FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)
AND
NRC FORM 313
APPLICATION FOR MATERIAL LICENSE, AND
SUPPLEMENTAL FORMS
NRC FORM 313A, TRAINING AND EXPERIENCE AND
NRC FORM 313B, PRECEPTOR STATEMENT
(3150-0120)
AND
10 CFR PART 20
STANDARDS FOR PROTECTION AGAINST RADIATION
(3150-0014)
COMPLETE REVISION OF PART 35

§35.633 Full calibration measurements on remote afterloaders.
- §35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
- §35.642 Periodic spot-checks for teletherapy units.
- §35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.
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Description of the Information Collection

Part 35 of Title 10 of the Code of Federal Regulations contains the Nuclear Regulatory Commission's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material.

This clearance package covers the requirements for all sections of Part 35. It reflects the elimination of 10 CFR §§ 35.32 and 35.33, currently cleared under OMB clearance number 3150-0171, "Quality Management Program and Misadministrations." It also incorporates the burden approved for the final rule for 10 CFR §35.75, "Criteria for the Release of Individuals Administered Radioactive Material," which was approved subsequent to the last Part 35 extension renewal. The recordkeeping and reporting requirements of Part 35 have been centralized into two Subparts: Subpart L - Records (§§ 35.2024-2655) and Subpart M - Reports (§§ 35.3045-3067). Cross references to the recordkeeping requirements appear in other related portions of the Part 35 rule, but these cross references do not constitute additional recordkeeping requirements.

This clearance package covers the requirements of Subpart J, "Training and experience requirements," which is part of the current Part 35 (§§ 35.900 - 35.980), as well as proposed new training and experience requirements in Subparts B and D-H of the proposed rule. Licensees will have the option to comply with the training and experience requirements in Subpart J or those in the proposed Subparts B and D-H until two years after the effective date of the final rule. At that time Subpart J will be deleted from Part 35.

The burden for the training and experience requirements under the current Subpart J, as well as the proposed new training and experience requirements in Subparts B and D-H of the proposed rule, are related as appropriate to the clearance for NRC Form 313, "Application for Material License," OMB clearance number 3150-0120, or to this clearance package for Part 35 requirements. Burdens not captured in the current clearance for NRC Form 313, including the supplemental forms 313A and 313B, are identified in the current clearance.

General requirements for radiation protection that are applicable to all NRC licensees are contained in 10 CFR Part 20. There are no burden changes to 10 CFR Part 20.

A. Justification

Part of the NRC's function is to license and regulate the use of byproduct materials, as required by the Atomic Energy Act as amended, in order to provide for the radiation safety of workers, the general public, and patients. The NRC requires licensees to perform certain tasks to ensure fulfillment of their obligations. The records required by Part 35 are the least burdensome way for licensees to demonstrate compliance with NRC's requirements. Occasionally, safety matters are of such significance that personnel need to be aware of the information in order to perform their jobs or work in a safe manner. In such cases, reports are required.

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

§35.6 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS.
This section would require a licensee that conducts research involving human subjects using byproduct material whose research is not conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects to apply for and receive approval of a specific amendment to its NRC license before conducting such research. This information is needed to enable the Commission to evaluate the licensee's compliance with the requirements for the protection of human subjects.

This section also would require all licensees that conduct research involving human subjects to obtain informed consent from the human subjects. This informed consent is needed to ensure that the human subjects understand the risks, if any, to them associated with the research and voluntarily agree to participate.

This section also would require all licensees that conduct research involving human subjects to obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of those terms as defined and described in the Federal Policy for the Protection of Human Subjects. This information is needed to evaluate the licensee's compliance with the requirements for the protection of human subjects.

§35.12 APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL.
Paragraphs 35.12(b) and (c) would require that applicants submit an original and one copy of a completed NRC Form 313, "Application for Material License." The form elicits an orderly description of the applicant's complete radiation safety program.

Paragraphs 35.12(b) and (c) would require that applicants submit requests for amendments and license renewals as an original and one copy in a letter format. The letter provides an orderly and efficient description of the basis for the license amendment or renewal.

Paragraph 35.12(d) would require that applicants for a license for medical use of byproduct material described in §35.1000 submit an original and one copy of a completed NRC Form 313. Because this license application is for a new medical use, not included in the provisions of Part 35, a licensee also would be required to provide additional information regarding any radiation safety aspects of the medical use of the material that is not addressed in the general requirements of Subparts A through C of Part 35. The licensee also would be required to provide specific information necessary for (1) radiation

safety precautions and instructions, (2) training and experience of proposed users, (3) methodology for measurement of dosages or doses to be administered to patients or human research subjects, and (4) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. The applicant or licensee also would be required to provide any other information requested by the Commission in its review of the application. This information is needed to enable the Commission to evaluate a license application for a new medical use of byproduct material. This report is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material.

The burden for Section 35.12 is included in the information collection burden for NRC Form 313. NRC Form 313 is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

§35.13 LICENSE AMENDMENTS.
This section would require that licensees apply for and receive a license amendment before receiving or using material for a clinical procedure that is permitted under Part 35, but is not authorized by the licensee's current license under this part; before permitting authorized users, authorized nuclear pharmacists, or authorized medical physicists who do not meet certain requirements to work under the license; before changing Radiation Safety Officers (RSO); before ordering more byproduct material or a different radionuclide or form than authorized by the license; before changing the area of use authorized for use of byproduct material under §§ 35.100 and 35.200; and before changing the addresses of authorized places of use. The triggering events are critical indicators of a potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection of the licensee's program. The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety.

The burden for Section 35.13 is included in the information collection burden for NRC Form 313.

§35.14 NOTIFICATIONS.
Paragraph 35.14(a) would require that licensees provide to the Commission a copy of the board certification and license or permit for each individual no later than 30 days after the date the licensee permits the individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP). The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety.

The burden to the individual to obtain proof of certification for submission to the licensee is included in the information collection burden estimate for Part 35. The burden to the licensee for submission of the notifications required by §35.14(a) is included in the information collection burden for NRC Form 313.

Paragraph 35.14(b) would require that licensees notify the NRC by letter no later than 30 days after an ANP, AU, AMP, or RSO ends his association with the licensee or has a name change; when the licensee's mailing address changes; when the licensee has a name change that is not a change in control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have a change in the areas of use. The report for AU and AMP is required in order to maintain the licensee's file with a current record of individuals authorized to use or prepare radioactive material. The report for changes in "key" workers is required because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure the safety of all licensed users. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use radioactive material safely. The NRC needs to be aware of name and mailing address changes to ensure that the licensee continues receiving correspondence such as information notices, bulletins, and other safety related documents. The NRC needs to be aware of changes of areas of use so that NRC can determine if the facilities are adequate to assure protection of public health and safety.

The burden to the licensee for submission of the notifications required by §35.14(b) is included in the information collection burden for NRC Form 313.

§35.24 AUTHORITY AND RESPONSIBILITIES FOR THE RADIATION PROTECTION PROGRAM.
Paragraph 35.24(a) would require a licensee's management to approve requests for license application, renewal, or amendment prior to submittal; any individual, prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require an amendment and are permitted under §35.26. Management approval is information that is necessary to ensure that actions affecting the radiation protection program have been reviewed by responsible licensee officials.

Paragraph 35.24(b) would require licensees with multiple modalities or multiple users to develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Procedures for interdepartmental/interdisciplinary coordination of the radiation protection program provide assurance both to the licensees and to NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program.

