

DRAFT OMB SUPPORTING STATEMENT FOR
10 CFR PART 34
LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY
REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

(3150-0007)

EXTENSION REQUEST WITH BURDEN REVISION

Description of the Information Collection

NRC regulations in 10 CFR Part 34 establish rules that specify radiation safety requirements for the use of licensed byproduct material in industrial radiography. The regulations provide for comprehensive and consistent radiation safety requirements in NRC and Agreement State regulations, and safety requirements designed to reduce the likelihood of accidents involving radioactive sources in industrial radiography.

A. Justification

1. Need for and Practical Utility of the Information

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.

Section 34.11 requires that applications for specific licenses for use of sealed sources in radiography be filed on NRC Form 313, "Application for Material License." The NRC materials licensing staff will review the information submitted on NRC Form 313 to determine whether an applicant for a license has training, experience, equipment, facilities, and procedures for the use of licensed material that are adequate to protect the public health and safety.

The use of NRC Form 313 has been previously approved by OMB under clearance number 3150-0120, which should be referred to for information collection burden and supporting data.

Section 34.13 provides that an applicant must submit the following information with the application:

- 34.13(b) - Schedule and description of training programs for radiographers and radiographers' assistants that meet the requirements of § 34.43;

- 34.13(c) - Procedures to verify and document the certification status of the radiographers it employs, including that the certification is valid;
- 34.13(d) - Written operating and emergency procedures as described in § 34.45 covering its radiation safety program;
- 34.13(e) - Program for semiannual inspections of the job performance of each radiographer and radiographers' assistant as described in § 34.43;
- 34.13(f) - Description of overall organizational structure as it applies to radiation safety responsibilities in radiography, including specified delegations of responsibility and authority;
- 34.13(g) - Identification and listing of the qualifications of the individual designated as the Radiation Safety Officer (RSO), responsible for implementing the licensee's radiation safety program, as described in § 34.42;
- 34.13(h) - For applicants that intend to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, a description of procedures for performing the tests and the qualifications of the person(s) authorized to do the leak testing; also, if the applicant intends to analyze its own leak test wipe samples, a description of the procedures to be followed;
- 34.13(i) - If the applicant intends to perform its own calibrations, a description of the methods to be used and the relevant experience of the person(s) who will perform the calibrations;
- 34.13(j) - An identification of locations of and a description of all field stations and permanent radiographic installations
- 34.13(k) - Specification of location where all documents and records required by this part and other parts of this chapter will be maintained as specified in §34.89;

This information is reviewed by the NRC staff to determine whether the training, radiation safety, and internal inspection programs and procedures and the licensee's organizational structure will provide adequate protection of the public health and safety. The NRC review and the findings therefrom form the basis for NRC licensing decisions.

The burden and cost associated with this requirement are incurred in connection with the submission of the application, NRC Form 313, referred to under Section 34.11, above. The use of NRC Form 313 has been previously approved by OMB under clearance number 3150-0120, which should be referred to for information collection burden and supporting data.

Section 34.20(b)(1) requires that each radiographic exposure device have an attached label bearing information identifying the radionuclide in the device, its activity and the date the activity was last measured, the manufacturer, serial, and model number, and the licensee's name, address, and telephone number. This information will serve as a safety

notice to users and members of the public. The label requirement has been incorporated in the regulations, in part, in conformance with ANSI Standard N432.

Section 34.25(b) requires that each radiation survey instrument be calibrated at intervals not to exceed 6 months and after each instrument servicing, and Section 34.25(c) requires that a record of the calibration be maintained in accordance with § 34.65. The radiation survey is one of the most important aspects of radiation safety, and the instruments must be periodically calibrated to assure reasonable accuracy when measuring radiation levels that individuals are exposed to during radiographic operations. The licensee will use the records to assure itself that the instruments available to radiographers and radiographers' assistants are properly calibrated. The records allow NRC inspectors to verify that required calibrations have been performed.

Section 34.27(c)(1) requires a licensee who uses sealed sources to have the source tested for leakage at intervals not to exceed 6 months, and Section 34.27(c)(2) requires the licensee to maintain records of leak test results of sealed sources in accordance with § 34.67. A leak test is the only effective method of determining the integrity of the sealed sources. Serious radiological hazards could result from a leaking source. The records allow NRC inspectors to verify that required leak tests have been performed.

Section 34.27(d) requires that licensees report within 5 days results of leak testing which indicate that a source is leaking. The report must describe the equipment involved, the test results, and the corrective action taken. The NRC staff uses the report in assessing whether the corrective actions initiated by the licensee are adequate to protect workers and the public from the hazards of a leaking source. The NRC staff also uses the report to identify generic problems with regard to source design, radiographic equipment design, or problems in source manufacturing and quality control.

Section 34.27(e) requires leak testing of the "S" tubes of those radiographic devices that use depleted uranium (DU) for shielding at least annually and maintain records of these tests in accordance with § 34.67. These records allow the licensee and the NRC to verify that the required tests have been performed to verify the condition of the "S" tube.

