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December 3, 1993

MEMORANDUM FOR: Brenda J. Shelton, Chief
 Information and Records Management Branch
 Division of Information Support Services
 Office of Information Resources Management

FROM: Donald A. Cool, Chief
 Radiation Protection and Health Effects Branch
 Division of Regulatory Application
 Office of Nuclear Regulatory Research

SUBJECT: 10 CFR 34, LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY
 REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

We have addressed the comments in your November 1, 1993 memo for the subject proposed rule and draft OMB clearance package for compliance with the Paperwork Reduction Act of 1980. A revised package is enclosed which incorporates your comments. The rulemaking package has been transmitted to the Commission to review (SECY-93-317). Thank you for your assistance in completing this action. Mary Thomas is the staff contact for this activity if you have any additional comments.

Original Signed By
 Donald A. Cool, Chief
 Radiation Protection and
 Health Effects Branch
 Division of Regulatory Application
 Office of Nuclear Regulatory Research

Enclosure:
 As stated

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OMB SUPPORTING STATEMENT FOR 10 CFR PART 34
LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS
FOR RADIOGRAPHIC OPERATIONS
(3150-0007)

Description of the Information Collection

10 CFR Part 34 provides certain requirements exclusive to licensees using byproduct material for purposes of industrial radiography, a technique of non-destructive testing. The byproduct material is normally employed in the form of sealed sources which emit high levels of radiation. Those sources are remotely moved from their shielded position in the radiographic device to an unshielded position up to 15 feet away and again returned to their shielded position following each radiograph. These radiographic devices are also often moved from location to location at a jobsite, and transported from jobsite to jobsite. The many manipulations of the sources, movement, and transport of the devices result in unique and continuing potential and actual hazardous radiological conditions.

This rulemaking revises 10 CFR Part 34 in its entirety. This revision includes additional safety requirements to enhance the level of protection of radiographers and the public and clarifies the regulations so that licensees may have a better understanding of what is expected in radiographic operations. This rulemaking includes a number of updated radiography regulations that have been adopted by many Agreement States.

A. JUSTIFICATION

1. Need and Practical Utility for the Collection of Information

The information collection requirements of the revised 10 CFR Part 34 are identified below.

§ 34.11 Application for a specific license, and § 34.13 Specific license for radiography.

Taken together, these two sections (currently at § 34.3 and § 34.11) require a license applicant to submit an application on NRC Form 313, to the NRC so that the NRC may determine whether the applicant's equipment, procedures, and personnel are adequate to protect public health and safety.

Paragraph 34.13(b), currently paragraph 34.11(b), requires applicants to have a training program for radiographers and radiographers' assistants, and to submit to the Commission a schedule or description of the program specifying (1) the initial training; (2) on-the-job training; (3) annual safety reviews;

and (4) means to be used to determine the radiographer's and radiographer's assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures. This information is reviewed by the NRC staff to ensure that radiographers and their assistants will have sufficient training to enable them to work safely and in compliance with NRC regulations, license conditions, and licensee operating and emergency procedures.

Paragraph 34.13(c), currently paragraph 34.11(b)(5) has been rewritten, it now requires applicants to establish and submit to the Commission a description of its procedures for verifying and documenting the certification status of its radiographers and for ensuring that the certification of individuals acting as radiographers remains valid. The procedures are intended to ensure the licensee has a program in place for assuring that individuals acting as radiographers are certified as required and that the licensee is aware when re-certification needs to be considered. The NRC reviews the procedures to ensure adequacy. A record of the verification is to be maintained in accordance with § 34.79.

Paragraph 34.13(d), currently paragraph 34.11(c), requires that applicant establish and submit to the Commission satisfactory written operating and emergency procedures. The operating and emergency procedures are intended to provide radiography personnel with step-by-step instructions and procedures so that the performance of industrial radiography will not endanger health or pose a danger to life or property. The preparation of operating and emergency procedures is intended to assure that radiography personnel are aware of specifically what needs to be done and how it should be done, so that there is no misunderstanding of what is required of each person involved in the overall radiography operation.

Paragraph 34.13(e), currently paragraph 34.11(d), requires that the applicant establish and submit its program for annual inspections of the job performance of each radiographer and radiographer's assistant as described in § 34.43(d). The existing rule requires quarterly inspections. The frequency was reduced to annual to reduce the burden on licensees. The inspections are necessary to ensure that radiographers and radiographers' assistants are performing their jobs in accordance with the operating and emergency procedures set forth in their license.

Paragraph 34.13(f), currently paragraph 34.11(e), requires that the applicant submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in radiography, including specified delegations of authority and responsibility. The NRC staff will review this information in order to ensure that the licensee's organization will provide adequate management oversight, supervision and accountability for safe operation of the radiography program and that the lines of authority and responsibility are clear and unambiguous.

Paragraph 34.13(g) is new. It requires the applicant to designate and identify a Radiation Safety Officer (RSO) responsible for implementing the

licensee's radiation safety program. This requirement, albeit, new to the document, is not a new requirement. This has always been assumed by the NRC to be "Individual Responsible for Radiation safety Program," Item 7, on NRC Form 313. It was separated from paragraph 34.13(f) in order to make it clear to the licensee/applicant the need to complete Item 7 on NRC Form 313. This information is reviewed by the NRC staff to ensure that a qualified individual is assigned for radiation safety.