Paragraph 35.24(d) would require a licensee to establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer. The statement is needed so that the duties, and responsibilities of the Radiation Safety Officer are clearly defined, and the Radiation Safety Officer is provided sufficient authority to assure that the licensee's radiation safety activities are being performed in accordance with regulatory requirements.

Paragraph 35.24(f) would require that a record of actions taken pursuant to paragraphs (a) and (d) be retained in accordance with §35.2024. A description of the contents of the record and the need for the record is provided under §35.2024.

§35.26 RADIATION PROTECTION PROGRAM CHANGES.
Paragraphs 35.26(a)(3) and (4) would allow a licensee to revise its radiation protection program without Commission approval if the revisions have been

reviewed and approved by the Radiation Safety Officer and licensee management, and if the affected individuals are instructed on the revised program before the changes are implemented, and if the revisions do not require an amendment under §35.13. Review and approval by licensee management will allow a licensee to make some changes in their radiation safety program, provided that the changes do not reduce radiation safety.

Paragraph 35.26(b) would require a record of each change to be retained in accordance with §35.2026. A description of the contents of the record and the need for the record is provided under §35.2026.

§35.27 SUPERVISION.
Paragraph 35.27(a) would require a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by §35.11(b) to instruct the supervised individual in the licensee's written radiation protection procedures, regulations in 10 CFR Part 35, and license conditions with respect to the use of byproduct material. This instruction will ensure that the supervised individual knows and follows all necessary radiation protection procedures.

Paragraph 35.27(b) would require a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user as allowed by §35.11(c) to instruct the supervised individual in the preparation of byproduct material for medical use. This instruction will ensure that the supervised individual properly prepares byproduct material for medical use.

Paragraph 35.27(c) would require a licensee to develop, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from the authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done, and from the authorized user and authorized nuclear pharmacist about the instructions and requirements provided in accordance with paragraphs (a) and (b) of §35.27. This policy will ensure that the supervised individual secures clarification, as needed, about supervised activities.

§35.40 WRITTEN DIRECTIVES.
Paragraph 35.40(c) would require licensees who, prior to certain specified medical administrations or procedures, have prepared a written directive containing the patient or human research subject's name and certain specified information pertaining to the administration or procedure, as specified in §35.40(b), to retain the written directive in accordance with §35.2040. A description of the contents of the record and the need for the record is provided under §35.2040.

§35.41 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE.
This section would require licensees to develop, maintain, and implement written procedures for any administration requiring a written directive that will provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. These procedures are necessary to ensure that administrations that require a written directive are given as directed by the authorized user physician.

§35.50 TRAINING FOR RADIATION SAFETY OFFICER.
Paragraph 35.50(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.50(b)(1) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.50(a) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.50(b)(2), a new requirement, would require that an individual obtain a written certification signed by a preceptor Radiation Safety Officer before the individual can be qualified as a Radiation Safety Officer. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.50(b)(2) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.50(b)(3) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed the examination is necessary to ensure that the individual has sufficient knowledge in radiation safety commensurate with the medical uses of byproduct material. This report is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material.

The information required by §35.50(b)(3) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.51 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST.
Paragraph 35.51(a) would require the licensee to require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process satisfies the requirements of §35.51(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

The information required by §35.51(a) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragaraph 35.51(b)(2) would require the individual to have obtained a written certification signed by a preceptor authorized medical physicist before

the individual can be qualified as a authorized medical physicist. This statement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

The information required by §35.51(b)(2) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.51(b)(3) would require the individual to have demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed an examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of byproduct material.

The information required by §35.51(b)(3) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.55 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST.

Paragraph 35.55(a) would require the licensee to require the authorized nuclear pharmacist to be a pharmacist who has been certified as a nuclear pharmacist by a specialty board whose certification process satisfies the requirements of §35.55(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.55(a) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.55(b)(2) would require the nuclear pharmacist to be an individual who has obtained a written certification signed by a preceptor authorized nuclear pharmacist before the individual can be qualified as a nuclear pharmacist. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.55(b)(2) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.55(b)(3) would require the nuclear pharmacist to be an individual who has demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of radiopharmaceuticals.

The information required by §35.55(b)(3) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.57 TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST.

Paragraph 35.57(c) would require a licensee to apply for and receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. This record is necessary to ensure that the NRC has reviewed the training and experience of an individual who, as a result of experience, is not required to comply with the training and experience requirements of §35.55(b) or §35.980 and §35.59 to qualify as an authorized nuclear pharmacist, and determined that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.57 will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.60 POSSESSION, USE, CALIBRATION, AND CHECK OF INSTRUMENTS TO MEASURE THE ACTIVITY OF PHOTON-EMITTING RADIONUCLIDES.

Paragraph 35.60(b) would require licensees to develop, maintain, and implement written procedures for proper operation of instruments to measure the activity of photon-emitting radionuclides. These procedures are required to show that the instruments are functioning correctly because confirmation of a dosage or adjustment of dosages must be based on properly-calibrated equipment.

Paragraph 35.60(e) would require licensees to retain a record of checks and tests required by §35.60(b) in accordance with §35.2060. A description of the contents of the record and the need for the record is provided under §35.2060.

§35.61 CALIBRATION AND CHECK OF SURVEY INSTRUMENTS.

Paragraph 35.61(a)(3) would require that the licensee conspicuously note on a survey instrument the date that the instrument was calibrated. This information is necessary to show that survey instruments were calibrated and operational.

Paragraph 35.61(b) would require the licensee to attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent. This information is necessary to enable instrument users to make necessary corrections.

Paragraph 35.61(d) would require that licensees retain a record of the survey instrument calibrations in accordance with §35.2061. A description of the contents of the record and the need for the record is provided under §35.2061.

§35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

Paragraph 35.62(b) would require licensees to develop, maintain, and implement procedures for the use of instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. Part 35 licensees may use procedures provided by the manufacturer of the instrumentation. These procedures are necessary to ensure that licensees use the instrumentation correctly, and that the instruments that are used to measure the dosages have been checked and are operating correctly.

Paragraph 35.62(d) would require licensees to retain a record of each check and test required by this section in accordance with §35.2060. A description of the contents of the record and the need for the record is provided under §35.2060.

§35.63 DETERMINATION OF DOSAGES OF UNSEALED BYPRODUCT MATERIAL FOR MEDICAL USE.
Paragraph 35.63(e) would require that licensees retain a record of each radiopharmaceutical dosage determination in accordance with §35.2063. A description of the contents of the record and the need for the record is provided under §35.2063.

§35.67 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES.
Paragraph 35.67(a) would require that licensees read, understand, and maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources for the duration of source use. These instructions are required so that individuals who handle sources can determine the specific safety measures appropriate for each kind of source used.

Paragraph 35.67(d) would require that licensees retain a record of sealed source leak tests in accordance with §35.2067. A description of the contents of the record and the need for the record is provided under §35.2067.

Paragraph 35.67(e)(2) would require that licensees file a report with the NRC within 5 days if leakage of a sealed source is detected in accordance with §35.3067. A description of the contents of the record and the need for the record is provided under §35.2067.

Paragraph 35.67(g) would require that licensees conduct a semi-annual sealed source and brachytherapy source inventory and retain the inventory record in accordance with §35.2067. A description of the contents of the record and the need for the record is provided under §35.2067.