Section 34.29(a) and (b) requires that the licensee conduct a quarterly physical inventory to account for all sealed sources, and all devices containing DU, received and possessed under the license, and maintain records of the inventories under § 34.69 for 3 years from the date of the inventory. This information is used by the licensee and NRC to verify that all radioactive material is accounted for and is properly stored.

Section 34.31(a), (b)(1), and (2) requires that the licensee have a program for inspection and maintenance of radiography devices, source changers, associated equipment, transport and storage containers, and survey instruments, and for inspection and maintenance of Type B packaging used to transport radioactive materials. Section 34.31(c) requires the licensee make a record of any equipment problems and any maintenance performed during the daily visual and operability checks specified in § 34.31(a), or during the inspections specified in § 34.31(b), and specifies that these records must be made in accordance with § 34.73 with each record retained for 3 years after it was made. The records are needed for the licensee and NRC to verify that appropriate actions have been taken if problems are found and to assist the licensee in keeping track of when

the equipment was last inspected and maintained and when the inspection is next due. The records are used by NRC staff to determine the extent of licensee compliance.

Section 34.33(b) requires that entrance controls and/or the visible and audible alarms on permanent radiographic installations required by Section 34.33(a) be tested and records of the tests maintained. Entrance controls are to be tested monthly while both visible and audible alarms must be tested at the beginning of each day the installation is to be used in order to ensure that they are functioning properly to prevent inadvertent entry into a radiographic installation (cell) while a source is in the unshielded position. Records of the alarm tests and entrance control tests are to be maintained under § 34.75 for 3 years after they are made. These alarms are an important backup to the radiation survey instrument and are intended to prevent inadvertent entry into a radiographic installation (cell) while a source is in the unshielded position. These records are used by NRC to ensure compliance with its regulations regarding worker and public health and safety.

Section 34.35(a) requires that the licensee not use a source changer or container to store licensed material unless the source changer or the container has securely attached to it a durable, legible, and clearly visible label that indicates who to notify in case of danger. This requirement ensures that any individual who may come in contact with the source changer or storage container is made aware of the presence of radioactive material and can notify the proper individual as necessary.

Section 34.35(b) requires that the licensee not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part 71. This is necessary so that the licensee may demonstrate that it is in compliance with regulations stated in Parts 34 and 71.

Section 34.41(c) requires applicants that intend to conduct lay barge, offshore platform, or underwater radiography, describe the procedures to be performed. This information is necessary because these activities require special operating and emergency procedures that are not normally expected of most licensees. This information is cleared under 3150-0120.

Section 34.43(b)(1) requires the licensee to provide radiographers with copies of pertinent sections of Parts 19, 20, 30, and 34, as well as instructions in applicable Department of Transportation regulations as referenced in Part 71, the NRC license, and the licensee's operating and emergency procedures. These are needed to ensure that radiographers are sufficiently knowledgeable of applicable regulations prior to using licensed material.

Section 34.43(c)(1) requires the licensee to provide radiographers' assistants with copies of pertinent sections of Parts 19, 20, 30 and 34, and instructions in applicable Department of Transportation regulations as referenced in Part 71, the NRC license, and the licensee's operating and emergency procedures. This is needed to ensure that radiographers' assistants are sufficiently knowledgeable of applicable regulations prior to using licensed material.

Section 34.43(f) requires that the licensee maintain records of training to include oral, written, and practical examinations, refresher safety training, and semiannual inspections of job performance, and that these records be maintained in accord with § 34.79 and kept for 3 years after the record is made. These records are needed to enable licensees to adequately administer their training program and to demonstrate compliance with NRC requirements. The retention of these records for 3 years allows the NRC to inspect to ensure that these individuals are properly trained.

Section 34.45(a) requires that licensees have a program for routine operations and emergencies for employees to follow in performing safety functions. This program, and its associated procedures, is necessary to ensure that individuals handling radioactive material will have guidance in appropriately carrying out safety functions and is to include: (1) safe handling and use of sealed sources and radiographic exposure devices, (2) conducting radiation surveys, (3) controlling access to radiographic areas, (4) locking and securing radiographic exposure devices, storage containers, and sealed sources; (5) personnel monitoring, (6) transporting sealed sources, (7) inspection, maintenance, and operability checks of radiographic exposure devices, transport and storage containers, and survey instruments, (8) steps to be taken if a pocket dosimeter reads off-scale, (9) identifying and reporting defects and noncompliance, (10) accident procedures, (11) minimizing exposure, (12) source recovery, and (13) maintenance of records.

Section 34.45(b) requires that the licensee maintain copies of current operating and emergency procedures in accordance with § 34.81 and § 34.89. These records are necessary to ensure that individuals have current procedures to use in the conduct of radiographic operations.

Section 34.47(b) requires radiographers to read and record the exposure on their direct reading dosimeters (pocket dosimeters or electronic personal dosimeters) at the beginning and end of each shift, and that records be maintained for 3 years after the record is made, as specified in § 34.83(a). The requirement is to ensure that the licensee knows the radiation exposure a worker received during a given shift in case the worker's personnel dosimeter is lost, so that the licensee can take appropriate action (e.g., adjust the worker's assignments so as to maintain the accumulated dose within regulatory limits). These records are reviewed by NRC to ensure compliance with regulatory limits.