Paragraph 34.13(h), currently paragraph 34.11(f), requires an applicant that desires to conduct its own leak tests to determine possible leakage or contamination from sources used in industrial radiography to identify the manufacturers and model numbers of the leak test kits to be used, and to provide its specific procedures for performing the tests. The procedures for performing the tests must specify the method of performing the leak test, the instrumentation to be used for measurement of the leak test sample, and the experience of the person who will perform the tests. The NRC staff reviews the procedures to ensure that the method of obtaining the leak test sample will be adequate to determine if there is any leakage or contamination, and that the person who will perform the leak tests has training and experience in performing such tests.

Paragraph 34.13(i) is new. It requires the applicant to identify the locations and describe all field stations and permanent radiographic installations. This requirement, albeit, new to the document, is not a new requirement. This has always been assumed by the NRC to be "Facilities and Equipment," Item 9, on NRC Form 313. It is addressed separately in order to make it clear to the licensee/applicant that they need to complete Item 9 on NRC Form 313. This information is necessary because field stations and permanent installations may be far removed from the home office and the information is needed to facilitate safety inspections.

Paragraph 34.13(j) is new. It allows the applicant the option to affirm that all individuals acting as radiographers will be certified in radiation safety by a certifying entity before commencing duties as radiographers. This affirmation is in lieu of describing the means used to determine the radiographer's knowledge and understanding of the subjects outlined in § 34.43(f). It also allows the applicant the option to substitute radiographer certification in lieu of the described means to determine the radiographer's knowledge and understanding of the subjects outlined in § 34.43(f).

The information required by sections 34.11 and 34.13 are submitted on the NRC Form 313, OMB Clearance number 3150-0120, as part of the application process. All information required by the revised sections is required by the current regulation except for annual safety reviews, required by paragraph 34.13(b), and identification of manufacturers and model numbers of leak test kits, required by paragraph 34.13(h), and the new requirements of paragraphs 34.13(g) and 34.13(i). The increase in burden for NRC Form 313 due to these added requirements is included in the licensee burden table.

§ 34.20 Performance requirements for radiography equipment.

Paragraph 34.20(b)(1) is unchanged from the current rule and requires that each radiographic exposure device have an attached label bearing information identifying the radionuclide in the device, its activity and the date that this activity was last measured, the manufacturer, model and serial 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.

Paragraph 34.20(b)(2) requires that radiographic exposure devices intended for use as Type B transport containers meet the applicable requirements of 10 CFR Part 71.

Paragraph 34.20(f) is new. It requires that all associated equipment acquired after January 10, 1996, be labelled to identify that the components have met the requirements of section 34.20. This was added to reduce the burden of proof on the licensee and to speed up the inspection process by reducing record searches for a component to ensure that it meets the requirements of Part 34.

§ 34.25 Radiation survey instruments and § 34.65 Records of radiation survey instruments.

Paragraphs (b) and (c) of § 34.25 require that each radiation survey instrument be calibrated at intervals not to exceed 6 months and after each instrument servicing, and that a record be maintained in accordance with § 34.65. The existing rule requires that radiation survey instruments be calibrated at 3 month intervals and a record maintained of the calibrations. The calibration interval is being extended from 3 months to 6 months because survey instruments are now sturdier and more reliable. The making of radiation surveys is one of the most important aspects of radiation safety and the instruments must provide reasonable accuracy in the measurement of the levels of radiation to which individuals are exposed during conduct of radiographic operations. 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. This is a burden reduction, since licensees will be required to maintain fewer records under the revised rule.

§ 34.27 Leak-testing and replacement of sealed sources and § 34.67 Records of leak testing and replacement of sealed sources.

Paragraph 34.27(b)(2) requires the licensee to maintain records of leak test results in accordance with § 34.67 and is the same as the existing requirements in § 34.25(c).

Paragraph 34.27(b)(3) requires that the licensee not use a sealed source in the absence of a certificate from the transferor that the source has been leak tested within the 6 months before the transfer, and is the same as the existing wording in paragraph 34.25(b).

Paragraph 34.27(c) requires that the licensee perform the leak test required by paragraph 34.27(h)(1) using a leak test kit or a method approved by the Commission or an Agreement State, and that the person performing the leak test be approved by the Commission or an Agreement State. This is necessary to ensure that the licensee performs the test properly.

Paragraph 34.27(d) requires that licensees report within 5 days of the leak testing any result which would indicate that a source is leaking and is the same as the existing requirement in paragraph 34.25(d). 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 respect to source design, radiographic equipment design, or problems in source manufacturing and quality control.

The only new requirement in this subsection is the addition of leak testing of "S" tubes. Paragraph 34.27(f) requires licensees to conduct leak tests of "S" tubes manufactured using depleted uranium for shielding, at least annually, and to maintain records of these tests in accordance with § 34.67. A leak test is the only effective method of determining the integrity of the sealed source. Serious health hazards could result from a leaking source. The records allow NRC inspectors to verify that required tests to detect radioactive contamination have been done.

§ 34.29 Quarterly inventory and § 34.69 Records of quarterly inventories.

Paragraph 34.29(a) requires the licensee to conduct a quarterly physical inventory to account for all sealed sources received and possessed under the license, and paragraph 34.29(b) requires the licensee to maintain records under § 34.69 of the material inventoried for 3 years, and is similar to the existing requirements in 34.26.

§ 34.31 Inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers and § 34.73 Records of inspection and maintenance of radiographic exposure devices, storage containers, and source changers.