§35.69 LABELING AND SHIELDING OF VIALS AND SYRINGES.
This section would require that licensees develop, maintain, and implement procedures for labeling each syringe, syringe radiation shield, or vial shield. Labeling is needed because review of misadministration reports has indicated that in many cases misadministrations are caused by inadvertent transposition of syringes or by drawing a dosage from the wrong vial of radioactive material. These procedures are necessary to ensure that licensees use the syringes, syringe shields, and vial shields correctly, to document the procedures, and to enable NRC to evaluate the procedures and make a determination that the procedures are sufficient.

§35.70 SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE.
This section would require that licensees survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered. Licensees would be required to retain a record of each survey in accordance with §35.2070. A description of the contents of the record and the need for the record is provided under §35.2070.

§35.75 RELEASE OF INDIVIDUALS CONTAINING RADIOPHARMACEUTICALS OR IMPLANTS.
Paragraph 35.75(b) would require that licensees must provide an individual who has been administered radiopharmaceuticals or implants containing radioactive material and who is being released from the licensee's control in accordance with §35.75(a) with instructions on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). The licensee must provide special instructions to the released individual if the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem), assuming there is no interruption of breast feeding. These instructions are needed to ensure that the released individual is aware of the actions recommended to maintain doses to other persons ALARA.

Paragraph 35.75(c) would require that licensees maintain a record of the basis for authorizing the release of an individual, in accordance with §35.2075(a). A description of the contents of the record and a statement of need for the record is provided under §35.2075.

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

§35.80 PROVISION OF MOBILE SERVICE.
Paragraph 35.80(a) would require a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address of use and delineates the authority and responsibility of each entity. This record is necessary to show that the client's management has permitted this work.

Paragraph 35.80(f) would require that the letter required in §35.80(a) and a record of the surveys required in §35.80(e) be retained in accordance with §35.2080. A description of the contents of the record and the need for the record is provided under §35.2080.

§35.92 DECAY-IN-STORAGE.
Paragraph 35.92(b) would require that licensees retain a record of disposal of waste that was decayed in storage and retain the record in accordance with §35.2092. A description of the contents of the record and the need for the record is provided under §35.2092.

§35.204 PERMISSIBLE MOLYBDENUM-99 CONCENTRATION.
Paragraph 35.204(c) would require that licensees measure the molybdenum-99 concentrations in eluates from a molybdenum-99/technetium-99m generator and retain the record in accordance with §35.2204. A description of the contents of the record and the need for the record is provided under §35.2204.

§35.290 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES.
Paragraph 35.290(a) would require the licensee to require an authorized user of a radiopharmaceutical for the uses listed in §35.100 to be a physician who has been certified by a specialty board whose certification process satisfies the requirements of §35.290(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the physician has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for the uses listed in §35.100.

The information required by §35.290(a) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.290(b)(2) would require the licensee to require an authorized user to be a physician who has obtained a written certification signed by a preceptor before the physician can independently function as an authorized user of a diagnostic radiopharmaceutical for the uses listed in §35.100. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for uptake, dilution, or excretion studies.

The information required by §35.290(b)(2) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.290(b)(3) would require the licensee to require an authorized user to be a physician who has demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using radiopharmaceuticals for uptake, dilution, or excretion studies.

The information required by §35.290(b)(3) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.292 TRAINING FOR IMAGING AND LOCALIZATION STUDIES.
Paragraph 35.292(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.292(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in §35.200.

The information required by §35.292(a) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.292(b)(2) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of diagnostic radiopharmaceuticals and generators for imaging and localization studies. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in §35.200.

The information required by §35.292(b)(2) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.292(b)(3) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using diagnostic radiopharmaceuticals and generators for the uses listed in §35.200.

The information required by §35.292(b)(3) will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.310 SAFETY INSTRUCTION.
Paragraph 35.310(a) would require that licensees provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received radiopharmaceutical therapy and cannot be released in accordance with §35.75. This instruction is needed to ensure that personnel receive instruction in limiting radiation exposure to the public and workers, and in the actions to be taken in the event of death or medical emergency.

Paragraph 35.310(b) would require licensees to retain a record of radiation safety instruction given to personnel who care for radiopharmaceutical therapy patients or human research subjects, in accordance with §35.2310. A description of the contents of the record and the need for the record are provided under §35.2310.

§35.315 SAFETY PRECAUTIONS.
Paragraph 35.315(a)(2) would require that the licensee post a radiopharmaceutical therapy patient's or human research subject's room with a "Radioactive Materials" sign. This provides notice to hospital workers and the public that there is radioactivity in the room. The section also would require that the licensee note in the patient's chart how long visitors may stay in the patient's room. This is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules.

Paragraph 35.315(b) would require that the licensee promptly notify the Radiation Safety Officer, or his designee, if the patient dies or has a medical

emergency. This notification is required so that the Radiation Safety Officer or his designee can take whatever actions are necessary to prevent radioactive contamination. The Radiation Safety Officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

§35.390 TRAINING FOR USE OF UNSEALED BYPRODUCT MATERIAL FOR THERAPY OR FOR USE OF UNSEALED BYPRODUCT MATERIAL THAT REQUIRES A WRITTEN DIRECTIVE.

Paragraph 35.390(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.390(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for therapy or to use unsealed byproduct material that requires a written directive.

The information required by §35.390(a) will be submitted on NRC Form 313 as a license amendment application, which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.390(b)(3) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic radiopharmaceuticals for the uses requiring a written directive. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for therapy.

The information required by §35.390(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.390(b)(4) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using unsealed byproduct material for therapy.

The information required by §35.390(b)(4) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.404 RADIATION SURVEYS OF PATIENTS OR HUMAN RESEARCH SUBJECTS TREATED WITH IMPLANTS.

Paragraph 35.404(c) would require a licensee to retain a record of the patient or human research subject surveys required by §35.404(a) after an implant and §35.404(b) after removing the implant in accordance with §35.2404. A description of the contents of the record and the need for the record is provided under §35.2404.

§35.406 BRACHYTHERAPY SOURCES INVENTORY.

Paragraph 35.406(c) would require licensees to make a record of brachytherapy source accountability in accordance with §35.2406. A description of the contents of the record and the need for the record is provided under §35.2406.

§35.410 SAFETY INSTRUCTION.

Paragraph 35.410(b) would require licensees to retain a record of radiation safety instruction for personnel who care for patients or human research subjects who are undergoing implant therapy, in accordance with §35.2310. A description of the contents of the record and the need for the record is provided under §35.2310.

§35.415 SAFETY PRECAUTIONS.

Paragraph 35.415(a) would require that the licensee post the patient's room with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room. This posting is required to help protect against excessive radiation exposure to visitors.

Paragraph 35.415(c) would require that the licensee promptly notify the Radiation Safety Officer, or his designee, and authorized user if the patient dies or has a medical emergency. This notification is required so that the Radiation Safety Officer, or his designee, or authorized user can take whatever actions are necessary to prevent a spread of radioactive contamination or loss of sources containing byproduct material. The Radiation Safety Officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

§35.432 FULL CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES.

Paragraph 35.432(f) would require licensees who perform full calibration measurements on brachytherapy sources before the first medical use of the source or the source/applicator configuration to retain a record of each calibration in accordance with §35.2432. A description of the contents of the record and the need for the record is provided under §35.2432.

§35.490 TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES.

Paragraph 35.490(a) would require licensees to require the authorized user of a manual brachytherapy source for the uses listed in §35.400 to be a physician certified by a specialty board whose certification process satisfies the requirements of §35.490(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.