Section 34.47(c) requires that pocket dosimeters or electronic personal dosimeters be checked at periods not to exceed 12 months for correct response to radiation, and that records shall be maintained for 3 years after the record is made as specified in § 34.83(a). These records are necessary for the licensee to be able to verify that the pocket dosimeter is responding correctly to radiation.

Section 34.47(d) requires that a determination of exposure be made if an individual's pocket dosimeter goes off-scale and that the result of the determination be maintained in accordance with § 34.83(d). This requirement restricts individuals from working with radiation after a dosimeter discharges, unless any exposure to radiation can be ruled out or the RSO makes a determination of the individual's exposure and makes a record of that determination. This determination is needed to verify that an individual's dose does not exceed regulatory limits.

Section 34.47(e) requires that if a personnel dosimeter is lost or damaged, the worker is required to cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage. In addition, the results of the calculated exposure and the time period involved must be included in the records as specified in § 34.83(d). This requirement is also to ensure that a worker's dose does not exceed regulatory limits.

Section 34.47(f) requires that the licensee maintain reports received from personnel dosimeter processors until the license is terminated and that the record be maintained in accordance with § 34.83(c). This information may be needed to reconstruct a worker's dose history in the event the worker loses his/her records, to permit a planned special exposure, and to show compliance with regulatory limits.

Section 34.47(g)(4) requires that alarm ratemeters be calibrated at periods not to exceed 1 year for correct response to radiation, and that the licensee must maintain records of the calibrations for 3 years after the record is made as specified in § 34.83(b). This requirement provides a means for the licensees to demonstrate that their alarm ratemeters are properly calibrated.

Section 34.49(c) requires that radiography licensees conduct a survey of the radiographic exposure device whenever a source is exchanged or before placing a radiographic exposure device in storage if that survey is the last one performed on the workday, and

Section 34.49(d) requires these surveys be recorded as specified under § 34.85. This information is needed to demonstrate that the radioactive source is in the fully shielded position at the end of the work day after the device has been placed in its storage location. Without such a survey, the device could, if the source is not fully shielded, cause excessive and unnecessary radiation exposure to workers and members of the public. These records are reviewed by NRC to ensure compliance with regulatory limits.

Section 34.61 requires the licensee to have a copy of the license, license conditions, documents incorporated by reference, and all amendments until the NRC terminates the license. The purpose is so that the licensee will have copies available for review and be able to verify that it is in compliance with the conditions of the license and the commitments that it has made.

Section 34.63 requires that the licensee maintain records showing receipts and transfers of sealed sources and devices using DU shielding for 3 years after the record is made. The records must include: the date, the individual making the record, the radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each sealed source and device, as appropriate. The records allow NRC inspectors to verify the sources/devices the licensee is presently using.

Section 34.65 requires that the licensee maintain records of the calibrations of their radiation survey instruments, and that the records be retained for 3 years. The records allow NRC inspectors to verify that required calibrations have been performed. The licensee will use the records to assure itself that the instruments available to radiographers and radiographers' assistants are properly calibrated. In addition, these records are

necessary to verify that the licensee is in compliance with NRC requirements as described in § 34.25, and to ensure the safety of the users of these instruments.

Section 34.67 requires that the licensee maintain records of leak test results and that the records be retained for 3 years. These records are necessary to verify that the licensee is in compliance with NRC requirements as described in § 34.27, and for the licensee to ensure the integrity of the sealed sources/devices in use.

Section 34.69(a) requires that the licensee maintain records of quarterly inventories of sealed sources and devices containing DU shielding as specified in § 34.29, and that each record be retained for 3 years after it is made. Section 34.69(b) requires that the record include the date of the inventory, the name of the individual conducting the inventory, the radionuclide and the number of becquerels (curies) in each device, location of sealed source and/or devices, and the manufacturer, model, and serial number of each sealed source and/or device, as appropriate. For devices containing DU shielding, the record must also show the mass of DU in each container. The inventories are used by the licensee to verify the location of sources and/or devices and to control the type, quantity and use of byproduct material. The records allow NRC inspectors to verify that the required inventories have been conducted and to ensure that the licensee is in compliance with authorized possession limits.

Section 34.71(a) requires that the licensee maintain utilization logs showing for each sealed radioactive source: (1) a description, including the make, model number, and serial number of the radiographic exposure device or transfer or storage container in which the sealed source is located; (2) the identity and signature of the radiographer to whom assigned; and (3) the plant or site where used and dates of use, including the dates removed from and returned to storage.

Section 34.71(b) requires that the licensee retain records of utilization logs for a period of 3 years after the record is made. The records required by this section allow NRC inspectors to determine whether the licensed material has been properly controlled and used.

Section 34.73(a) requires that the licensee maintain records of any equipment problems and any maintenance performed under § 34.31(a) and (b) during inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments and that the records be retained for 3 years after they are made.

Section 34.73(b) states that records of equipment problems and maintenance as required by § 34.73(a) must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, were done. The records are needed to enable the licensee to keep track of when the equipment was last inspected and maintained and when inspection is next due. The records are used by NRC staff to determine the extent of compliance by the licensee.

