of 162 reporting respondents (18 NRC and 144 Agreement State) and the addition of

99 recordkeepers (11 NRC and 88 Agreement State). The NRC does not have data on the number of licensees subject to 10 CFR Part 20 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. For this clearance, the total number of Agreement State licensees was estimated using the ratio of the total number of Agreement State materials licensees to the total of NRC materials licensees. The current ratio is 8 (8 Agreement State licensees: 1 NRC licensee). Because there are an estimated 18 NRC licensees that would be affected by this proposed rule, the NRC staff estimates there would be 144 Agreement State licensees that would be affected by this proposed rule under this part.

Part 34:
For the purposes of this supporting statement, the NRC estimates there would be 594 Part 34 entities (66 NRC licensees and 528 Agreement State licensees) affected during the three-year period covered by this clearance (2027-2029). After the effective date of the rule, specific duties and authorities of the Radiation Safety Officer for industrial radiography under 10 CFR 34.42(c) will no longer be required, and therefore the number of respondents would be 0. Currently, an estimated 66 NRC licensees are affected by these requirements. The NRC does not have data on the number of licensees subject to 10 CFR Part 34 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. For this clearance, the total number of Agreement State licensees was estimated using the ratio of the total number of Agreement State materials licensees to the total of NRC materials licensees. The current ratio is 8 (8 Agreement State licensees: 1 NRC licensee). Because there are an estimated 66 NRC licensees that would be affected by this proposed rule, the NRC staff estimates there would be 528 Agreement State licensees that would be affected by this proposed rule under this part.

Part 35:
For the purposes of this supporting statement, the NRC estimates there would be 3,825 Part 35 entities (425 NRC licensees and 3,400 Agreement State licensees) affected during the three-year period covered by this clearance (2027-2029). After the effective date of the rule, the NRC staff estimates there are about 425 NRC medical licensees who administer byproduct material that would be affected by this proposed rule. The NRC does not have data on the number of licensees subject to 10 CFR Part 35 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. For this clearance, the total number of Agreement State licensees was estimated using the ratio of the total number of Agreement State materials licensees to the total of NRC materials licensees. The current ratio is 8 (8 Agreement State licensees: 1 NRC licensee). Because there are an estimated 425 NRC licensees that would be affected by this proposed rule, the NRC staff estimates there would be 3,400 Agreement State licensees that would be affected by this proposed rule under this part.

Part 50:
For the purposes of this supporting statement, the NRC estimates there would be 150 Part 50 entities affected during the three-year period covered by this clearance (2027-2029). Entities (OL and COL holders) who currently submit an annual report to the Commission specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months will now be required to only develop and maintain the annual report(s). The report, or reports, must be maintained as records as

specified in 10 CFR 50.71(c). The technical specifications required by 10 CFR 50.36a(a) of this section shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 50.4. These entities must also establish an appropriate surveillance and monitoring program. These changes will affect the estimated 150 entities who are currently affected by 10 CFR 50.36a.

Part 53:
For the purposes of this supporting statement, the NRC estimates there would be 0 Part 53 entities affected during the three-year period covered by this clearance (2027-2029). Entities (OL and COL holders) who currently must submit radiological reports as well as an Annual Radioactive Effluent Release Report and an Annual Radiological Environmental Operating Report to the Commission will now be required to only develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the surveillance and monitoring program required by 10 CFR 53.850(a) and 53.850(b) during the previous 12 months. The report, or reports, must be maintained as records as specified in 10 CFR 53.1620. The program required by 10 CFR 53.850(a) and 53.850(b) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 53.040. The NRC estimates that there will be 0 holders of an OL or COL under Part 53 during this clearance period, and 0 entities responding to requirements listed in 10 CFR 53.1645(a) and therefore estimates that 0 entities will be affected by this change under this part.

Part 72:
For the purposes of this supporting statement, the NRC estimates there would be 85 Part 72 entities affected during the three-year period covered by this clearance (2027-2029). Entities who currently submit an annual report to the Commission specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months will now be required to only develop and maintain the annual report(s). The report, or reports, must be maintained as records until termination of the license. The technical specifications shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 72.4. These changes will affect the estimated 85 entities who are currently affected by 10 CFR 72.44(d)(3).

Information Collections

Part 20:
The Part 20 information collection requirements impacted by the proposed rule are identified below. A more detailed description of each provision is provided at the end of this supporting statement in “Description of Information Collection Requirements.”

- The proposed rule would remove the following existing sections, impacting information collection requirements:
    - 10 CFR 20.1302(c), under 10 CFR 20.1302, “Compliance with dose limits for individual members of the public.”
- The proposed rule would add the following sections and paragraphs, impacting information collection requirements:
    - 10 CFR 20.1010, “Alternative dosimetry methods.”
    - 10 CFR 20.1205, “Planned occupational dose limit extensions.”
    - 10 CFR 20.1705(c), under 10 CFR 20.1705, “Application for use of higher assigned protection factors.”

    - 10 CFR 20.2105(b), under 10 CFR 20.2105, “Records of planned occupational dose limit extensions and planned special exposures.”
    - 10 CFR 20.2107(c) and (d), under 10 CFR 20.2107, “Records of dose to individual members of the public.”
- The proposed rule would amend the following sections, impacting information collection requirements:
    - 10 CFR 20.1101(d), under 10 CFR 20.1101, “Radiation protection programs.”
    - 10 CFR 20.1301(b), under 10 CFR 20.1301, “Dose limits for individual members of the public.”
    - 10 CFR 20.1403(e)(1), under 10 CFR 20.1403, “Criteria for license termination under restricted conditions.”
    - 10 CFR 20.1703(b), under 10 CFR 20.1703, “Alternate respiratory protection equipment.”
    - 10 CFR 20.2105, “Records of planned occupational dose limit extensions and planned special exposures.”