The information required by §35.490(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.490(b)(3) would require licensees to require the authorized user to be a physician who has obtained a written certification signed by a

preceptor before the individual can independently function as an authorized user of manual brachytherapy sources. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.

The information required by §35.490(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.490(b)(4) would require licensees to require the authorized user to have demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using manual brachytherapy.

The information required by §35.490(b)(4) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.590 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS.
Paragraph 35.590(a) would require the licensee to require the authorized user of a diagnostic sealed source for use in a device listed in §35.500 to be a physician, dentist, or podiatrist who has been certified by a specialty board approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of sealed sources for diagnosis.

The information required by §35.590(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.604 RADIATION SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS TREATED WITH REMOTE AFTERLOADERS.
Paragraph 35.604(b) would require licensees who use sealed sources in devices for therapeutic medical uses and who immediately after retracting the source from the patient into its shielded position in the device have performed a radiation survey of the patient or human research subject as required by §35.604(a) to retain a record of the survey in accordance with §35.2404. A description of the contents of the record and the need for the record is provided under §35.2404.

§35.605 INSTALLATION, MAINTENANCE, AND REPAIR.
Paragraph 35.605(d) would require licensees to retain a record of each installation, maintenance, and repair of a therapeutic medical device in accordance with §35.2605. A description of the contents of the record and the need for the record is provided under §35.2605.

§35.610 SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADERS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.
Paragraph 35.610(a) would require licensees to develop, maintain, and implement specified safety procedures. These procedures are necessary because of the complexity and higher radiation risk associated with these units.

Paragraph 35.610(b) would require licensees to physically locate a copy of the procedures at the unit console. These safety procedures are necessary to ensure that workers at the console have physical access to the procedures.

Paragraph 35.610(c) would require licensees to post instructions for individuals who operate the devices at the device console providing the locations of the procedures and emergency names and telephone numbers. These instructions are necessary to inform workers of the procedures and to serve as a quick reference in case of emergencies or equipment malfunction.

Paragraph 35.610(e) would require licensees to make a record of initial instruction, refresher training, and practice drills for individuals who operate devices and retain the record in accordance with §35.2310. A description of the contents of the record and the need for the record is provided under §35.2310.

§35.630 DOSIMETRY EQUIPMENT.
Paragraph 35.630(c) would require licensees to retain a record of each calibration, intercomparison, and comparison of calibrated dosimetry equipment in accordance with §35.2630. A description of the contents of the record and the need for the record is provided under §35.2630.

§35.632 FULL CALIBRATION MEASUREMENTS ON TELETHERAPY UNITS.
Paragraph 35.632(g) would require licensees to retain a record of full calibration measurements on teletherapy units in accordance with §35.2632. A description of the contents of the record and the need for the record is provided under §35.2632.

§35.633 FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADERS.
Paragraph 35.633(h) would require licensees to retain a record of full calibration measurements on remote afterloaders in accordance with §35.2633. A description of the contents of the record and the need for the record is provided under §35.2633.

§35.635 FULL CALIBRATION MEASUREMENTS ON GAMMA STEREOTACTIC RADIOSURGERY UNITS.
Paragraph 35.635(g) would require licensees to retain a record of full calibration measurements on gamma stereotactic radiosurgery units in accordance with §35.2635. A description of the contents of the record and the need for the record is provided under §35.2635.

§35.642 PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS.
Paragraph 35.642(c) would require that the authorized medical physicist review and report the results of teletherapy unit output spot-checks promptly to the licensee. This report is needed to assure the licensee that the results of each spot-check have been reviewed by an expert.

Paragraph 35.642(f) would require licensees to retain a copy of each report of monthly teletherapy unit output spot-checks and each monthly teletherapy unit safety spot-checks in accordance with §35.2642. A description of the contents of the record and the need for the record is provided

under §35.2642.

§35.643 PERIODIC SPOT-CHECKS FOR HIGH DOSE-RATE AND PULSED DOSE-RATE REMOTE AFTERLOADERS.
Paragraph 35.643(b) would require licensees to have the authorized medical physicist establish procedures for performing periodic spot-checks on high dose-rate and pulsed dose-rate remote afterloaders. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.643(h) would require licensees to retain a copy of each report of weekly and daily spot-checks in accordance with §35.2643. A description of the contents of the record and the need for the record is provided under §35.2643.

§35.644 PERIODIC SPOT-CHECKS FOR LOW DOSE-RATE REMOTE AFTERLOADERS.
Paragraph 35.644(c) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on low dose-rate remote afterloaders prior to each patient treatment and after each source installation. The authorized medical physicist is the most qualified individual to ensure that the procedures are in accordance with published recommendations of nationally recognized bodies. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.644(e) would require licensees to retain a copy of each report of spot-checks on low dose-rate remote afterloaders in accordance with §35.2643. A description of the contents of the record and the need for the record is provided under §35.2643.

§35.645 PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS.
Paragraph 35.645(b)(1) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on gamma stereotactic radiosurgery units monthly and prior to each day of use. The authorized medical physicist is the most qualified individual to ensure that the procedures are performed in accordance with published recommendations of nationally recognized bodies. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(b)(2) would require licensees to have the authorised medical physicist review the results of each spot-check of a gamma stereotactic radiosurgery unit within three days of each spot-check. This review is necessary to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(g) would require licensees to retain a record of each spot-check in accordance with §35.2645. A description of the contents of the record and the need for the record is provided under §35.2645.

§35.647 ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADERS.
Paragraph 35.647(e) would require licensees to retain a record of each check of mobile remote afterloaders prior to each change of address of use as required by §35.647(b) in accordance with §35.2647. A description of the contents of the record and the need for the record is provided under §35.2647.

§35.652 RADIATION SURVEYS.
Paragraph 35.652(c) would require that licensees who make radiation surveys as required by §35.652(b) at installation of a new source and following repairs to the source(s) shielding, source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the sources, to retain a record of the radiation surveys in accordance with §35.2652. A description of the contents of the record and the need for the record is provided under §35.2652.

§35.655 FIVE-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.
Paragraph 35.655(c) would require licensees to keep a record of the teletherapy unit and gamma stereotactic radiosurgery unit 5-year inspection and servicing required by §35.655(a) in accordance with §35.2655. A description of the contents of the record and the need for the record is provided under §35.2655.

§35.690 TRAINING FOR USE OF THERAPEUTIC MEDICAL DEVICES.
Paragraph 35.690(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.690(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

The information required by §35.690(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.690(b)(3) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic medical device. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

The information required by §35.690(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.690(b)(4) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using therapeutic medical devices.

The information required by §35.690(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.900 RADIATION SAFETY OFFICER.
Paragraph 35.900(a) would require that, except as provided in §35.57 with respect to training for an experienced Radiation Safety Officer, a licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who is certified by one of nine listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.900 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this requirement is included in the licensee burden table.

§35.910 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES.
Paragraph 35.910(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a radiopharmaceutical in §35.100(a) to be a physician who is certified by one of five listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for uptake, dilution, and excretion studies.

The information required by §35.910 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this requirement is included in the licensee burden table.

§35.920 TRAINING FOR IMAGING AND LOCALIZATION STUDIES.
Paragraph 35.920(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a radiopharmaceutical, generator, or reagent kit in §35.200(a) to be a physician who is certified by one of five listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for imaging and localization studies.

The information required by §35.920 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.930 TRAINING FOR THERAPEUTIC USE OF UNSEALED BYPRODUCT MATERIAL.
Paragraph 35.930(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of radiopharmaceuticals in §35.300 to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic use of unsealed byproduct material.