Section 34.75 requires that the licensee maintain records of the alarm system and entrance control device tests at permanent radiographic installations as specified under § 34.33 and retain each record for 3 years after it is made. The records are needed to

enable the licensee to keep track of when entrance control and alarm system tests were last performed and when they are next due. The records are also used by NRC inspectors to determine compliance with required testing of important safety equipment.

Section 34.79 requires that the licensee maintain records of training of radiographers and radiographers' assistants in accordance with § 34.43(f). Section 34.79(a) requires that the record includes certification documents, copies of written tests, dates of practical examinations, and names of individuals conducting and receiving the practical examinations. Section 34.79(b) requires that records of refresher safety training and semiannual inspections for each radiographer and each radiographer's assistant be maintained. The records must list the topics discussed, the dates of the training, and names of the instructors and attendees. For the semiannual inspections of each radiographer and radiographer's assistant by the RSO or designee, specified in § 34.43(e), the records must also include a list of the items checked and any noncompliances observed. This is needed to enable licensees to demonstrate compliance with NRC requirements and to keep track of when training is required. The records of the semiannual inspections of job performance will be used by the licensee to ensure that workers are conducting operations in accordance with the license. The records are used by NRC staff to determine the extent of compliance by the licensee.

Section 34.81 requires the licensee to retain records of current operating and emergency procedures specified in § 34.45, until the Commission terminates the license. The records allow the operators to have access to an up-to-date set of written operating procedures so that they can operate the radiography equipment properly. The NRC inspectors review these procedures to ensure that previous instructions are being provided to the workers.

Section 34.83 requires licensees to maintain exposure records specified in § 34.47 as follows: (a) direct reading dosimeter readings and yearly operability tests and retain them for 3 years after the record is made, (b) records of alarm ratemeter calibrations and retain them for 3 years from the date the record was made, (c) reports from personnel dosimeter processor until the Commission terminates the license, and (d) records of estimates of exposures as a result of off-scale personal direct reading dosimeters or lost or damaged personnel dosimeters until the Commission terminates the license. The records serve as an important mechanism for controlling exposure on a day-to-day basis, provide indications of inadvertent exposure, and provide a backup record of estimated exposure in case a personnel dosimeter is lost. The records are used by NRC staff to determine the extent of compliance by the licensee.

Section 34.85 requires the licensee to maintain a record of the last survey made on each radiographic exposure device on each day it is used, just prior to placing the device in storage, as specified in § 34.49(c). Each record must be maintained for 3 years after it is made. These records enable the licensee to verify that the required radiation surveys have been done and that they are in compliance with the radiation dose limits.

Section 34.87 requires the licensee to maintain each record in a legible form, which may include electronic storage media, and that includes all pertinent information throughout the specified retention period.

Section 34.89(a) requires licensees to maintain copies of records required by this part and other applicable parts of this chapter at the location specified in § 34.13(k) to demonstrate compliance with NRC regulations in conducting radiographic operations and to ensure that adequate information is available to safely handle radioactive material.

Section 34.89(b) requires licensees to maintain copies of documents and records sufficient to demonstrate compliance at any field stations and each temporary job site as applicable. The purpose is to demonstrate compliance with NRC regulations in conducting radiographic operations and to ensure that adequate information is available at sites where radioactive material is handled. These documents and records include: (1) the license authorizing the use of licensed material; (2) a copy of Parts 19, 20, and 34 of NRC regulations; (3) utilization records for each radiographic exposure device dispatched from that location as required by § 34.71; (4) records of equipment problems in daily checks of equipment as required by § 34.73(a); (5) records of alarm system and entrance control checks required by § 34.75, if applicable; (6) daily pocket dosimeter readings as required by § 34.47(b); (7) operating and emergency procedures required by § 34.45; (8) evidence of the latest calibration of the radiation survey instrument in use at the site, as required by § 34.65; (9) evidence of the latest calibration of alarm ratemeters and operability checks of pocket dosimeters as required by § 34.47(c); (10) latest survey records required by § 34.85; (11) the shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and (12) when operating under reciprocity pursuant to § 150.20 of this chapter, a copy of the Agreement State license authorizing the use of licensed materials.

Section 34.101(a) requires written reports within 30 days of the occurrence of the following: 1) unintentional disconnection of the source assembly, 2) inability to retract the source assembly to its fully shielded position and secure it in this position, and 3) failure of any component critical to safe operation to properly perform its intended function.

Section 34.101(b) specifies that the report required under Section 34.101(a) is to include: 1) description of the equipment problem, 2) cause of the problem, 3) manufacturer name and model number of equipment involved, 4) date, time, and place of the incident, 5) actions taken to establish normal operations, 6) corrective action(s) taken to prevent recurrence, and 7) qualifications of personnel involved in incident.

Section 34.101(c) requires the licensee to notify the appropriate NRC regional office prior to conducting radiographic operations or storing radioactive material in excess of 180 days at any location not listed on the license. These requirements are necessary in order to provide the NRC with information in a timely manner to permit inspection of radioactive material at these locations to ensure that they are in compliance with NRC safety regulations.