Paragraph 34.31(a) requires that the licensee visually check for obvious defects in radiographic exposure devices, storage containers, associated equipment, and source changers prior to use each day the equipment is used to ensure that the equipment is in good working condition and that required labeling is present. While the current rule requires a daily check, no requirement for follow-up actions was included and associated equipment is not

included in the current rule. Associated equipment has been added to the new rule because experience has shown that defects in this equipment can affect safety. The revised rule specifies that if defects are found, the equipment must be removed from service until repaired, and a record must be made in accordance with § 34.73. The new requirement was added to ensure that licensees take appropriate actions if defective equipment is found. A record is needed for licensees to demonstrate that the appropriate actions have been taken if defects are found.

Paragraph 34.31(b) requires that the licensee have a program to inspect for obvious defects of radiographic exposure devices, source changers, associated equipment and storage containers at three month intervals to ensure the proper functioning of equipment, to remove defective equipment from service until it is repaired, and to make a record under § 34.73 of each quarterly inspection and any defects found during the inspection and to keep these records for 3 years. The revised recordkeeping requirements in paragraph 34.73(b) are an expansion of what is presently in § 34.28(b) which requires that records be kept of inspections for 3 years but did not specify what information to keep. The records assist the licensee in keeping 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, and to detect problems that may be generic to the equipment so that corrective action might be taken.

§ 34.33 Permanent radiographic installations and § 34.75 Records of permanent radiographic installations.

Paragraph 34.33(b) requires that the alarms on permanent radiographic installations required by § 34.33(a) be tested at the beginning of each day of equipment use 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. Defective control devices on alarms are to be immediately labeled as such and repaired before use. This is necessary to warn personnel of potential radiation hazards. The testing frequency has increased from quarterly in the current rule to daily in the revised rule to prevent personnel overexposures due to defective alarms. Records of the alarm test are to be maintained under § 34.75 for 3 years, which is the same as the current requirement in § 34.29(c), with the additional requirement of recording the alarm system tests performed before each day of use. 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.

§ 34.35 Labels, storage, and transportation precautions.

Paragraph 34.35(a)(2) is a new section that 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 10 CFR Part 71, including documentation of the QA program requirements outlined in § 71.105. This is necessary to ensure that

the licensee is in compliance with regulations stated in this part and in Part 71.

§ 34.42 Radiation Safety Officer

This is a new section which requires that the Radiation Safety Officer (RSO) meet certain training and documented experience qualifications prior to being designated as the RSO. The RSO is responsible for establishing and overseeing the development of procedures required by § 34.45; ALARA procedures as required by 10 CFR Part 20; overseeing the training program required by § 34.43; and overseeing the performance of radiation surveys and leak tests required by § 34.49 and § 34.27 respectively; that records of personnel monitoring results are maintained and that timely notifications are made as required by § 20.2203. The RSO is to be listed on the license application as required in § 34.13(g).

§ 34.43 Training and § 34.79 Records of training and certification.

Paragraph 34.43(a)(2) is new. It requires that radiographers be certified by a certifying entity according to the criteria in 10 CFR Part 34, Appendix A. An independent organization must submit a request to NRC to be recognized as a certifying entity.

Paragraph 34.43(a)(3), currently 34.31(a)(2), contains a new requirement for the licensee to provide radiographers with copies of pertinent sections of Parts 30 and 71, and instructions in applicable Department of Transportation regulations as referenced in 10 CFR Part 71, in addition to the existing requirement to provide copies of pertinent sections of Parts 19, 20, and 34; the NRC license; and operating and emergency procedures. This is needed to ensure that radiographers are sufficiently knowledgeable of NRC regulations prior to using licensed material.

Paragraph 34.43(b)(1), currently 34.31(b)(1), contains a new requirement for the licensee to provide radiographer's assistants with copies of pertinent sections of Parts 30, and 71, and instructions in applicable Department of Transportation regulations as referenced in 10 CFR Part 71, and the NRC license under which the assistant will perform radiography, in addition to the existing requirement to provide copies of pertinent sections of Parts 19, 20, and 34; and operating and emergency procedures. This is needed to ensure that radiographer's assistants are sufficiently knowledgeable of NRC regulations prior to using licensed material.

Paragraph 34.43(c) is a new requirement to conduct annual safety reviews for radiographers and radiographers' assistants, with records maintained in accordance with paragraph 34.43(e). This requirement replaces the requirement in paragraph 34.13(b) for periodic training and was revised to make it clear what was meant by periodic training.

Paragraph 34.43(d), currently 34.20(d)(1), which requires inspection and recording of job performance, on a quarterly basis, has been reduced to annual

to reduce the administrative burden on the licensee. For individuals who have not performed radiographic operations for more than six months, an inspection of job performance would be required as in the existing rule at the time they next participate in a radiographic operation. This reduction was done primarily in response to comments made at the Radiography Workshop conducted in November, 1992.

Paragraph 34.43(e) requires that the licensee maintain records of training to include certification documents, written and field examinations, annual safety reviews, and annual inspections of job performance. The licensee shall maintain records of the aforementioned items in § 34.79, which is currently required in § 34.31(c) with the addition of the new requirement for documenting the information covered in annual safety reviews. The existing regulation does not have a specific recordkeeping requirement except for tests administered. The revised rule requires licensees to keep track of when and what training was provided, who provided the training and who received the training. This is needed to enable licensees to demonstrate compliance with NRC requirements. The records of the annual inspections of job performance will be used by the licensee to keep track of deficiencies, if noted, so that they can be corrected. Section 34.79 requires that the licensee retain these records for a period of 3 years after the record is made so that the NRC can inspect to ensure that these individuals are properly trained.