Part 34:
The Part 34 information collection requirements impacted by the proposed rule are identified below. The proposed rule would remove the following sections, impacting information collection requirements:

- 10 CFR 34.42(c)(1) requires the licensee to establish and oversee all operating, emergency, and ALARA procedures as required by 10 CFR Part 20 of this chapter and review them regularly to ensure that the procedures in use conform to current 10 CFR Part 20 procedures, conform to other NRC regulations and to the license conditions. These records are used by NRC to ensure compliance with its regulations regarding worker and public health and safety.
- 10 CFR 34.42(c)(2) requires the licensee to oversee and approve all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught. These records are used by NRC to ensure compliance with its regulations regarding worker and public health and safety.
- 10 CFR 34.42(c)(3) requires the licensee to ensure that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits. These records are used by NRC to ensure compliance with its regulations regarding worker and public health and safety.
- 10 CFR 34.42(c)(4) requires the licensee to ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 10 CFR 20.2203 of this chapter. The records allow NRC inspectors to verify that required calibrations have been performed.
- 10 CFR 34.42(c)(5) requires the licensee to ensure that operations are conducted safely and to assume control for instituting corrective actions including stopping operations when necessary. These records are used by NRC to ensure compliance with its regulations regarding worker and public health and safety.

Part 35:
The Part 35 information collection requirements impacted by the proposed rule are identified below.

- The proposed rule would remove the following existing sections, impacting information collection requirements:

    - 10 CFR 35.75(c) requires licensees to maintain a record of the basis for authorizing the release of an individual, in accordance with current 10 CFR 35.2075(a).
    - 10 CFR 35.75(d) requires licensees to maintain a record of the instructions that were provided to breast-feeding women in accordance with current 10 CFR 35.2075(b).
    - 10 CFR 35.2075(a) requires licensees to retain a record of the basis for authorizing the release of an individual in accordance with current 10 CFR 35.75, if the total effective dose equivalent is calculated by: using the retained activity rather than the activity administered; using an occupancy factor less than 0.25 at 1 meter; using the biological or effective half-life; or considering the shielding by tissue. These records are necessary to document the basis for releasing individuals containing radiopharmaceuticals or implants from the control of licensees, and into situations where they could expose members of the general public.
    - 10 CFR 35.2075(b) requires licensees to retain a record that the instructions required by current 10 CFR 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisievert (0.5 rem). This record is necessary to show that nursing mothers have been provided with necessary information for the protection of an infant or child.
- The proposed rule would add the following sections, impacting information collection requirements:
    - Proposed 10 CFR 35.75(a), “Release of individuals containing byproduct material,” would require that licensees develop, implement, and maintain written procedures to authorize release of a patient administered byproduct material in accordance with 10 CFR 35.75(b) and (c).
    - Proposed 10 CFR 35.2075, “Records of the release of individuals containing byproduct material,” would require that licensees retain a copy of the procedures for release of a patient administered byproduct material for the length of license.

Part 50:
The Part 50 information collection requirements impacted by the proposed rule are identified below.

- 10 CFR 50.36a requires each nuclear power reactor license and each applicant for a design certification or a manufacturing license to include technical specifications on effluents. Currently, 10 CFR 50.36(a)(2) requires the submission of an annual report specifying the quantity of each of the principal radionuclides released to the environment in liquid and gaseous effluents during the previous 12 months of operation and such other information as may be required by the Commission to estimate maximum radiation dose commitment to the public resulting from effluent releases. The information submitted pursuant to these technical specification requirements is reviewed by the NRC staff to determine whether the technical specifications provide an adequate margin of protection for public health and safety and the environment, and to ascertain whether licensee operations are consistent with the commitments made in the application and technical specifications.
- Proposed revisions to 10 CFR 50.36a would require the holder of an OL under this part or a combined license under Part 52 after the Commission has made the finding under 10 CFR 52.103(g) for a nuclear power reactor using the technical specifications to develop and maintain an annual report, or reports, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents

during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in 10 CFR 50.71(c). The technical specifications required by 10 CFR 50.36a(a) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 50.4.

Part 53:
The Part 53 information collection requirements impacted by the proposed rule are identified below.

- Currently, 10 CFR 53.1645 requires OL and COL licensees to submit radiological reports to the NRC as required by 10 CFR Part 20, as well as an Annual Radioactive Effluent Release Report and an Annual Radiological Environmental Operating Report. The Annual Radioactive Effluent Release Report needs to specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous calendar year. The Annual Radiological Environmental Operating Report needs to provide data on measurable levels of radiation and radioactive materials in the environment and include the results of environmental monitoring during the previous calendar year.
- Proposed revisions to 10 CFR 53.1645 would require OL and COL licensees to develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the surveillance and monitoring program required by 10 CFR 53.850(a) and 53.850(b) during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in 10 CFR 53.1620. The program required by 10 CFR 53.850(a) and 53.850(b) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 53.040.

Part 72:
The Part 72 information collection requirements impacted by the proposed rule are identified below.