The information required by §35.930 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.940 TRAINING FOR USE OF BRACHYTHERAPY SOURCES.
This section requires that except as provided in §35.57 with respect to training for an experienced authorized user a licensee must require the authorized user of a brachytherapy source listed in §35.400 for therapy to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for brachytherapy sources.

The information required by §35.940 will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.950 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS.
This section requires that except as provided in §35.57 with respect to training for an experienced authorized user a licensee must require the authorized user of a sealed source in a device listed in §35.500 to be a physician, dentist, or podiatrist who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for use of sealed sources for diagnosis.

The information required by §35.950 will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.960 TRAINING FOR TELETHERAPY.
This section requires that except as provided in §35.57 with respect to training for an experienced authorized user a licensee must require the authorized user of a sealed source listed in §35.600 in a teletherapy unit to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for teletherapy.

The information required by §35.960 will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.961 TRAINING FOR TELETHERAPY PHYSICIST.
This section requires that the licensee shall require the teletherapy physicist to be an individual who is certified by one of two listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a teletherapy physicist.

The information required by §35.961 will be submitted on NRC Form 313 or as a license amendment application, both of which are cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.980 TRAINING FOR AUTHORIZED NUCLEAR PHARMACIST.
Paragraphs 35.980(a) and (b)(2) would require that the licensee shall require the authorized nuclear pharmacist to be a pharmacist who is certified by a listed certifying organization or has obtained another certification signed by a preceptor who is an authorized nuclear pharmacist that the applicants training has been satisfactorily completed. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

The information required by §35.980 will be submitted on NRC Form 313 or as a license amendment application, which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.2024 RECORDS OF AUTHORITY AND RESPONSIBILITIES FOR RADIATION PROTECTION PROGRAMS.
Paragraph 35.2024(a) would require licensees to retain a record of actions taken in accordance with §35.24(a) for five years. This record must include a summary of actions taken and the signature of licensee management for requests for license application, renewal, or amendment; approvals or disapprovals of requests to allow an individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and approval or disapproval of radiation protection program changes that do not require an amendment. This record is needed to document these actions and the basis for them because they are important to the licensee's radiation safety program.

Paragraph 35.2024(b) requires that licensees maintain for the life of the license a current copy of the authorities, duties, and responsibilities of the radiation safety officer as required by §35.24(d). The record must include the signature of the radiation safety officer and licensee management. This record is important to show that the RSO has sufficient authority, time, resources, and management prerogative to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

§35.2026 RECORDS OF RADIATION SAFETY PROGRAM CHANGES.
This section would require licensees to retain a record of each radiation protection program change as required by §35.26(a) for five years. The record must include a copy of the old and new procedures and the signatures of the radiation safety officer and licensee management that reviewed and approved the change. This record is needed to document what radiation safety factors were considered before implementing the minor change. This record facilitates the Commission's evaluation of the nature and appropriateness of the minor changes during inspections prior to renewal, and provides the licensee with a complete record of the radiation safety program changes until the changes are incorporated into the license when renewed.

§35.2040 RECORDS OF WRITTEN DIRECTIVES.
This section would require licensees to retain a copy of each written directive as required by §35.40 for three years. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician. Retention of the written directives and records of each administration for three years after the date of the administration will allow NRC to ensure that administrations were in accordance with the written directives by reviewing a sample of written directives and records during an NRC inspection.

§35.2045 RECORDS OF MEDICAL EVENTS AND PERCURSOR EVENTS.
This section would require licensees to maintain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for three years. The record must contain the licensee's name; names of all the licensee's personnel involved, and the affected or potentially affected individual's social security number or other identification number if one has been assigned, a brief description of the medical event or precursor event, why it occurred, the effect on the individual, and the actions taken to prevent recurrence. This record is needed to document medical events and precursor events for licensee and Commission review, so that the Commission can ascertain whether medical events have been investigated by the licensee and that corrective actions have been taken.

§35.2060 RECORDS OF INSTRUMENT CALIBRATIONS.
This section would require licensees to retain a record of instrument calibrations performed in accordance with §§ 35.60 and 35.62 for three years. The records must include:

(1) For constancy, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the activity measured, and the name of the individual who performed the check.

(2) For accuracy, the model and serial number of the instrument, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test, and the name of the individual who performed the test.

(3) For linearity, the model and serial number of the instrument, the calculated activities, the measured activities, and the date of the test, and the name of the individual who performed the test.

(4) For geometric dependence, the model and serial number of the instrument, the configuration of the source measured, the activity measured for each volume measured, and the date of the test, and the name of the individual who performed the test.

The records of the checks and tests in §§ 35.60 and 35.62 are necessary to demonstrate that the instruments used to measure the activity of alpha-, beta-, and photon-emitting radionuclides are functioning correctly and are capable of accurately measuring dosages; to establish trends in equipment performance; and to show compliance with regulatory requirements.

§35.2061 RECORDS OF RADIATION SURVEY INSTRUMENT CALIBRATIONS.

This section would require licensees to retain a record of radiation survey instrument calibrations required by §35.61 for three years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the name of the individual who performed the calibration.

This record of calibration of survey instruments is required to show that survey instruments were calibrated and are functioning correctly.

§35.2063 RECORDS OF DOSAGES OF UNSEALED BYPRODUCT MATERIAL FOR MEDICAL USE.
This section would require licensees to retain a record of dosage determinations required by §35.63 for three years. The record must contain the radionuclide, radiopharmaceutical and its lot number; patient's or human research subject's name, or identification number; prescribed dosage and activity at the time of determination, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); date and time of the determination; and name of the individual who determined the dosage.

This record is required for demonstrate that are maintaining control of the use of radiopharmaceuticals.

§35.2067 RECORDS OF POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES.
Paragraph 35.2067(a) would require licensees to retain records of leak tests required by §35.67(b) for three years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test. This record is required to demonstrate that the leak test was done as required, and that the source was not leaking.

Paragraph 35.2067(b) would require that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by §35.67(g) for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each sourcethe activity of each test samplelocation of each source, and the name of the individual who performed the survey. This inventory record is needed to show that possession of sealed sources did not exceed the amount authorized by the license.

§35.2070 RECORDS OF SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE.
This section would require licensees to retain a record of each survey required by §35.70 for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millrem per hour of the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the name of the individual who performed the survey. The records are needed to document that the surveys were performed, and that the ambient radiation exposure rates are below the limits set for protection of workers and the public.

§35.2075 RECORDS OF THE RELEASE OF INDIVIDUALS CONTAINING RADIOPHARMACEUTICALS OR IMPLANTS.
Paragraph 35.2075(a) would require that licensees retain records of the release of individuals containing radiopharmaceuticals or implants in accordance with §35.75 for three years after the date of release. Retention of the release records for three years after the date of the release will allow NRC to ensure that releases were in accordance with the criteria for release by reviewing a sample of the records during an NRC inspection.

Paragraph 35.2075(b) would require a licensee to retain a record that describes the basis for authorizing the release of individuals if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

These records are necessary to document the basis for releasing individuals containing radiopharmaceuticals or implants from the control of licensees, and into situations where they could expose members of the general public.

Paragraph 35.2075(c) would require licensees to retain a record that the instructions required by §35.75(b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem). This record is necessary to show that nursing mothers have been provided with necessary information to ensure that an infant or child does not receive excess exposure to radiation. These instructions are necessary to provide for the radiation safety of the general public.