§ 34.45 Operating and emergency procedures and § 34.81 Records of operating and emergency procedures.

Paragraph 34.45(a), currently 34.32, requires that licensees develop procedures for routine operations and emergencies for employees to follow in performing safety functions. These include the safe handling and use of sealed sources and radiographic exposure devices; conducting radiation surveys; controlling access to radiographic areas; locking and securing radiographic exposure devices, storage containers, and sealed sources; personnel monitoring; transporting sealed sources; inspection and maintenance of radiographic exposure devices and storage containers; steps to be taken if a pocket dosimeter is off-scale; procedures for identifying and reporting defects and noncompliance; accident procedures; minimizing exposure; a source recovery procedure if the licensee will perform this function rather than using a consultant (which is a new requirement); and maintenance of records. Paragraph 34.45(a)(6), currently 34.32(f), is not new, the word "posting" has been changed to "placarding" to fit better when discussing transportation issues, and the reference to the Department of Transportation, 49 CFR Parts 171, 172, and 173 has been added to provide further information regarding transportation of radioactive materials. The requirement for a source recovery procedure in paragraph 34.45(a)(12) is new. It is necessary for the licensee to have this procedure if the licensee is going to recover sources on their own.

Paragraph 34.45(b) requires that the licensee maintain copies of current operating and emergency procedures in § 34.81 which is unchanged from the requirements currently in § 34.32.

§ 34.47 Personnel monitoring.

Paragraph 34.47(b) requires radiographers to read and record the exposure on their pocket dosimeters at the beginning and end of each shift, and that records shall be maintained for 3 years as specified in paragraph 34.83(a). This is to ensure that radiographers determine and maintain adequate records of their occupational exposures. The current rule requires pocket dosimeters to be read and exposures recorded daily, but many have misinterpreted this requirement, so the language was revised to clarify the intent that the exposure recorded be only the one received on a shift. When the radiographer records the pocket dosimeter reading, the licensee then knows the amount of exposure a worker received during a given shift and the licensee can take needed actions (e.g., adjust the worker's assignments so as to maintain their accumulated dose within regulatory limits or provide training to improve their work habits and thus reduce their dose).

Paragraph 34.47(c) requires that the pocket dosimeters be checked at periods not to exceed 12 months (rather than 1 year as in the current rule) for correct response to radiation, and that records shall be maintained for 3 years as specified in § 34.83(a). The changes are to clarify that 1 year means not to exceed 12 months, and to include maintenance of records of pocket dosimeter checks. These records are necessary to verify that the pocket dosimeter is responding correctly to radiation.

Paragraph 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 is revised from the current rule to restrict individuals from working with a discharged dosimeter, 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 is needed to verify that an individual's dose is within regulatory limits.

Paragraph 34.47(e) requires that if a film badge or TLD is lost or damaged that the exposure be calculated for the time period from issuance to loss or damage, and that a record be maintained of the calculation in accordance with § 34.83(d).

Paragraph 34.47(f) requires that the licensee maintain reports received from film badge and TLD processors until the license is terminated as specified in the current rule under § 34.33(e) and in § 34.83(c) of the revised rule.

Paragraph (g) of § 34.47 requires that alarm ratemeters be calibrated at periods not to exceed one year for correct response to radiation. A new requirement is added that the licensee must maintain records of the calibrations for 3 years after the record is made as specified in § 34.83(b). This was added to provide a means for the licensees to demonstrate to NRC that their alarm ratemeters are properly calibrated.

§ 34.49 Radiation surveys and § 34.85 Records of radiation surveys.

Paragraph (f) of § 34.49 requires that radiography licensees maintain records of storage surveys required by paragraphs (d) and (e) in accordance with § 34.85 for 3 years. A record of the survey is required by paragraph (d) of § 34.49 when that survey is the last one that is performed on that day and is unchanged from the current rule. It is intended 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. A device may remain stored for an extended period and, if the source is not fully shielded, it could cause excessive and unnecessary radiation exposure to unsuspecting individuals. This is a current requirement at § 34.43(c) and is not being revised. Records of surveys conducted initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change as required by paragraph (e), are necessary to ensure that radiation levels do not exceed the limits specified in 10 CFR 20.1301.

The following sections are not entirely new. Most of the requirements contained in these sections are imbedded throughout the current rule. This subpart has been added to place recordkeeping requirements in one location in the rule.

§ 34.61 Records of specific licenses for radiography.

This new section requires the licensee to have a copy of the license, license conditions, documents incorporated by reference, and amendments until the NRC terminates the license. The purpose is so that the licensee will review the documents regularly to verify that they are in compliance with the conditions of the license and the commitments that it has made.

§ 34.63 Records of receipt and transfer.

This section requires that the licensee maintain records showing receipts and transfers of sealed sources for 3 years after the record is made. Section 30.51 already requires radiography licensees covered under Part 34 to maintain records of byproduct material receipt and transfer for 3 years. This provision was added to Part 34 because some licensees misunderstood the applicability of this requirement. The following information must be included in the record: the date, the individual making the record, the radionuclide, number of curies, and make, model, and serial number of each sealed source and device, as appropriate. The records allow NRC inspectors to verify the sources the licensee is presently using.