- 10 CFR 72.44(d) requires that each license include technical specifications, which are submitted by the applicant, stating the limits on the release of radioactive materials for compliance with limits of Part 20 and the “as low as reasonably achievable” objectives for effluents. Currently, 10 CFR 72.44(d)(3) requires the submission of an annual report specifying the quantity of each of the principal radionuclides released to the environment in liquid and gaseous effluents during the previous 12 months of operation and such other information as may be required by the Commission to estimate maximum radiation dose commitment to the public resulting from effluent releases. The information submitted pursuant to these technical specification requirements is reviewed by the NRC staff to determine whether the technical specifications provide an adequate margin of protection for public health and safety and the environment, and to ascertain whether licensee operations are consistent with the commitments made in the application and technical specifications. The technical specifications and reports provide a structured basis for assessing the effectiveness of regulation of releases of radioactive material

from an independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS) to unrestricted areas by engineering design features and administrative controls.

- Proposed revisions to 10 CFR 72.44(d)(3) would require holders of each license authorizing the receipt, handling, and storage of spent fuel, high-level radioactive waste, and/or reactor-related Greater than Class C (GTCC) waste under this part to develop and maintain an annual report, or reports, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records until termination of the license.

A. JUSTIFICATION

1. Need for the Collection of Information

Part 20:
The information collections contained in Part 20 are necessary for the NRC to evaluate the effectiveness of NRC regulations and to discern any trends, problems, or special situations requiring additional controls. The NRC uses information on worker exposures and effluents from facilities such as nuclear power plants to analyze trends and compare licensee performance. This information is also published in annual reports for use by industry and other interested organizations. The NRC also uses the information to assess applications for decommissioning and license termination.

Part 34:
Part 34 provides certain requirements exclusive to licensees using byproduct material for purposes of industrial radiography, a technique of nondestructive testing. The byproduct material is normally employed in the form of sealed sources which emit high levels of radiation for the purpose of examining structures and various materials. The sources are remotely moved from their shielded position in the radiographic device to an unshielded position up to several meters away from the device and again returned to their shielded position at the completion of each radiograph. These radiographic devices are also often moved from location to location at a job site and also transported from job site to job site. The many manipulations of the sources and movement and transport of the devices result in unique and continuing potential and actual hazardous radiological conditions.

Part 35:
The NRC regulates the use of byproduct material in medicine as necessary to provide for the radiation safety of workers and the general public in a risk-informed and performance-based manner. Part 35 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the public, patients, and human research subjects.

Part 50:
Pursuant to the Atomic Energy Act of 1954, as amended, NRC has the responsibility and authority for licensing and regulating nuclear power plants, non-power reactors (research and test facilities), fuel reprocessing plants and other utilization and production facilities. This review responsibility also encompasses applications for approval of design certifications. Information provided by the applicant as part of the application is crucial to the licensing process as it provides the NRC with the information it needs to make a decision with regard to the proposed plant's impact on the health and safety of the public. Once a facility is licensed, the NRC continues to regulate its licensed activities. Licensees must comply with the reporting and recordkeeping requirements in Part 50 so that the NRC will have the information it needs to ensure that licensed activities are being conducted without endangering the health and safety of the public.

Part 53:
The information collection requirements contained in Part 53 are necessary for the NRC to evaluate applications for, issue, and regulate operations under Part 53 licenses. Moreover, these requirements enable the NRC to exercise its oversight functions in an effective and efficient manner to ensure protection of public health and safety, the promotion of the common defense and security, and the protection of the environment. The NRC uses the information collected to make decisions regarding applications and license amendments, assess licensee compliance with Part 53, and take corrective actions as needed.

Part 72:
The information collection requirements contained in Part 72 require an applicant to submit financial, safeguards, technical, and environmental information. Such information is needed both to provide safety assurance and to comply with complementary NRC regulations for environmental protection (10 CFR Part 51) and safeguards requirements (10 CFR Part 73).

2. Agency Use and Practical Utility of Information

Part 20:
The NRC uses the required information collection and reports to ensure that doses to workers and members of the public do not exceed limits. The NRC also used the required information collection reports to ensure that that radioactive materials are stored, handled, and that facilities are decommissioned, in a way that will adequately protect the health and safety of workers and the public.

Part 34:
The NRC uses the information required by this part, including the records that 10 CFR Part 34 requires licensees to maintain during the application process, inspections, license renewals, and license amendment reviews to assure that licensees are complying with NRC radiation safety requirements for possession and use of licensed radioactive material in radiography.

Part 35:
The NRC uses the records and reports required in this part to ascertain that licensees' medical use programs are adequate to protect public health and minimize danger to life and property and that licensees' personnel are aware of and follow up

on the information and steps needed to perform licensed activities in a safe manner. The NRC uses the specialty board application letter and supporting documentation to determine if the specialty board certification process meets the NRC requirements for recognition under the appropriate regulation. In addition, the specialty board submits information on any change in their processes, to allow the NRC to verify that the specialty board continues to meet the requirements. The staff makes use of the specialty board letters and licensee records to determine whether the licensee has individuals with adequate training and experience to safely use byproduct material or radiation from byproduct material to be administered to patients or human research subjects. The staff also makes use of the records and reports to determine whether the licensee has the facilities and equipment necessary to assure protection of public health and safety. The NRC also uses the information to develop reports to inform Congress and the public about the measures taken to provide for the radiation safety of workers, the public, and patients, and to alert licensees to issues of general concern. Reports of medical events are required to ensure that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or to alert other medical use licensees, to prevent similar events that may have generic implications. In addition, collection of this information enables the NRC to ascertain whether such events are evaluated by the licensee, reported to patients or human research subjects, and referring physicians and that corrective action is taken.