§35.2080 RECORDS OF ADMINISTRATIVE AND TECHNICAL REQUIREMENTS THAT APPLY TO THE PROVISION OF MOBILE SERVICES.
Paragraph 35.2080(a) would require that licensees providing mobile services retain a copy of the letters signed by the management of each client as required by §35.80(a) for three years after the last provision of service. The letter must delineate the authority and responsibility of each entity. These records are necessary to show that the licensees had permission to use byproduct material at the client's address of use.

Paragraph 35.2080(b) would require that licensees retain a record of each survey required by §35.80(e) for three years. The record must include the date of the survey, a plan of each area surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the name of the individual who performed the survey. These records are needed to show that the required surveys were made.

§35.2092 RECORDS OF WASTE DISPOSAL.
This section would require that licensees retain records of the disposal of licensed materials made pursuant to §35.92 for three years. The records must include the date of disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. These records are needed to show that materials were decayed for the required length of time, that their radioactivity cannot be distinguished from background radiation levels, and that a proper survey of each waste container was made prior to disposal. These records are also needed to show that radioactive material is not disposed of as ordinary waste.

§35.2204 RECORDS OF MOLYBDENUM-99 CONCENTRATION.
This section would require that licensees retain records of molybdenum-99 concentration tests required by §35.204(b) for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the name of the individual who made the measurement. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

§35.2310 RECORDS OF INSTRUCTION AND TRAINING.
This section would require that licensees retain records of instructions and training required by §§ 35.310, 35.410, and 35.610 for three years. The record must include a description of the instruction, the date of instruction, and the name(s) of the individual(s) who attended the training and the name(s) of the individual(s) who provided the instruction. This record is needed to show that the required initial and refresher training was given and that the drills were performed so that individuals are aware of the safety procedures to be used in caring for patients and human research subjects treated with byproduct material or radiation therefrom.

§35.2404 RECORDS OF RADIATION SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS.
This section would require that licensees retain a record of the radiation surveys of patients and human research subjects required by §§ 35.404 and 35.604 for three years. Each record must include the date and results of the survey, an identifier for the patient or the human research subject, and the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced.

§35.2406 RECORDS OF BRACHYTHERAPY SOURCE INVENTORY.
This section would require that licensees retain records of brachytherapy source accountability required by §35.406 for three years. For temporary implants, the record must include: (1) the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use: (2) the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage. For permanent implants, the record must include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources returned to storage, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

§35.2432 RECORDS OF FULL CALIBRATIONS OF BRACHYTHERAPY SOURCES.
This section would require that licensees retain records of full calibrations on brachytherapy sources required by §35.432 for three years after the last use of the source. The record must include the date of calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

§35.2605 RECORDS OF INSTALLATION, MAINTENANCE, AND REPAIR.
This section would require that licensees retain records of installation, maintenance and repair of therapeutic medical devices required by §35.605 for three years. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individuals who performed the work. This record is necessary to show that the devices are properly installed, maintained, and repaired, to establish trends in device performance, and to establish a service history that may be used in evaluation of generic equipment problems.

§35.2630 RECORDS OF DOSIMETRY EQUIPMENT.
This section would require that licensees retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with §35.630 for the duration of the license. For each calibration, intercomparison, or comparison, the record must include: the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison. This record is needed to show that calibrations of medical devices were made with properly calibrated instruments.

§35.2632 RECORDS OF TELETHERAPY FULL CALIBRATIONS.
This section would require that licensees retain records of teletherapy full calibrations required by §35.632 for three years. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for the teletherapy unit, the source, and instruments used to calibrate the teletherapy unit; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; an assessment of timer

accuracy and linearity; the calculated on-off error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the teletherapy unit.

§35.2633 RECORDS OF REMOTE AFTERLOADER FULL CALIBRATIONS.
This section would require that licensees retain records of remote afterloader full calibrations required by §35.633 for three years. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the high dose-rate remote afterloader, source, and instruments used to calibrate the unit; the source output; an assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, source retraction functionality; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from remote afterloader devices.

§35.2635 RECORDS OF GAMMA STEREOTACTIC RADIOSURGERY UNIT FULL CALIBRATIONS.
This section would require that licensees retain records of gamma stereotactic radiosurgery full calibrations required by §35.635 for three years. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit; the unit output; an assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the gamma stereotactic radiosurgery unit.

§35.2642 RECORDS OF PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS.
This section would require that licensees retain a record of each periodic spot-check for teletherapy units required by §35.642 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring or localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and the signature of the individual who performed the periodic spot-check. This record is needed to show that the spot-checks were performed and that the units are operating correctly.

§35.2643 RECORDS OF PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADERS.
This section would require that licensees retain records of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the rate remote afterloader; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the periodic spot-check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§35.2645 RECORDS OF PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS.
This section would require that licensees retain records of each spot-check for gamma stereotactic radiosurgery units required by §35.645 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, the manufacturer's name, model number and serial number of the instrument used to measure the output of the unit; the measured source output and source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff switches and stereotactic frames and localizing devices (trunnions); and the signature of the individual who performed the periodic spot-check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§35.2647 RECORDS OF ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADERS.
This section would require that licensees retain records of each check for mobile remote afterloaders required by §35.647 for three years. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader; notations accounting for all sources before departing from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the check. This record is necessary to show that the checks were performed and that the units are operating correctly.

§35.2652 RECORDS OF SURVEYS OF THERAPEUTIC TREATMENT UNITS.
This section would require that licensees retain records of radiation surveys of treatment units made in accordance with §35.652 for the duration of use of the unit. The record must include the date of the measurements, the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels, and each dose rate measured around the source while the unit is in the off position and the average of all measurements, and the signature of the Radiation Safety Officer. This record is necessary to show that the surveys were performed and that the units do not exceed occupational dose levels with the sources in the shielded position.

§35.2655 RECORDS OF FIVE-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.
This section would require that licensees retain records of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by §35.655 for the duration of use of the unit. The record must contain the inspector's name, the inspector's radioactive materials license number, the date of inspection, the manufacturer's name and model number and serial number for both the treatment unit and source, a list of components inspected, and a list of components serviced, and the type of service, and the signature of the inspector. This record is needed to document the type of

service that was performed and that any required work was done.

§35.3045 REPORTS OF MEDICAL EVENTS.
Paragraph 35.3045(b) would require licensees to notify NRC by telephone no later than the next calendar day after discovery of the medical event that involves an administration of byproduct material or radiation therefrom that meets or exceeds the criteria in §3045(a). Paragraph 35.3045(a) would require a licensee to report any administration of byproduct material or radiation therefrom that meets the definition in §35.3045(a)(1) and (2) and is not the direct result of intervention by the patient that could have been reasonably prevented by the physician. This reporting requirement is needed to ensure that NRC is aware of medical events and to promptly take any necessary actions based on the circumstances.

Paragraph 35.3045(c) would require licensees to submit a written report to NRC within 15 days of the discovery of the medical event. The report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it appears the precipitating event might be generic.

Paragraph 35.3045(d) would require the licensee to notify the referring physician and the individual affected by the medical event, or to that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Paragraph 35.3045(e) would require the licensee to furnish a written report of the medical event to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect the individual. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee. This report is needed to ensure that patients obtain a written report as a record of information furnished to them verbally.