§ 34.65 Records of radiation survey instruments.

This new section requires that the licensee maintain records of the calibrations of their radiation survey instruments, and that the records be retained for 3 years. These requirements are the same as those in the current § 34.24. 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 radiographer's assistants are properly calibrated. Because instruments will be required to be calibrated semiannually under the revised rule versus quarterly under the current rule, this is a burden reduction, since licensees will be required to maintain fewer records. 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.

§ 34.67 Records of leak-testing and replacement of sealed sources.

This new section requires that the licensee maintain records of leak test results and that the records be retained for 3 years. These requirements are the same as those in the current § 34.35(c). These records are necessary to verify that the licensee is in compliance with NRC requirements as described in § 34.27, and to ensure the safety of sealed sources.

§ 34.69 Records of quarterly inventory.

This section requires that the licensee maintain records of quarterly inventories. Paragraph (a) requires that the records be retained for 3 years. Most of these requirements are the same as those in the current § 34.26. Paragraph (b) requires that the record include the quantities and kinds of byproduct material (including the model number, the serial number and manufacturer), location of sealed sources, the name of the individual conducting the inventory and the date of the inventory. The new requirements are the model and serial numbers, the manufacturer of the sealed source, and the name of the individual conducting the inventory. These new requirements were added to ensure that licensees maintain complete records to ensure traceability of sealed sources. The inventories are used by the licensee to verify the location of the sources 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.

§ 34.71 Utilization logs.

Paragraph (a) of this section requires that the licensee maintain current utilization logs. These logs must show for each sealed source the following information: (1) a description, including the make, model number and serial number of the radiographic exposure device or storage container in which the sealed source is located; (2) the identity and signature of the radiographer to whom assigned; (3) the plant or site where used and dates of use, including the dates removed from and returned to storage. The new requirements in this section are the model and serial numbers and the manufacturer of the radiographic exposure device, the signature of the radiographer to whom assigned, and the dates the device is removed from and returned to storage. These requirements were added to demonstrate adequate control of licensed material. The current regulation only requires a description of the device or storage container, the identity of the radiographer to whom assigned and the

plant or site where used and the dates of use. The records required by this section are used by the licensee to maintain control of licensed material, and allow NRC inspectors to determine whether the licensed material has been properly controlled and used. Paragraph (b) of this section requires that the licensee retain these records for a period of 3 years after the record is made.

§ 34.73 Records of inspection and maintenance of radiographic exposure devices, storage containers, and source changers.

This new section requires that the licensee maintain records of inspection and maintenance of radiographic exposure devices, storage containers, and source changers, and that the records be retained for 3 years. The records specified at § 34.73 must include the date of check, equipment inspected, name of inspector, and any defects found and repairs made. The records assist the licensee in keeping 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, and to detect problems that may be generic to the equipment so that corrective action might be taken.

§ 34.75 Records of permanent radiographic installations.

This new section requires that the licensee maintain records of the alarm checks at permanent radiographic installations, and that the records be retained for 3 years. The records are used by the licensee to keep track of when the 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 and to ensure that personnel are not inadvertently exposed by the existence of malfunctioning alarms.

§ 34.79 Records of training and certification.

This new section requires that the licensee maintain records of training and certification of radiographers and radiographers' assistants. It requires that the licensee retain these records so that the NRC can inspect to ensure that these individuals are properly trained. The existing regulation does not have a specific recordkeeping requirement except for tests administered. The revised rule requires licensees to keep track of the dates of specific training provided, and who provided and received training. This is needed to enable licensees to demonstrate compliance with NRC requirements. The records of the annual inspections of job performance will be used by the licensee to keep track of deficiencies, if noted, so that they can be corrected. Paragraph (a) requires that the record include radiographer certification documents, certification status verification, copies of written tests, dates of field examinations, and names of individuals conducting the field examinations. Paragraph (b) requires that records of annual safety reviews and annual inspections for each radiographer and each radiographer's assistant be maintained. The records must list the topics discussed, the dates of the reviews, and names of the instructors and attendees. For annual inspections

the records must also include a list of the questions asked and any non-compliances observed.

§ 34.81 Records of operating and emergency procedures.

This new section requires that the licensee retain records of operating and emergency procedures until the Commission terminates the license and that the licensee retain copies of superseded material for 3 years after each change. 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 current instructions are being provided.

§ 34.83 Records of personnel monitoring.

Section 34.83 revises the current § 34.33(b) and requires licensees to maintain records of alarm ratemeter calibrations, pocket dosimeter readings and operability checks for 3 years from the date the record was made, and to maintain records of film badge or TLD reports, and records of estimates of exposures as a result of off-scale pocket dosimeters or lost or damaged film badges or TLDs 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 film badge or thermoluminescent dosimeter is lost. Pocket dosimeter readings are often the first indication a radiographer has of an overexposure or an improperly stored source. Records of pocket dosimeter readings are needed in investigations of incidents and overexposures, since they are the only available record for the exposure received that day.

§ 34.85 Records of radiation surveys.

This new section requires that the licensee maintain records of each exposure device survey conducted before placing the device in storage in accordance with § 34.49(e) for 3 years after the record is made, if that survey is the last one performed in the work day. The records allow NRC inspectors to verify that the required radiation surveys have been done and that the radiation dose limits are being complied with.

§ 34.87 Forms of records.