Part 50:
Applicants or licensees requesting approval to construct or operate utilization or production facilities are required by the Atomic Energy Act of 1954, as amended (the Act), to provide information and data that the NRC may determine necessary to ensure the health and safety of the public.

The NRC uses the records and reports required in this part to ascertain that licensees' licensing the design, construction, operation, and decommissioning of commercial nuclear power plants and other nuclear facilities programs are adequate to protect public health and minimize danger to life and property and that licensees' personnel are aware of and follow up on the information and steps needed to perform licensed activities in a safe manner. The reports and recordkeeping requirements allow NRC to determine whether to take actions, such as to conduct inspections or to alert other licensees to prevent similar events that may have generic implications.

Part 53:
The NRC uses the records and reports required in this part to ascertain that licensing the design, construction, operation, and decommissioning of commercial nuclear plants under Part 53 is adequate to protect public health, promote the common defense and security, and protect the environment. The reports and recordkeeping requirements allow NRC to determine whether to take actions, such as to conduct inspections or to alert other licensees to prevent similar events that may have generic implications.

Part 72:
The information included in the applications, reports, and records is reviewed by the NRC staff to ensure the provision of an adequate level of protection of public health

and safety, common defense and security, and the environment.

3. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC*, which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (e.g. CD-ROM, DVD), by facsimile or by email. The following are the estimates for the percentage of electronic submissions for each collection:

Information collection	**Percent of electronic submissions**
10 CFR Part 20	80%
10 CFR Part 34	90%
10 CFR Part 35	75%
10 CFR Part 50	45%
10 CFR Part 53	90%
10 CFR Part 72	75%

10 CFR Part 20, Appendix G, allows licensees to use substitute forms provided that they are equivalent to the original NRC Forms 540, 540A, 541, 541A, 542, and 542A documentation with respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, the forms may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Licensees can use software packages from several commercial vendors to generate NRC Forms 540, 540A, 541, 541A, 542, and 542A, or equivalent Agreement State forms electronically. The electronic facsimiles of the forms must be equivalent to the original documentation in respect to content, clarity, size, and location of information and include the Office of Management and Budget (OMB) clearance number, and Paperwork Reduction Act statement. The Department of Transportation requires shipping papers to physically accompany the shipment. Therefore, NRC Forms 540 and 540A, or Agreement State equivalent forms, must accompany the shipment. It cannot be limited to solely electronic transmission between waste generators, brokers, and waste disposal facilities.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

Part 20:
Some of the licensees who use byproduct, source, and special nuclear materials are small businesses. However, since the health and safety consequences of improper handling or use of these materials are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

Part 34:
Most of the NRC radiography licensees are small businesses. Efforts have been made to keep the requirements for information to a minimum. However, since the health and safety consequences of improper handling or use of a radiography source are likely to be the same for large and small entities, it is not possible to further reduce the burden on small businesses by less frequent or less complete recordkeeping or reporting

Part 35:
While a number of medical licensees are considered small businesses under the NRC's current definitions, the health and safety consequences of improper use of byproduct material are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures while maintaining the required level of safety. The NRC staff estimates that 37 percent of respondents are small businesses.

Parts 50, 53, and 72:
Not applicable. The affected entities are not small businesses.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

Part 20:
Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will adequately protect the health and safety of the public. If the information were not collected, it would not be possible for NRC to intervene if safety were to decline at a licensed facility in order to ensure the continued health and safety of the public and workers.

Part 34:
If the information collection was not conducted, or was conducted less frequently, the NRC would not have the information needed to assure that licensees are conducting and will continue programs in a manner that will assure adequate protection of the public health and safety. Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for license renewals are

submitted every 15 years. Information submitted in previous applications may be referenced without being resubmitted.

Part 35:
If the information is not collected, NRC will not be in a position to assess whether this category of licensee is operating within the specific radiation safety requirements applicable to the medical use, possession, or transfer of byproduct material for medical use. In addition, NRC will not be able to report to Congress and evaluate those medical events constituting “abnormal occurrences” or to ensure that patients, human research subjects, and referring physicians are informed of “medical events”. Applications are required to be submitted for the initial license, for amendments, and for renewals. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has adequate training, experience, equipment, and facilities to protect the public health and safety. Other reporting and recordkeeping requirements apply to specific actions or events.

Part 50:
If the information is not collected, the NRC will not be able to assess whether licensees are operating within the specific safety requirements applicable to the licensing, constructing, and operating activities for nuclear power reactors; research and test reactors; and other production and utilization facilities.

Part 53:
If the information is not collected, the NRC will not be able to assess whether Part 53 licensees are operating within the specific safety requirements applicable to the licensing and operating activities for commercial nuclear plants. The information and required frequency from licensees is essential to the NRC’s determination of whether the applicant has adequate equipment, training, funds, and experience throughout the life of the licensee to protect the public health and safety.

Part 72:
Conduct of this collection of information at the required frequency is essential to the assurance of protection of the health and safety of workers and the public. Applications are only required to be submitted for the initial license or certificate, amendments, and for renewals every 40 years, with the final rule on certificate terms and conditions becoming effective May 21, 2011. The application process requires that applicants and licensees perform comprehensive safety and environmental reviews to assure that all activities will be or are being conducted safely and in accordance with NRC regulations. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has training, experience, equipment, facilities, and procedures adequate to protect the public health and safety and the environment. Other reporting and recordkeeping requirements are occasioned by specific events such as tests and experiments, annual environmental reporting, and transfers and inventories of licensed material.