§35.3046 REPORTS OF PRECURSOR EVENTS.
Paragraph 35.3046(a) would require that licensees notify the NRC Operations Center by telephone no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event. This report is needed to ensure that NRC is aware of defects that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

Paragraph 35.3046(b) would require the licensee to submit a written report within 15 days after discovery of the precursor event to the appropriate NRC Regional Office. The report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. This written report will ensure that NRC is aware of events that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

§35.3047 REPORT OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD.
Paragraph 35.3047(a) would require the licensee to report any administration of byproduct material or radiation therefrom to a pregnant woman unless the administration was specifically approved, in advance, by the authorized user if the administration results in a dose that is greater than 5mSv (500 mrem) total dose equivalent to a nursing child. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(b) would require the licensee to report any administration of byproduct material to a breast feeding woman, unless the administration was specifically approved, in advance, by the authorized user, if the administration results in a dose that is greater than 5mSv (500 mrem) total dose equivalent to a nursing child. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(c) would require the licensee to notify by telephone the NRC Operation Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Paragraph 35.3047(d) would require the licensee to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). The written report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

§35.3067 REPORTS OF LEAKING SOURCES.
This section would require that licensees report detection of a leaking source by submitting a written report within 5 days after a leakage test reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office. The report must include the model number and serial number, if assigned, of the leaking source; radionuclide and its estimated activity; the measured

activity of each test sample expressed in microcuries; a description of the method used to measure each test sample, and the date of the test. This will enable NRC to promptly determine if the necessary follow-up actions are necessary following discovery of the leaking source.

Appendix A

Appendix A would specify the requirements for an independent organization or entity that submits an application for approval of the Commission to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.290(b)(3), 35.292(b)(3), 35.390(b)(4), 35.490(b)(4), or 35.690(b)(4). Each such organization or entity that submits an application shall:

Appendix A, Part I, item 1 would require the independent organization to make its examination process available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability. This ensures that the independent organization will 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 2 would require the independent organization to have an adequate staff, a viable system for financing its operations, and a policy- and decision-making review board. This would ensure that the organization will have the resources to maintain an adequate program.

Appendix A, Part I, item 3 would require the independent organization to 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. This would ensure that the independent organization has a program in place for monitoring and enforcing its by-laws and policies.

Appendix A, Part I, item 4 would require the independent organization to have a committee, whose members can carry out their responsibilities impartially, to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program. This would ensure that the organization has a mechanism in place for ensuring the technical quality of the examination.

Appendix A, Part I, item 5 would require the independent organization to have a committee, whose members can carry out their responsibilities impartially, to review complaints by examined individuals. This would ensure that the independent organization will provide a mechanism to resolve disputes concerning the examination results.

Appendix A, Part I, item 6 would require the independent organization to have written procedures describing all aspects of its examination program, maintain records of the current status of each individual's examination and the administration of its examination program. The procedures are needed to ensure that the examination program is adequate to identify properly trained individuals and to ensure that the examination results are maintained in case of inquiry.

Appendix A, Part I, item 7 would require the independent organization to have procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area. The procedures are needed to ensure that the organization provides an independent and objective assessment of the candidate's qualifications.

Appendix A, Part I, item 8 would require the independent organization to have procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program, including the process of being examined. The procedures are needed to ensure that the independent organization provides individuals adequate due process.

Appendix A, Part I, item 9 would require the independent organization to have procedures for proctoring examinations, including qualifications for proctors. The procedures are needed to help ensure fairness in the examination process.

Appendix A, Part I, item 10 would require the independent organization to exchange information about examined individuals with the Commission and other independent examining organizations and/or Agreement States and allows periodic review of its examination 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 11 would require the independent organization to 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 provides for appropriate examination sites and environments.

Appendix A, Part I, item 12 would require the independent organization to submit its request to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. Submission of the request is necessary so that the request can be reviewed by NRC.

Appendix A, Part II, item 2 would require all examination programs to include procedures to ensure that all examination questions are protected from disclosure. The purpose of these procedures is to ensure the fairness of the examination.

Appendix A, Part III, item 2 would require all examinations to have test items drawn from a question bank containing psychometrically valid questions based on the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations. The purpose of this question bank is to ensure that the test questions adequately address knowledge and understanding of the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations.

Appendix A, Part III, item 3 would require sample questions from all examinations to be submitted to the Commission for review initially and every 5 years. The purpose of this submission is to enable NRC to verify that the test questions adequately address knowledge and understanding of the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations.

2. Agency Use of Information

The NRC uses the records and reports required in this part to ensure that licensees' medical use programs are adequate to protect health and minimize danger to life and property and to ensure that licensees' personnel are aware of the information needed to perform their jobs and work in a safe manner. The staff makes use of the records and reports to determine whether the licensee has individuals with adequate training and experience to safely use radioactive material in the treatment of patients or human research subjects, and has the facilities and equipment necessary to assure protection of public health and safety. NRC also uses the information to develop reports to inform the public about the measures taken to provide for the radiation safety of workers, the general public, and patients and to alert licensees to issues of general concern. Reports of medical events and precursor events that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or

to alert other medical use licensees, to prevent similar events that may have generic implications.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information, the applications and reports do not lend themselves readily to the use of automated information technology for submission. Section 35.5 of the rule would provide that records under Part 35 may be stored in electronic media.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. In general, information required by the NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. Portions of the needed information might also be contained in other information submittals to the NRC or other Federal agencies. However, duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

5. Effort to Reduce Small Business Burden

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

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

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the possession, use, or transfer of byproduct material.

Applications are required to be submitted for the initial license, for amendments, and for renewals. 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. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has the training, experience, equipment, and facilities that are adequate to protect the public health and safety. Other reporting and recordkeeping requirements are occasioned by specific events, such as inventories of licensed material, calibrations and checks of medical devices, medical events, and precursor events. Collection of information at the required frequency from licensees that use byproduct material in the treatment of patients or human research subjects is essential to protect the health and safety of workers and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

Section 35.24(b) would require licensees with multiple modalities or multiple users to develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.27(c) would require a licensee to develop, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from the authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done, and from the authorized user and authorized nuclear pharmacist about the instructions and requirements provided in accordance with paragraphs (a) and (b) of §35.27. Such policies would be retained for the life of the license, or until superseded by new or revised policies, in order to ensure that they remain available for reference.

Section 35.41(a) would require licensees to develop, maintain, and implement written procedures for any administration requiring a written directive that will provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.60(b) would require licensees to develop, maintain, and implement written procedures for proper operation of instruments to measure the activity of photon-emitting radionuclides. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.62(b) would require licensees to develop, maintain, and implement procedures for the use of instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. Part 35 licensees may use procedures provided by the manufacturer of the instrumentation. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.67(a) would require that licensees read, understand, and maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources for the duration of source use. Such instructions would be retained for the duration of source use, in order to ensure that they remain available for reference.

Section 35.67(e)(2) would require that licensees file a report within five days of the leakage test in accordance with §35.3067. The justification for this variation from OMB guidelines is provided under §35.3067.

Section 35.69(a) would require that licensees develop, maintain, and implement procedures for labeling each syringe, syringe radiation shield, or vial shield. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.315(b) would require that the licensee notify the Radiation Safety Officer, or his designee, and the authorized user immediately if the patient dies or has a medical emergency. This immediate notification is necessary to permit the Radiation Safety Officer and authorized user to ensure that the necessary radiation safety precautions are used for handling an individual who has been treated with unsealed byproduct material for a therapeutic medical use.