Section 34.111 provides that the Commission may grant exemptions from the requirements of Part 34 under specified conditions, upon the application of any interested person or on its own initiative. Applications under this section are examined by the NRC materials licensing staff to determine whether the requested exemption is authorized by law and whether it will not endanger life or property or the common defense and security, and to determine if it is otherwise in the public interest. Burden and cost has been approved under OMB clearance number 3150-0120.

The following describes the information collection requirements of Appendix A to § 34.43(a) and their need and practical utility. Appendix A specifies the requirements to be an independent organization and the certification program criteria all organizations must address. Appendix A does not impose requirements on NRC's radiography licensees. Part I of the Appendix provides the requirements to be an independent certifying organization. Parts II and III provide the requirements for the certification program and written examinations for a certifying entity, including the Agreement States. NRC anticipates that certifying entities will maintain their program procedures as long as the organization is identified by NRC as a certifying entity.

For information required under each Part of Appendix A, NRC would review the program description to ensure that it includes the elements in that Part.

Appendix A, Part I, item 6 requires that an independent certifying organization have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies. The procedures are needed to ensure the independent certifying organization has a program in place for monitoring and enforcing its by-laws and policies.

Appendix A, Part I, item 9 requires that an independent certifying organization have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program. The Procedures are needed to ensure that the independent certifying organization has an adequate certification program. The records are needed by the certifying organization to maintain an awareness of each individual's certification, and to record its activities on the administration of its certification program. They would review the records during periodic program reviews.

Appendix A, Part I, item 10 requires that an independent certifying organization have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals. The procedures are needed to ensure that the independent certifying organization provide certified individuals adequate due process.

Appendix A, Part I, item 11 requires that an independent certifying organization have procedures for proctoring examinations and for ensuring that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees. The procedures are needed to help ensure fairness in the examination process.

Appendix A, Part I, item 12 requires that independent certifying organizations and/or Agreement States exchange information about certified individuals with the Commission and the Agreement States. This information is needed to ensure that knowledge about certified individuals is shared between the regulatory bodies and the certifying organization.

Appendix A, Part I, item 13 requires that an independent certifying organization provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment. The procedures are needed to ensure that the independent certifying organization provide for appropriate examination sites and environments.

Appendix A, Part II, item 2 requires that a certification program must require applicants for certification to provide documentation that demonstrates that the applicant has: (a) received training in the topics set forth in Appendix A to this part; (b) satisfactorily completed a minimum period of on-the-job training; and (c) received verification by an Agreement State or an NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer. Submission of this documentation to the certifying organization is necessary for the certifying organization to verify an applicant's training and to determine that the applicant meets certain certification criteria.

Appendix A, Part II, item 3 requires that a certification program must include procedures to ensure that all examination questions are protected from disclosure. The procedures are intended to ensure that the examinees will not have access to certification examination questions.

Appendix A, Part II, item 4 requires that a certification program must include procedures whereby an application can be denied or a certification revoked, suspended, and reinstated. NRC would review an independent certifying organization's program description to ensure that it includes this element. The procedures are intended to ensure that the certification program include provisions for denying applications, revoking, suspending, and reinstating an individual's certification.

Appendix A, Part II, item 6 requires that a certification program must include procedures for renewing the certifications and, if the procedures allow renewals without examination, require evidence of recent active full-time employment and annual refresher training. The procedures are intended to ensure that the certification program include provisions for certification renewal.

Appendix A, Part II, item 7 requires that the certification program provide for timely responses to public enquiries concerning an individual's certification status.

Appendix A, Part III, item 3 requires that test items in written examinations be drawn from a question bank containing psychometrically valid questions based on the material in § 34.43(g).

2. Agency Use of the Information

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.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use new automated information technology when it would be beneficial to them. NRC issued a regulation October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. Requests which are not for personal records that require verification of identity of the requester are being accepted by electronic mail and facsimile transmission in addition to mail and in-person written requests. Because of the types of information and the infrequency of submission, the applications and reports may not lend themselves readily to the use of automated information technology for submission. It is estimated that less than 1% of the responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

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

Approximately 48% of 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.

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

If the information collection was not conducted, or was conducted less frequently, 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 10 years. Information submitted in previous applications may be referenced without being resubmitted.

7. Circumstances Which Justify Variation from OMB Guidelines

Section 34.27(d) varies from OMB guidelines in requiring that licensees report within 5 days of the leak testing any result which would indicate that a source is leaking. This requirement for a report in less than 30 days is necessary because a leaking source could present a radiological hazard to workers and the public, and NRC must be notified promptly in order to be able to assess whether corrective actions initiated by the licensee are adequate.

Section 34.61 varies from OMB guidelines in requiring that licensees maintain a copy of the license, license conditions, documents incorporated by reference, and all amendments until the NRC terminates the license. This information is needed so that the licensee will have copies available for review and be able to verify that it is in compliance with the conditions of the license and the commitments that it has made.

Section 34.81 varies from OMB guidelines by requiring that licensees retain records of current operating and emergency procedures specified in § 34.45, until the Commission terminates the license. This information is needed so that operators have access to an up-to-date set of written operating and emergency procedures so that they can operate the radiography equipment properly and plan accordingly for emergencies.