7. Circumstances Which Justify Variations from OMB Guidelines

Part 20:
Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.5(d)(2)(iv), the NRC would require some records to be maintained for more than 3 years. Specifically, the records pertaining to the planned occupational dose limit extensions and planned special exposures, as required by 10 CFR 20.2105 and 20.2106, must be retained until the Commission terminates each pertinent license requiring these records.

Part 35:
Contrary to OMB guidelines in 5 CFR 1320.5(d)(2)(iv), the NRC would require some information to be retained for more than three years. Specifically, the regulations in 10 CFR 35.2075 would require that licensees retain a copy of the procedures for patient release for the duration of the license. These records would be used by inspectors to assess regulatory compliance.

Part 72:
Contrary to OMB guidelines in 5 CFR 1320.5(d)(2)(iv), the NRC would require some information to be retained for more than three years. Specifically, the regulations in 10 CFR 72.44(d)(3) would require that reports specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents be maintained as records until termination of the license.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

Not applicable

12. Estimated Burden and Burden Hour Cost

The table below shows the estimated number of annual respondents for each part.

	Respondents	
	NRC Licensees	**AS Licensees**
Part 20	18	144
Part 34	-66	-528
Part 35	425	3,400
Part 50	150	N/A
Part 53	0	N/A
Part 72	85	N/A
Total	612	3,016

Part 20:
- Reporting: 18 less NRC respondents and 144 less Agreement State (AS) respondents.
- Recordkeeping: 11 more NRC recordkeepers and 88 more AS recordkeepers.

Part 34:
- Recordkeeping: 66 less NRC respondents and 528 less AS respondents. 10 CFR 34.42(c) requirements are being removed, but entities must still comply with other requirements in Part 34.

Note: Section 274 of the Atomic Energy Act (AEA) provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with Section 274b of the AEA. Licensees operating in these "Agreement States" are referred to in this supporting statement as "Agreement State Licensees." A map of Agreement States and non-Agreement States is located on NRC's website at https://scp.nrc.gov/rulemaking.html. The NRC has established compatibility requirements for Agreement States to implement their own regulations in a manner consistent with NRC regulations.

The NRC does not have data on the number of licensees subject to 10 CFR Parts 20, 34, and 35 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. For this clearance, the total number of Agreement State licensees was estimated using the ratio of the total number of Agreement State materials licensees to the total of NRC materials licensees. The current ratio is 8 (8 Agreement State licensees: 1 NRC licensee)

The estimated burden and responses for the proposed rule are as follows:

	Total Burden for Reforming and Modernizing the NRC's Radiation Protection Framework Proposed Rule (Hours)			
	Reporting	**Recordkeeping**	**Third Party**	**Total**
Part 20	-2,268.0	162.0	36.0	-2,070.0
Part 34	0.0	-33,264.0	0.0	-33,264.0
Part 35	0.0	-2,613.8	650.3	-1,963.5
Part 50	-300.0	300.0	0.0	0.0
Part 53	0.0	0.0	0.0	0.0
Part 72	-170.0	170.0	0.0	0.0
Total	-2,738.0	-35,245.8	686.3	-37,297.5

	Responses for Reforming and Modernizing the NRC's Radiation Protection Framework Proposed Rule			
	Reporting	**Recordkeeping**	**Third Party**	**Total**
Part 20	-162.0	99	18.0	-45.0
Part 34	0.0	-594.0	0.0	-594.0
Part 35	0.0	3,825.0	3,825.0	7,650.0
Part 50	150.0	150.0	0.0	300.0
Part 53	0.0	0.0	0.0	0.0
Part 72	85.0	85.0	0.0	170.0
Total	73.0	3,565.0	3,843.0	7,481.0

See the supplemental burden spreadsheet titled, "Burden table for the Proposed Rule, Reforming and Modernizing the NRC's Radiation Protection Framework," for detailed burden estimates.

The NRC's average labor rate of $154 per hour for FY 2026 was used to calculate burden costs to the public because it aligns with 2024 Bureau of Labor Statistics data showing comparable hourly mean wages across five key occupational groups (executives, management, technical staff, licensing staff, and physicists) within the nuclear industry.

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to $0.12 per recordkeeping burden hour. Therefore, the storage cost for this clearance is estimated to be the following:

	Additional costs
Part 20	$19.44
Part 34	-$3,991.68
Part 35	-$313.65
Part 50	$36.00

Part 53	$0.00
Part 72	$20.40
Total	-$4,229.49

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government for conducting this information collection. These estimates are based on staff experience and subject-matter expertise and include the burden of reviewing, analyzing, and processing the collected information and any relevant operational expenses.

	Cost to the Federal Government
Part 20	-$1,330,560
Part 34	$0.00
Part 35	$0.00
Part 50	-$184,800
Part 53	$0.00
Part 72	-$104,720
Total	-$1,620,080

See the supplemental burden spreadsheet titled, “Burden table for the Proposed Rule, Reforming and Modernizing the NRC’s Radiation Protection Framework” for detailed cost estimates.

15. Reasons for Changes in Burden or Cost

Part 20:
Within the proposed rule, several reporting requirements are being made to be not required if appropriate records are maintained. This results in a decrease in reporting burden and a slight increase in recordkeeping burden for these respondents. Additionally, existing requirements are being removed related to requests to adjust effluent values and reportable event notifications. Finally, new reporting requirements are being introduced as a result of additions and revisions to Part 20 related to alternative dosimetry methods, applications for higher dose limit to members of the public who have access to controlled areas, criteria for license termination, planned special exposure and occupational dose limit extension records, and records pertaining to dose received by a caregiver.