This section describes allowable forms for official records. This section (currently at § 34.4) is not new. The word "maintenance" was changed to "form" in keeping with the latest language used in NRC regulations. It requires that the records required by Part 34 be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored

in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 34.89 Documents and records required at field stations and permanent installations.

This new section adds the requirement to maintain copies of the following records at field stations to demonstrate compliance with NRC regulations in conducting radiographic operations and to ensure that adequate information is available to safely handle radioactive material:

- (a) A copy of Parts 19, 20, and 34 of NRC Regulations;
- (b) The license authorizing the use of licensed material;
- (c) Operating and emergency procedures required by § 34.45;
- (d) The record of radiation survey instrument calibrations required by § 34.65;
- (e) Records of leak test results required by § 34.67;
- (f) Quarterly inventory records required by § 34.69;
- (g) Utilization records required by § 34.71;
- (h) Records of inspection and maintenance required by § 34.73;
- (i) For permanent installations, records of alarm system and entrance control checks required by § 34.75.
- (j) Training and certification records required by § 34.79;
- (k) Survey records required by § 34.85.
- (l) Personnel monitoring records as required by § 34.83; and
- (m) Records of receipt and transfer of sealed sources required by § 34.63.

§ 34.91 Documents and records required at temporary jobsites and use or storage locations exceeding 180 days.

This new section adds the requirement that each licensee conducting operations at a temporary jobsite shall maintain copies of the following documents and records at the temporary jobsite in order to have the information available to safely perform radiographic operations:

- (a) Operating and emergency procedures required by § 34.45.
- (b) Evidence of latest calibration of the radiation survey instruments in use at the site required by § 34.65.
- (c) Evidence of latest calibration of alarm ratemeters and operability checks of pocket dosimeters required by § 34.83.
- (d) Latest survey records required by § 34.85.
- (e) The shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and
- (f) When operating under reciprocity pursuant to § 150.20 of this chapter, a copy of the Agreement State license authorizing use of licensed materials.

34.101 Notifications.

This section, currently at § 34.30, contains notification requirements. Sections 34.101(a) and (b) specify requirements for notifying the NRC within 30 days of significant health and safety events and are unchanged from the current rule. A new subparagraph, 34.101(c), has been added that requires the licensee to notify the appropriate NRC regional office in writing within 30 days prior to conducting radiographic operations or storing radioactive material at any location not listed on the license in excess of 180 days. This requirement is 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.

Appendix A

Appendix A would specify the requirements to be an independent organization and certification program criteria all organizations must address. Appendix A does not impose new requirements on NRC's radiography licensees. Part I of this Appendix provides the requirements to be an independent certifying organization. Parts II and III of Appendix A provides the requirements for 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 a certifying entity.

Appendix A, Part I, item 3 would require that an independent certifying organization have a certification program that is open to non-members. This is necessary to uphold 10 CFR Part 4, Subpart A -- Regulations Implementing Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974 with respect to prohibiting discriminatory actions.

Appendix A, Part I, item 5 would require that an independent certifying organization have a permanent full-time staff, a viable system for financing its operations, and a policy- and decision-making review board. This ensures that the organization will have the resources to maintain an adequate program.

Appendix A, Part I, item 6 would require 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 intended to ensure the independent certifying organization has a program in place for monitoring and enforcing its by-laws and policies. The NRC reviews the procedures to ensure adequacy.

Appendix A, Part I, item 9 would require 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 on the administration of its certification program. The procedures are intended to ensure the independent certifying organization has an adequate certification program. The NRC reviews the

procedures to ensure adequacy. The records are necessary for the certifying organization to maintain an awareness of each individual's certification, and to record its activities on the administration of its certification program. The records would be reviewed during periodic program reviews.

Appendix A, Part I, item 10 would require 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 intended to ensure the independent certifying organization provide certified individuals adequate due process. The NRC reviews the procedures to ensure adequacy.

Appendix A, Part I, item 11 would require that an independent certifying organization have procedures to ensure 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 intended to help ensure fairness in the examination process. The NRC reviews the procedures to ensure adequacy.

Appendix A, Part I, item 12 would require that an independent certifying organization exchange information about certified individuals with the Commission and the Agreement States and allow periodic review of its certification program and related records. The exchange of information and periodic review are to ensure that all individuals' certifications are current and valid.

Appendix A, Part I, item 13 would require 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 intended to ensure that the independent certifying organization provide for appropriate examination sites and environments. The NRC reviews the procedures to ensure adequacy.

Appendix A, Part II, item 2 would require that a certification program must require applicants for certification to provide documentation that demonstrates that the applicant: (a) has 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) has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer. Submission of this documentation is necessary for the certifying entity to verify an applicant's training and to determine that the applicant meets certain certification criteria. NRC would review the program description to ensure that it include this element.

Appendix A, Part II, item 3 would require 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 certification program include provisions for protecting examination questions. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 4 would require that a certification program must include procedures whereby an application or certification would be considered null and void if the applicant or certified individual is prohibited from acting as a radiographer by a regulatory agency at the time of making the application. The procedures are intended to ensure that the certification program include provisions for automatically denying certification to an individual if the individual has been prohibited from acting as a radiographer by the NRC or an Agreement State. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 6 would require 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. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 7 would require that a certification program must include procedures whereby an individual's certification may be revoked, suspended, or restricted for willful or significant failure to comply with his or her employer's operating or emergency procedures, or the Commission's or a Agreement State's regulations. The procedures are intended to ensure that the certification program include provisions for revoking, suspending, or restricting an individual's certification in the event of a willful or significant failure to comply. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 8 would require that a certification program must provide for automatic suspension of an individual's certification, based on Commission or Agreement State action prohibiting the individual from acting as a radiographer. This requirement is intended to ensure that the certification program include a provision for automatic suspension that would prohibit an individual from acting as a radiographer. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 9 would require that a certification program must provide for sanctions imposed against certified individuals that are at least as severe as any action taken by the Commission or an Agreement State. This requirement is intended to ensure that the certification program include a provision to impose sanctions against certified individuals, and would uphold the proposed 10 CFR Part 34, Subpart H -- Violations. NRC would review the program description to ensure that it includes this element.

2. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The revision to 10 CFR Part 34 encourages licensees, who so desire, to submit information in electronic format. Records may be retained in electronic format.

3. Effort to Identify Duplication

The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

4. Effort to Use Similar Information

There is no similar information available to the NRC.

5. Effort to Reduce Small Business Burden

Many NRC radiography licensees are small businesses. Efforts have been made to keep the requirements for information to a minimum. However, since the consequences of mishandling 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 of Less Frequent Collection

Applications are only required to be submitted for the initial license, for amendments, and for renewal every 5 years. The application process requires that applicants and licensees perform a comprehensive review of their entire radiation safety program to assure that all activities will be or are being conducted safely and in accordance with NRC regulations. Requests for certification program approval proposed in § 34.43(a)(2) need to be submitted only once. Requests for certification program changes would be submitted on an "as-needed" basis. The submission of the required information is essential to NRC's determination of whether the applicant has procedures that are adequate to protect the public health and safety and meet regulatory guidelines. 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 for the use of byproduct material that are adequate to protect the public health and safety. Other reporting and recordkeeping requirements are occasioned by specified events such as leak tests, instrument calibrations, and inventories of licensed material. Conduct of these tests and other events and collection of information concerning them at the required frequency is essential to provide the assurance of protection for the health and safety of workers and the public.

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 34.81 varies from OMB guidelines in requiring that licensees retain a copy of current operating and emergency procedures as a record until the Commission terminates the license. It is necessary that these procedures be retained longer than 3 years because the information is used by the licensee

and its employees throughout the period of licensed activity to guide the handling and use of radioactive material in normal and emergency situations.

Sections 34.83 (c and d) vary from OMB guidelines in requiring that licensees maintain reports received from the film badge or TLD processor and records of estimates of exposures as a result of off-scale pocket dosimeters or lost or damaged film badges or TLDs until the Commission terminates the license.

8. Consultations Outside the NRC

American Society for Nondestructive Testing, Inc. (ASNT) was consulted concerning the certification program development and information collection requirements. The revised rule will be published in the Federal Register for public comment.

9. Confidentiality of Information

None, except for proprietary information.

10. Justification for Sensitive Questions

There are no questions regarding sensitive issues.

11. Estimated Annualized Cost to the Federal Government

The estimated annual cost professional staff effort for activities other than application review, which is included in OMB Clearance 3150-0120, NRC Form 313, is \$10,925,640 (82,770 hours @ \$132/hr).

12. Estimate of Burden

See Tables 1, 2 and 3. Total 10 CFR Part 34 burden is estimated for recordkeeping and reporting is estimated to be 99,120 hours. Total cost for licensees is estimated at \$13,071,960 (\$132 X 99,120 hrs). In addition, there is an increase in burden for NRC Form 313 of 2 hours each for 700 licensees, or an increase of 1,400 hours and a cost for NRC Form 313 of \$184,800 (\$132 X 1,400 hours).

13. Reasons for Change in Burden

The change in burden is due to the revision of 10 CFR Part 34 in its entirety and additional information to be submitted on NRC Form 313, cleared under OMB Clearance number 3150-0120.

14. Publication for Statistical Use

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not employed in the collection of information.

TABLE 1
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH
RECORDKEEPING REQUIREMENTS OF THE REVISED 10 CFR PART 34

SECTION	LIC AFFECTED	HRS/LIC	TOTAL BURDEN	COST AT \$132/HR	REC. RET.	NOTES
34.13(c)	700	1	700	92,400	3 Yrs	
34.20(b)(1)	700	1	700	92,400	3 Yrs	Labels
34.20(f)	700	1	700	92,400	3 Yrs	New, labels
34.25(c)	700		0		3 Yrs	see § 34.65
34.27(b)(2)	700		0		3 Yrs	see § 34.67
34.27(b)(3)	350	1	350	46,200	3 Yrs	
34.27(c)	350	3	1,050	138,600	3 Yrs	
34.27(f)	350	3	1,050	138,600	3 Yrs	
34.29(b)	700		0			see § 34.69
34.31(a)	700		0			see § 34.73
34.31(b)	700		0			see § 34.73
34.33(b)	175		0			see § 34.75
34.35(a)(2)	700	10	7,000	924,000	3 Yrs	
34.42	700		0			see § 34.13(g)
34.43(a)	700	1	700	92,400		some new
34.43(b)	700	1	700	92,400		some new
34.43(c)	700	0	0			see § 34.43(e) new
34.43(d)	700	0	0			see § 34.43(e) new

TABLE 1 (cont'd)
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH THE
RECORDKEEPING REQUIREMENTS OF THE REVISED 10 CFR PART 34