Section 34.83(c) requires that licensees maintain reports received from the personnel dosimeter processor. This requirement restates existing requirements in 10 CFR Part 20, which is cleared under OMB clearance number 3150-0014.

Section 34.83(d) varies from OMB guidelines by requiring that licensees maintain records of estimates of exposures as a result of off-scale pocket dosimeters or lost or damaged personnel dosimeters until the Commission terminates the license. This information may be needed to reconstruct a worker's dose history in the event the worker loses his/her records, and to permit a planned special exposure.

Section 34.89(a) requires licensees to maintain certain documents and records at specified locations. The retention periods for the various documents vary and may be required for as long as the license is in effect. This information is needed at the various sites so that the licensee's operating personnel can have easy access to the documents they need to perform the job safely.

Section 34.89 (b) requires licensees conducting operations at temporary job sites to maintain certain documents and records at each temporary job site. The retention periods for the various documents vary and may be required for as long as the license is in effect. This information is needed so that the licensee's operating personnel can have easy access to the documents they need to perform the job safely.

Appendix A requires the development of procedures, policies and application records in various sections of the Appendix. The expectation is that a certifying entity would maintain copies of these procedures throughout the life of the program or as long as an individual's certification remains in effect. The retention is necessary to ensure the certifying entity maintains an up-to-date description of its program and records of the certifications issued.

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 is requested, although proprietary information may be submitted.

11. Sensitive Questions

None.

12. Estimated Burden and Burden Hour Cost

The estimates are based on submittals to NRC in past years. The cost to licensees and applicants is calculated at a rate of \$257 per hour for professional staff. This rate is based on NRC's fully recoverable fee rate.

The number of NRC licensees is known, whereas the total number of Agreement State licensees is an estimate based on NRC's best information available from the Agreement States. NRC uses the ratio of the total of NRC licensees (subject to Part 34) to the total number Agreement State licensees to estimate the number of Agreement State respondents for each section. NRC uses this ratio approach as the total number of Agreement State licensees subject to various Part 34 Sections is not known exactly and, therefore, must be estimated. For the estimates in this document, NRC used a ratio of 6.6 Agreement State licensees to every 1 NRC licensee.

The information in the following table summarizes the information in Tables 1 and 2 for NRC licensees and in Tables 3 and 4 for Agreement State licensees.

	NRC Licensees (hrs/yr)	Agreement State Licensees (hrs/yr)	TOTAL for All Licensees
Reporting	69	434	503
Recordkeeping	37,612	246,753	284,365
Total	37,681	247,187	284,868

The total number of respondents is 745 (647 Agreement State licensees plus 98 NRC licensees). The total number of responses for Part 34 is 1,116 (371 reporting responses plus 745 recordkeepers).

The total burden and cost for Part 34 is 284,868 hours (37,681 plus 247,187) and \$73,211,076 (284,868 hours x \$257/hr). The burden estimates are based on staff's best estimate of the time required to perform information collection activities. Cost estimates are based on the rate used in NRC's license fee rule.

13. Estimate of Other Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be \$29,233 (284,365 hours x \$257 x .0004)

14. Estimated Annualized Cost to the Federal Government

For the requested clearance period, the annualized burden and cost to NRC staff for application reviews under Part 34 is estimated to be 48 hours and \$12,336 (48 hrs x \$257) (see Table 5). These costs are fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

15. Reason for Change in Burden or Cost

The total burden increased by 86,743 from 199,125 to 284,868. The burden for NRC licensees decreased and the burden for Agreement States increased as follows:

- NRC Licensees. Although the overall burden increased, the burden for NRC licensees decreased by 5,716 hours (from 43,397 to 37,681 hours). The burden decreased as a result of a decrease in the number of NRC licensees. The actual number of NRC licensees has decreased by 15, from 113 to 98 because Pennsylvania, Virginia, and New Jersey became Agreement States since the last renewal, and licensees in these states are no longer counted as NRC licensees.
- Agreement State Licensees. The burden for Agreement State licensees increased by 91,459 hours (from 155,728 to 247,187 hours) due to a change in the ratio used to calculate the number of Agreement State licensees. The number of NRC licensees is known, whereas the total number of Agreement State licensees is an estimate based on NRC's best information available from the Agreement States. NRC uses the ratio of the total of NRC licensees (subject to Part 34) to the total number Agreement State licensees to estimate the number of Agreement State respondents for each section. NRC uses this ratio approach as the total number of Agreement State licensees subject to various Part 34 Sections is not known exactly and, therefore, must be estimated. The ratio used to estimate Agreement State respondents changed from 3.6 to 6.6; therefore, the number of Agreement State licensees increased by 240, from 407 to 647. This resulted in a burden increase of 91,459 hours from 155,728 to 247,187 hours.

The ratio changed because the difference in the number of NRC licensees versus Agreement States licensees has increased (three States: Pennsylvania, Virginia, and New Jersey, all of whom have a large number of material licensees, become Agreement States since the last renewal). This change affected the overall ratio used to calculate the number of Agreement State to NRC Part 34 licensees. The increase in the number of licensees is tied to a corresponding increase in the number of expected responses for various sections, resulting in an overall increase in the burden hour estimate.