Part 34:
The proposed rule would decrease the burden under Part 34 due to the removal of recordkeeping for specific duties and authorities for Radiation Safety Officers under 10 CFR 34.42(c).

Part 35:
The decrease in overall burden is a result of changes in 10 CFR 35.75 requiring only development, implementation, and retention of a procedure for releasing

patients administered radioactive material in place of documentation of justification for individual patients. These new requirements provide flexibility for licensees while maintaining adequate protection of public health and safety. The proposed rule would have a minimal impact on the costs to the Federal Government under this clearance, as compliance with patient release regulations in 10 CFR 35.75 and 35.2075 will continue to be assessed during inspection.

Part 50:
The proposed rule would change the requirements regarding annual reports specifying the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. Currently, OL and COL holders under this part must submit these report to the Commission annually. The proposed rule would change the requirement so that the report, or reports, only need to be developed and maintained as records as specified in 10 CFR 50.71(c). This change would decrease the reporting burden and slightly increase the recordkeeping burden for license holders under this part.

Part 53:
The proposed rule would change the requirements regarding annual reports of radiation exposure to members of the public. Currently, OL and COL holders must submit radiological reports to the Commission on an annual basis. The proposed rule would change the requirement so that the report, or reports, only need to be developed and maintained as records as specified in 10 CFR 53.1620. This change would decrease the reporting burden and slightly increase the recordkeeping burden for license holders under this part.

Part 72:
The proposed rule would change the requirements regarding annual reports specifying the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. Currently, each license authorizing the receipt, handling, and storage of spent fuel, high-level radioactive waste, and/or reactor-related GTCC waste under this part must submit these report to the Commission annually. The proposed rule would change the requirement so that the report, or reports, only need to be developed and maintained as records until termination of the license. This change would decrease the reporting burden and slightly increase the recordkeeping burden for license holders under this part.

16. Publication for Statistical Use

Not applicable.

17. Reason for Not Displaying the Expiration Date

The reporting and recordkeeping requirements for this information collection in Parts 20, 34, 35, 50, 53, and 72 are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR 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. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

10 CFR 20.1010(b) would allow the use of alternative dosimetry methods consistent with one or more of the standards incorporated by reference and listed in appendix H to Part 20. A licensee or applicant may also apply for NRC authorization to use an alternative dosimetry method not listed in appendix H to Part 20. (New)

10 CFR 20.1101 currently requires licensees to develop, document and implement radiation protection programs; establish radiation protection procedures; and perform program reviews periodically. This is necessary to ensure the health and safety of the workers and the general public. 10 CFR 20.1101(d) requires the establishment of a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, other than those subject to 10 CFR 50.34a or 53.260, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 25 mrem (0.25 mSv) per year from these emissions. Recordkeeping burden under 10 CFR 20.1101 would not change; a reference to ALARA has been removed. A new reporting provision would allow a licensee or applicant the option to request prior NRC authorization to establish a higher constraint, provided that the proposed constraint provides an ample margin of safety to protect public health. The burden for this reporting requirement is contained in 10 CFR 20.2203. (Amended)

10 CFR 20.1205 would set limits for planned occupational dose limit extensions. This is necessary to ensure the health and safety of workers. The recordkeeping requirements for this section are contained in 10 CFR 20.2105. 10 CFR 20.1205(b) would require the licensee to inform individuals of the purpose and risks of a planned occupational dose limit extension operation. This is a new third-party disclosure requirement. (New)

10 CFR 20.1301 currently provides dose limits for individual members of the public. 10 CFR 20.1301(b) requires each licensee to conduct operations so that if the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals. This paragraph would be revised to allow a licensee or applicant to request prior NRC authorization for an annual dose limit in excess of 0.1 rem (1 mSv) for members of the public who have access to controlled areas, provided that dose is appropriately managed. (Amended)

10 CFR 20.1302(c) would be deleted. It currently allows licensees to apply to the Commission for permission to use alternate effluent release concentration limits based on actual physical and chemical characteristics of the effluent released. (Removed)

10 CFR 20.1403(a)-(c) and (e)(1) would require certain information from the licensee if restrictions on future use of the site are proposed. The licensee would continue to have to make adequate provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent (TEDE) from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem per year, and make provisions for sufficient financial assurance to enable an independent

third party to assume and carry out responsibilities for any necessary control and maintenance of the site. The proposed rule would amend 10 CFR 20.1403(a) to require demonstration that further reductions in residual radioactivity necessary to release the site for unrestricted use would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal; would result in net public or environmental harm; or would not be justified through a cost-benefit analysis. The proposed rule would also amend 10 CFR 20.1403(e)(1) to require demonstrating that residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group would not exceed 100 mrem per year, provided that the licensee demonstrates that further reductions in residual radioactivity would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal. Finally, the proposed rule would remove references to ALARA in 10 CFR 20.1403. (Amended)

10 CFR 20.1703(b) currently allows licensees to submit an application to the Commission for permission to use respiratory protection equipment that has not been tested or certified for use by the National Institute for Occupational Safety and Health. Records of this application and its approval are required to ensure that licensee practices are in compliance with regulations. The proposed rule would amend this paragraph to state that the use of equipment that has not been tested or certified by NIOSH, but has previously been approved for use by the NRC, does not require an application and its approval as described in this paragraph, provided that the licensee maintains an evaluation to demonstrate that the bases for the previous NRC approval—as documented in the applicable safety evaluation—are applicable to the licensee's facility. (Amended, Change in Respondents)