SECTION	LIC AFFECTED	HRS/ LIC	TOTAL BURDEN	COST AT \$132/HR	REC. RET.	NOTES
34.43(e)	700		0			see § 34.79
34.45(b)	700		0		RULT ¹	see § 34.81
34.47(b)	700		0		3 Yrs	see § 34.83(a)
34.47(c)	700		0		3 Yrs	see § 34.83(a)
34.47(d)	35		0		RULT ¹	New, see § 34.83(d)
34.47(e)	35		0		RULT ¹	New, see § 34.83(d)
34.47(f)	700		0		RULT ¹	see § 34.83(c)
34.47(g)(5)	700		0		3 Yrs	New, see § 34.83(b)
34.49(f)	700		0		3 Yrs	see § 34.85
34.61	700	1	700	92,400	RULT ¹	New
34.63	700	1	700	92,400	3 Yrs	
34.65	700	3	2,100	277,200	3 Yrs	
34.67	700	2	1,400	184,800	3 Yrs	
34.69	700	4	2,800	369,600	3 Yrs	
34.71(a, b)	700	50	35,000	4,620,000	3 Yrs	some info new
34.73(a, b)	700	14	9,800	1,293,600	3 Yrs	some new info

¹Retain until license is terminated.

TABLE 1 (cont'd)
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH THE
RECORDKEEPING REQUIREMENTS OF THE REVISED 10 CFR PART 34

SECTION	LIC AFFECTED	HRS/ LIC	TOTAL BURDEN	COST AT \$132/HR	REC. RET.	NOTES
34.75	175	12	2,100	277,200	3 Yrs	frequency of record increased
34.79(a, b, & c)	700	6	4,200	554,400	3 Yrs	
34.81	700	2	1,400	184,800	RULT ¹	
34.83(a)	700	2	1,400	184,800	3 Yrs	some new
34.83(b)	700	1	700	92,400	3 Yrs	some new
34.83(c)	700	6	4,200	554,400	RULT ¹	
34.83(d)	35	2	70	9,240	RULT ¹	some new
34.85	700	1	700	92,400	3 Yrs	some new
34.87	700		0			Format only
34.89	525	3	1,575	207,900	3 Yrs	
34.91	175	3	525	69,300	3 Yrs	New
Appendix A, Part I, item 3	1				life of program	See Appendix A, Part I, Item 9
Appendix A, Part I, item 5	1				life of program	See Appendix A, Part I, Item 9
Appendix A, Part I, item 6	1	10	10	1,320	life of program	

¹Retain until license is terminated.

TABLE 1 (cont'd)
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH THE
RECORDKEEPING REQUIREMENTS OF THE REVISED 10 CFR PART 34

SECTION	LIC AFFECTED	HRS/ LIC	TOTAL BURDEN	COST AT \$132/HR	REC. RET.	NOTES
Appendix A, Part I, item 9	1	40	40	52,800	life of program	
Appendix A, Part I, item 10	1	10	10	1,320	life of program	
Appendix A, Part I, item 11	1	10	10	1,320	life of program	
Appendix A, Part I, item 13	1	10	10	1,320	life of program	
Appendix A, Part II, item 2	300	1	300	39,600		
Appendix A, Part II, item 3	1	10	10	1,320	life of program	
Appendix A, Part II, item 4	1	10	10	1,320	life of program	
Appendix A, Part II, item 6	1	10	10	1,320	life of program	
Appendix A, Part II, item 7	1	10	10	1,320	life of program	
Appendix A, Part II, item 8	1	10	10	1,320	life of program	
Appendix A, Part II, item 9	1	10	10	1,320	life of program	
TOTALS	N/A		82,770	10,925,640	N/A	N/A

TABLE 2
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH
REPORTING REQUIREMENTS OF THE REVISED 10 CFR PART 34

SECTION	LICENSEES AFFECTED	HOURS/ LICENSEE	TOTAL BURDEN	COST AT \$132/HR	REP. RET.	NOTES
34.13(c)	700	1	700	92,400	RULT ¹	
34.13(g)	700	10	7,000	924,000	RULT ¹	New
34.13(i)	700	10	7,000	924,000	RULT ¹	New
34.13(j)	100	1	100	1,320		New
34.27(d)	20	2	40	5,280		
34.101 (a and b)	20	10	100	13,200		
34.101 (c)	700	2	1,400	184,800		New
Appendix A, Part I, item 13	1	10	10	1,320	life of program	
TOTALS	N/A		16,350	2,146,320	N/A	N/A

¹Retain until license is terminated.

TABLE 3
 INFORMATION COLLECTION BURDENS ASSOCIATED WITH
REPORTING REQUIREMENTS OF THE REVISED 10 CFR PART 34
 THAT ARE COVERED BY OMB CLEARANCE NO. 3150-0120

SECTION	LICENSEES AFFECTED	HOURS/ LICENSEE	TOTAL BURDEN	COST AT \$132/HR	REP. RET.	NOTES
34.11	700				RULT ¹	See OMB Clearance No. 3150-0120
34.13(b)	700	1	700	92,400	RULT ¹	See OMB Clearance No. 3150-0120
34.13(d)	700				RULT ¹	See OMB Clearance No. 3150-0120
34.13(e)	700				RULT ¹	See OMB Clearance No. 3150-0120
34.13(h)	700	1	700	92,400	RULT ¹	See OMB Clearance No. 3150-0120
34.43(a) (2)						See OMB Clearance No. 3150-0120
TOTAL	N/A	2	1,400	184,800		

¹Retain until license is terminated.