In the last submittal for this information collection, recordkeepers were not counted as respondents. The current submission has correctly identified all respondents, including

licensees reporting information to the NRC as well as those required to retain records. As a result of this adjustment, the number of respondents has increased from 253 to 745 (647 Agreement State licensees plus 98 NRC licensees). Note that licensees reporting information are a subset of the licensees who are recordkeepers, and do not represent an additional group of licensees.

The number of responses was correctly calculated in the previous submission, including recordkeeping as a response. The number of responses has increased from 778 to 1,116 (152 NRC licensee responses [54 reporting responses plus 98 recordkeepers] + 964 Agreement state responses [317 reporting responses plus 647 recordkeepers]).

There was a slight decrease in professional cost from \$258/hr to \$257/hr.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The requirement is 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. Collections of Information Employing Statistical Methods

Statistical methods are not employed in this collection of information.

TABLE 1

ANNUAL RECORDKEEPING REQUIREMENTS OF 10 CFR PART 34
FOR NRC LICENSEES

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Hr/Yr	Record Retention Period
34.20(b)(1)	98	0.4	39	
34.25(b)&(c) - see § 34.65	98	-	0	
34.27(c)(1)&(2) - see § 34.67	98	-	0	
34.27(e) - see § 34.67	98	-	0	
34.29(a)&(b) - see § 34.69	98	-	0	
34.31(a)&(b)(1)&(2)&(c) - see § 34.73	98	-	0	
34.33(b) - see § 34.75	25	-	0	
34.35(a)	98	0.8	78	3 Years
34.35(b)	98	36	3,528	3 Years
34.43(b)(1)&(c)(1)	98	2.5	245	3 Years
34.43(f) - see § 34.79	98	-	0	
34.45(a)&(b) - see § 34.81	98	-	0	
34.47(b) - see § 34.83(a)	98	-	0	
34.47(c) - see § 34.83(a)	98	-	0	
34.47(d) - see § 34.83(d)	98	-	0	
34.47(e) - see § 34.83(d)	98	-	0	
34.47(f) - see § 34.83(c)	98	-	0	
34.47(g)(4) - see § 34.83(b)	98	-	0	
34.49(c)&(d) -see Section 34.85	98	-	0	
34.61	98	0.16	16	RULT ¹

¹Retain until license is terminated.

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Hr/Yr	Record Retention Period
34.63	98	1.6	157	3 Years
34.65	98	1.6	157	3 Years
34.67	98	1.2	118	3 Years
34.69(a)&(b)	98	2	196	3 Years
34.71(a)&(b)	98	36	3,528	3 Years
34.73(a)&(b)	98	27	2,646	3 Years
34.75	25	48.2	1,205	3 Years
34.79(a)&(b)	98	5	490	3 Years
34.81	98	0.08	8	RULT ¹
34.83(a)	98	122.5	12,005	3 Years
34.83(b)	98	2.5	245	3 Years
34.83(c)&(d)	98	3.2	314	3 Years
34.85	98	120	11,760	3 Years
34.87	98	0	0	life of program
34.89(a)&(b)	98	5.4	529	RULT
Appendix A, Part I, item 6	1	10	10	life of program
Appendix A, Part I, item 9	1	70	70	life of program
Appendix A, Part I, item 10	1	10	10	life of program
Appendix A, Part I, item 11	1	10	10	life of program
Appendix A, Part I, item 13	1	10	10	life of program
Appendix A, Part II, item 2	1	38	38	life of program

¹Retain until license is terminated.

Note: Since Appendix A, Part 1 items only apply to an independent certifying entity and there are currently no Agreement State certifying entities, the burden for this entity is only provided in this Table.

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Hr/Yr	Record Retention Period
Appendix A, Part II, item 3	1	10	10	life of program
Appendix A, Part II, item 4	1	10	10	life of program
Appendix A, Part II, item 6	1	10	10	life of program
Appendix A, Part II, item 7	1	50	50	life of program
Appendix A, Part III, item 3	1	120	120	life of program
TOTAL			37,612	

TABLE 2

ANNUAL REPORTING REQUIREMENTS OF 10 CFR PART 34
FOR NRC LICENSEES

Section	Number of Respondents	Responses Per Respondent	Total Responses/yr	Burden Hrs/response	Total Burden hr/yr
34.11 - see OMB clearance No. 3150-0120	0	0	0	0	0
34.13(b)-(k) - see OMB clearance No. 3150-0120	0	0	0	0	0
34.27(d)	1	1	1	4	4
34.41(c) - see OMB clearance No. 3150-0120	0	0	0	0	0
34.101 (a)&(b)	4	1	4	10	40
34.101 (c)	43	1	43	0.5	22
34.111 - see OMB clearance No. 3150-0120	0	0	0	0	0
Appendix A, Part I, Item 12	1	6	6	0.5	3
TOTALS	49		54		69