10 CFR 20.1705(a) and (b) currently require licensees to submit an application to the Commission before using assigned protection factors higher than those in Appendix A to 10 CFR Part 20 for the purpose of calculating exposures. Records of this application and its approval are required to ensure that respiratory protective equipment is being used in a manner that will protect the health and safety of workers. Paragraph (c) would be added to state that the use of higher assigned protection factors that have previously been approved for use by the Commission does not require an application and its approval as described in this section, provided that the licensee maintains an evaluation to demonstrate that the bases for the previous Commission approval—as documented in the applicable safety evaluation—are applicable to the licensee's facility. (Amended, Change in Respondents)

10 CFR 20.2104 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 personnel radiation monitoring is required. The proposed rule would expand this section to apply prior to a licensee permitting an individual to participate in a planned occupational dose limit extension, alongside existing requirements for a planned special exposure. This recordkeeping requirement is covered in a separate OMB clearance for NRC Form 4 (OMB clearance number 3150-0005). (Amended)

10 CFR 20.2105 currently requires licensees to maintain records of planned special exposures until the Commission terminates the license since they form the basis for assessing dose to an individual. The proposed rule would expand this section to require the licensee to, when using the provisions of 10 CFR 20.1205 for planned occupational dose limit extensions, maintain similar records that describe the circumstances requiring the extension of occupational dose limits, how doses were managed, and the doses received by individuals involved in the planned occupational

dose limit extensions. (New, Amended)

10 CFR 20.2106 requires licensees to record and maintain the results of individual monitoring until the Commission terminates the license. The proposed rule would update this section so that, in cases where monitoring was required pursuant to 10 CFR 20.1502, but the dose received did not exceed 10 percent of the applicable monitoring criteria, the licensee may, instead of recording the numerical value of the dose received, annotate that an occupational dose was received but did not exceed the criteria for recording. This recordkeeping requirement is covered in a separate OMB clearance for NRC Form 5 (OMB clearance number 3150-0006). (Amended)

10 CFR 20.2107(c) would require the licensee to retain a record of the justification for the dose received by a caregiver. This is needed to permit assessment of the dose to the caregiver in order to confirm compliance with dose limits. (New)

10 CFR 20.2107(d) would require that the records required in 10 CFR 20.2107(c) be maintained for 3 years after the final date of the allowed exposure. (New)

10 CFR 20.2203(a) establishes that, in addition to the notification required by 10 CFR 20.2202, each licensee is required to submit a written report within 30 days after learning of specific incidents involving doses or concentrations of radioactive materials in excess of limits, with some exceptions. This is needed to ensure that there are appropriate follow-up actions to avoid a recurrence. 10 CFR 20.2203(b) contains the requirements for the content of reports required by 10 CFR 20.2203(a). The proposed rule would amend the requirement for reporting doses in excess of the limits for an individual member of the public in 10 CFR 20.1301 by providing an exception that reporting of exceedances of the limit in 10 CFR 20.1301(a) is required only if the total dose to a single individual for the current year and the preceding four years exceeds 500 mrem. (Amended, Change in Respondents)

Appendix G to Part 20 provides requirements for transfers of low-level radioactive waste intended for disposal at licensed land disposal facilities. The appendix currently requires a waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility to prepare a Manifest (OMB Control Numbers 3150-0164, 3150-0165, and 3150-0166) reflecting information requested on applicable NRC Forms 540, 541, and, if necessary, on an applicable NRC Form 542. The proposed rule would amend the appendix to allow respondents to provide the information in another format other than the official NRC Forms as long as the Manifest reflects the information requested on the applicable NRC Forms. (Amended, no change in burden)

10 CFR 34.42(c)(1) would be deleted. This paragraph currently requires the licensee to establish and oversee all operating, emergency, and ALARA procedures as required by 10 CFR Part 20 of this chapter and review them regularly to ensure that the procedures in use conform to current 10 CFR Part 20 procedures, conform to other NRC regulations and to the license conditions. (Removed)

10 CFR 34.42(c)(2) would be deleted. This paragraph currently requires the licensee to oversee and approve all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught. (Removed)

10 CFR 34.42(c)(3) would be deleted. This paragraph currently requires the licensee to ensure that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits. (Removed)

10 CFR 34.42(c)(4) would be deleted. This paragraph currently requires the licensee to ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 10 CFR 20.2203 of this chapter. (Removed)

10 CFR 34.42(c)(5) would be deleted. This paragraph currently requires the licensee to ensure that operations are conducted safely and to assume control for instituting corrective actions including stopping operations when necessary. (Removed)

DESCRIPTION OF INFORMATION COLLECTIONS CONTAINED IN THE
REFORMING AND MODERNIZING THE NRC'S RADIATION PROTECTION FRAMEWORK
PROPOSED RULE
10 CFR PART 35

3150-0010

Proposed 10 CFR 35.75(a) would require that licensees develop, implement, and maintain written procedures to authorize release of a patient administered byproduct material in accordance with 10 CFR 35.75(b) and (c). (Amended)

Proposed 10 CFR 35.75(b)(1) would require instruction be provided to caregivers on the radiation risks to the caregiver and methods to manage exposure to the caregiver if the total effective dose equivalent to the caregiver is likely to exceed 5 mSv (0.5 rem) and is not likely to exceed 50 mSv (5 rem) per patient administration regimen. This is a new third-party disclosure requirement. (New)

10 CFR 35.75(c) requires licensees to maintain a record of the basis for authorizing the release of an individual, in accordance with 10 CFR 35.2075(a). A description of the contents of the records and a statement of need for the records is provided under 10 CFR 35.2075. (Removed)

10 CFR 35.75(d) requires licensees to maintain a record of the instructions that were provided to breast-feeding women in accordance with 10 CFR 35.2075(b). A description of the contents of the record and a statement of need for the record is provided under 10 CFR 35.2075. (Removed)

Proposed 10 CFR 35.2075 would require that licensees retain a copy of the procedures for release of a patient administered byproduct material for the length of license. (Amended)

10 CFR 35.2075(a) requires licensees to retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75, if the TEDE is calculated by: using the retained activity rather than the activity administered; using an occupancy factor less than 0.25 at 1 meter; using the biological or effective half-life; or considering the shielding by tissue. These records are necessary to document the basis for releasing individuals containing radiopharmaceuticals or implants from the control of licensees, and into situations where they could expose members of the general public. (Removed)

10 CFR 35.2075(b) requires licensees to retain a record that the instructions required by 10 CFR 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 millisievert (0.5 rem). This record is necessary to show that nursing mothers have been provided with necessary information for the protection of an infant or child. (Deleted)

DESCRIPTION OF INFORMATION COLLECTIONS CONTAINED IN THE
REFORMING AND MODERNIZING THE NRC'S RADIATION PROTECTION FRAMEWORK
PROPOSED RULE
10 CFR PART 50

3150-0011

10 CFR 50.36a requires each nuclear power reactor license and each applicant for a design certification or a manufacturing license to include technical specifications on effluents. The NRC staff developed "Radiological Effluent Technical Specifications (RETS) for PWRs" (NUREG-0472) and "Radiological Effluent Technical Specifications for BWRs" (NUREG-0473). Generic Letter 89-01, "Implementation of Programmatic Controls for Radiological Effluent Technical Specifications in the Administrative Controls Section of the Technical Specifications and the Relocation of the Procedural Details of RETS to the Offsite Dose Calculation Manual (ODCM) or to the Process Control Program (PCP)," permits relocation of the description of the radioactive effluent report content to the ODCM or the PCP.

10 CFR 50.36a(a)(2) Requires the submission of an annual report specifying the quantity of each of the principal radionuclides released to the environment in liquid and gaseous effluents during the previous 12 months of operation and such other information as may be required by the Commission to estimate maximum radiation dose commitment to the public resulting from effluent releases. The information submitted pursuant to these technical specification requirements is reviewed by the NRC staff to determine whether the technical specifications provide an adequate margin of protection for public health and safety and the environment, and to ascertain whether licensee operations are consistent with the commitments made in the application and technical specifications. (Amended)

Proposed revisions to 10 CFR 50.36a(a)(2) would require the holder of either an OL under this part or a combined license under Part 52 after the Commission has made the finding under 10 CFR 52.103(g) for a nuclear power reactor using the technical specifications to develop and maintain an annual report, or reports, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in 10 CFR 50.71(c). The technical specifications required by 10 CFR 50.36a(a) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 50.4. (Amended)

DESCRIPTION OF INFORMATION COLLECTIONS CONTAINED IN THE
REFORMING AND MODERNIZING THE NRC'S RADIATION PROTECTION FRAMEWORK
PROPOSED RULE
10 CFR PART 53

3150-0274

10 CFR 53.1645 requires OL and COL licensees to a submit radiological reports to the NRC as required by 10 CFR Part 20, as well as an Annual Radioactive Effluent Release Report and an Annual Radiological Environmental Operating Report. The Annual Radioactive Effluent Release Report needs to specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous calendar year. The Annual Radiological Environmental Operating Report needs to provide data on measurable levels of radiation and radioactive materials in the environment and include the results of environmental monitoring during the previous calendar year. (Amended)

Proposed revisions to 10 CFR 53.1645 would require OL and COL licensees to develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the surveillance and monitoring program required by 10 CFR 53.850(a) and 53.850(b) during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in 10 CFR 53.1620. The program required by 10 CFR 53.850(a) and 53.850(b) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in 10 CFR 53.040. (Amended)

DESCRIPTION OF INFORMATION COLLECTIONS CONTAINED IN THE
REFORMING AND MODERNIZING THE NRC'S RADIATION PROTECTION FRAMEWORK
PROPOSED RULE
10 CFR PART 72

3150-0132

10 CFR 72.44(d) requires that each license include technical specifications, which are submitted by the applicant, stating the limits on the release of radioactive materials for compliance with limits of Part 20 and the "as low as reasonably achievable" objectives for effluents. 10 CFR 72.44(d)(3) requires technical specifications that require the submission of an annual report specifying the quantity of each of the principal radionuclides released to the environment in liquid and gaseous effluents during the previous 12 months of operation and such other information as may be required by the Commission to estimate maximum radiation dose commitment to the public resulting from effluent releases. (Amended)

The information submitted pursuant to these technical specification requirements is reviewed by the NRC staff to determine whether the technical specifications provide an adequate margin of protection for public health and safety and the environment, and to ascertain whether licensee operations are consistent with the commitments made in the application and technical specifications. The technical specifications and reports provide a structured basis for assessing the effectiveness of regulation of releases of radioactive material from an ISFSI or MRS to unrestricted areas by engineering design features and administrative controls.

Proposed revisions to 10 CFR 72.44(d)(3) would require holders of each license authorizing the receipt, handling, and storage of spent fuel, high-level radioactive waste, and/or reactor-related GTCC waste under this part to develop and maintain an annual report, or reports, specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records until termination of the license. (Amended)