NRC Licensees Burden and Cost

Reporting: 69 burden hours

Recordkeeping: 37,612 hours

Total hours: 37,681 hours

Total cost: \$9,684,017 (37,681 hrs x \$257/hr)

Respondents: 98 (the 49 reporting respondents are a subset of the 98 recordkeepers)

Responses: 152 (54 reporting responses plus 98 recordkeepers)

TABLE 3

ANNUAL RECORDKEEPING REQUIREMENTS OF 10 CFR PART 34
FOR AGREEMENT STATE LICENSEES

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Hrs/Yr	Record Retention Period
34.20(b)(1)	647	0.4	259	
34.25(b)&(c) - see § 34.65	647		0	
34.27(c)(1)&(2) - see § 34.67	647		0	
34.27(e) - see § 34.67	647		0	
34.29(a)&(b) - see § 34.69	647		0	
34.31(a)&(b)(1)&(2)&(c) - see § 34.73	647		0	
34.33(b) - see § 34.75	165		0	
34.35(a)	647	0.8	518	3 Years
34.35(b)	647	36	23,292	3 Years
34.43(b)(1)&(c)(1)	647	2.5	1,618	3 Years
34.43(f) - see § 34.79	647		0	
34.45(a)&(b) - see § 34.81	647		0	
34.47(b) - see § 34.83(a)	647		0	
34.47(c) - see § 34.83(a)	647		0	
34.47(d) - see § 34.83(d)	647		0	
34.47(e) - see § 34.83(d)	647		0	
34.47(f) - see § 34.83(c)	647		0	
34.47(g)(4) - see § 34.83(b)	647		0	
34.49(c)&(d) – see Section 34.85	647		0	
34.61	647	0.16	104	RULT ¹
34.63	647	1.6	1,035	3 Years
34.65	647	1.6	1,035	3 Years
34.67	647	1.2	776	3 Years

¹Retain until license is terminated.

Section	Number of Recordkeepers	Burden Hrs Per Recordkeeper	Total Hrs/Yr	Record Retention Period
34.69(a)&(b)	647	2	1,294	3 Years
34.71(a)&(b)	647	36	23,292	3 Years
34.73(a)&(b)	647	27	17,469	3 Years
34.75	165	48.2	7,953	3 Years
34.79(a)&(b)	647	5	3,235	3 Years
34.81	647	0.08	52	RULT ¹
34.83(a)	647	122.5	79,258	3 Years
34.83(b)	647	2.5	1,618	3 Years
34.83(c)&(d)	647	3.2	2,070	3 Years
34.85	647	120	77,640	3 Years
34.87	647	0	0	life of program
34.89(a)&(b)	647	5.4	3,494	RULT
Appendix A, Part II, item 2	9	14	126	life of program
Appendix A, Part II, item 3	9	10	90	life of program
Appendix A, Part II, item 4	9	10	90	life of program
Appendix A, Part II, item 6	9	10	90	life of program
Appendix A, Part II, item 7	9	25	225	
Appendix A, Part III, item 3	1	120	120	life of program
TOTAL			246,753	

¹Retain until license is terminated.

NOTE: Appendix A items are applicable to certifying entities. There is only one NRC certifying entity for Appendix A Part I requirements. However, there are several Agreement States who are certifying States for Appendix A Part II and III items.

TABLE 4
ANNUAL REPORTING REQUIREMENTS OF 10 CFR PART 34
FOR AGREEMENT STATE LICENSEES

Section	Number of Respondents	Responses Per Respondent	Total Responses/yr	Burden Hrs/Response	Total Burden hr/yr
34.11 - see OMB clearance No. 3150-0120	0	0	0	0	0
34.13(b)-(k) - see OMB clearance No. 3150-0120	0	0	0	0	0
34.27(d)	8	1	8	4	32
34.41(c) - see OMB clearance No. 3150-0120	0	0	0	0	0
34.101 (a)&(b)	26	1	26	10	260
34.101 (c)	283	1	283	0.5	142
TOTALS	317		317		434

Agreement State Licensees Burden and Cost

Reporting: 434 burden hours
Recordkeeping: 246,753 hours
Total hours: 247,187 hours
Total cost: \$63,527,059 (247,187 hrs x \$257/hr).
Respondents: 647 (317 reporting respondents are a subset of the 647 recordkeepers)
Responses: 964 (317 reporting responses plus 647 recordkeepers)

TOTAL BURDEN AND COST (NRC Licensees plus Agreement State Licensees)

Reporting: 503 burden hours
Recordkeeping: 284,365 hours
Total hours: 284,868 hours
Total costs: \$732,11,076 (284,868 hrs x \$257/hr).
Respondents: 745 (647 Agreement State licensees plus 98 NRC licensees)
Responses: 1,116 (371 reporting responses plus 745 recordkeepers)

TABLE 5

ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT
FOR REVIEW OF REPORTS ASSOCIATED WITH 10 CFR PART 34

Section	No. of Licensee Responses	Fed Gov. Staff Hours Per Response	Total Staff Hours
34.27(d)	1	4	4
34.101(a) and (b)	4	4	16
34.101(c)	43	0.50	22
Appendix A, Part I, Item 12	6	1	6
TOTALS	54		48