Section 35.415(c) would require that the licensee notify the Radiation Safety Officer, or his designee, immediately if the patient dies or has a medical emergency. This immediate notification is necessary to permit the Radiation Safety Officer to ensure that safety requirements are met for removal or disposal of the implanted radioactive material.

Section 35.610(a) would require that the licensee develop, maintain, and implement safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.610(b) would require that licensees physically locate a copy of the procedures at the unit console. These safety procedures would be retained for the life of the license or the devices, or until superseded by new or revised procedures, in order to ensure that they remain available for reference.

Section 35.610(c) would require that licensees post instructions for individuals who operate the devices at the device console. These instructions would be retained for the life of the license or the devices, or until superseded by new or revised instructions, in order to ensure that they remain available for reference.

Section 35.643(b) would require that the licensee have the authorized medical physicist establish procedures for performing periodic spot-checks on high dose-rate and pulsed dose-rate remote afterloaders. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.644(c) would require that the licensee shall have the authorized medical physicist establish procedures for performing spot-checks on low dose-rate remote afterloaders prior to each patient treatment and after each source installation. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.645(b)(1) would require that the licensee have the authorized medical physicist establish procedures for performing spot-checks on gamma stereotactic radiosurgery units monthly and prior to each day of use. Retaining these procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would allow the NRC to evaluate the nature and appropriateness of such procedures during inspections.

Section 35.2024(a) would require that licensees retain a record of actions taken by licensee's management in accordance with §35.24(a) for five years. Maintaining this record for five years would allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2024(b) would require that licensees maintain a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer in accordance with §35.24(d). Maintaining a current copy of the authorities, duties, and responsibilities would ensure that they remain available for reference and would allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2026 would require that licensees retain a record of radiation safety program changes in accordance with §35.26 for five years. Maintaining this record for five years would allow the NRC to evaluate the nature and appropriateness of such changes during inspections.

Section 35.2630 would require that licensees retain a record of each calibration, intercomparison, and comparison of dosimetry equipment done in accordance with §35.630 for the duration of the license. These records are necessary to show throughout the period of use of the equipment that calibrations of medical devices were made with properly calibrated equipment.

Section 35.2652 would require that licensees retain a record of radiation surveys of treatment units made in accordance with §35.652 for the duration of use of the unit. These records are necessary throughout the period of use of the unit to provide assurance that the source was properly installed or repaired and that the unit did not exceed occupational dose levels with the sources in the shielded position. They would also be necessary in reconstruction following an incident involving the unit.

Section 35.2655 would require that licensees keep a record of five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by §35.655 for the duration of use of the unit. This record is required throughout the period of use of the unit to show that the required work was done and to establish a service history that may be used in incident investigations and evaluation of generic equipment problems.

Section 35.3045(b) would require that licensees report an administration of byproduct material or radiation therefrom that meets or exceeds the criteria in §35.3045(a) for a medical event within one calendar day after discovery of the medical event. This requirement is the minimum frequency to inform the NRC about a medical event so that any follow-up action can be taken. In addition, prompt notification is necessary because a medical event may present a radiation hazard to a member of the public that might be mitigated by NRC assistance.

Section 35.3045(c) would require that licensees submit a written report to the approriate NRC Regional Office listed in §30.6 within 15 days after discovery of the medical event. This written report is necessary to provide a detailed record of the medical event. The report also may be used to satisfy the requirements of §35.3045(e)(1).

Section 35.3045(d) would require the licensee to notify the referring physician and the individual affected by the medical event, or to that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. This requirement is the minimum frequency to inform the individuals and their referring physician(s), or the individual's responsible relative or guardian, of the medical event in order to allow them to make timely decisions regarding possible health care needs.

Section 35.3045(e) would require that if the individual affected by the medical event has been notified orally of the medical event, the licensee must furnish a written report of the medical event to the patient within 15 days after the discovery of the medical event. This requirement is the minimum frequency to ensure that complete written information is furnished to an individual so that adequate followup to the medical event can be provided, if needed.

Section 35.3046(a) would require licenses to notify by telephone the NRC Operations Center no later than the next calendar day after identifying any precursor events. Submission of the notice no later than the next calendar day is necessary so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.3046(b) requires that licensees file a report with the NRC within 15 days of any precursor event. Submission of written report is necessary to provide a detailed record of the precursor event, to support any necessary followup actions by NRC to notify other licensees, and to address the root causes of the precursor event.

Section 35.3047(c) would require the licensee to notify by telephone the NRC Operation Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). Notification within five days is necessary to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Section 35.3047(d) would require the licensee to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). Submission of a written report is needed to provide detailied information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Section 35.3067 would require licensees to file a report with the NRC within 5 days if a leakage test required by §35.67 reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination. This report is necessary so that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee up to five days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

8. Consultations Outside the Agency

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through *Federal Register* notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards (listed below); putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA and Chicago, IL, held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997 and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

In addition, the rulemaking process is using a working group, steering group, and guidance consolidation team that includes not only members from the NRC headquarters offices, but also members from the regional licensing and inspection staff that are in frequent contact with NRC's medical licensees. Representatives of two Agreement States and a non-Agreement State are members of the groups developing the rule and guidance. The Agreement State representative on the working group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process will enhance development of corresponding rules in State regulations and will provide an early opportunity for State input. In addition, it will allow the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance are noted in the NRC meeting announcements and are open to the public.

The NRC has benefitted from all of the comments received during these interactions, as well as the written comments received in response to the request for input in the *Federal Register* notice.

Interactions with Medical Professional Societies

Date	Location	Society
6/4/97	San Antonio, TX	Society of Nuclear Medicine American College of Nuclear Physicians
6/11/97	Lake Tahoe, CA/NV	American College of Medical Physicists
9/7/97	Atlanta, GA	American College of Radiology
9/16/97	Rockville, MD	American College of Radiation Oncology
9/26/97	San Francisco, CA	American Association of Clinical Endocrinologists
9/97	Professional Journal Notice	Oncology Nursing Services
10/16/97	Chicago, IL	American Hospital Association
10/18/97	Los Angeles, CA	Organization of Agreement States
10/20/97	Orlando, FL	American Society of Therapeutic Radiology and Oncology
10/22/97	Bethesda, MD	American College of Cardiology American Society of Nuclear Cardiology
12/2/97	Chicago, IL	Radiation Society of North America
12/18/97	Rockville, MD	Society of Nuclear Medicine
2/1/98	Las Vegas, NV	Society of Nuclear Medicine

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

This information is usually not confidential. If it were, the information would be handled as proprietary in accordance with 10 CFR 2.790 of the NRC regulations.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:

The total annual burden is estimated to be about 468,623 hours per year (about 246 hours per licensee) for the 1,902 licensees covered by 10 CFR Part 35. The details are shown in Tables 1 and 2. The total cost for the NRC licensees is estimated at $56,703,383 (468,623 hours x $121.00 per hour).

NRC estimates that the burden for §§ 35.50, 35.51, 35.55, 35.290, 35.292, 35.390, 35.490, or 35.690, or equivalent Agreement State regulations will be somewhat smaller than estimated over the 3-year period for this clearance package. Existing training and experience requirements for licensees under Subpart J are expected to be phased out over an approximately 2-year period following the effective date of the rule. The burden for those requirements is less than the burden for the requirements being substituted by the proposed rule. The difference in burden will be determined by the period of time required for certifying organizations to submit applications and for the NRC to review and approve them.

Agreement State Licensees:

This rule has several compatibility categories. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety requirement. Implementing procedures for the Policy Statement establish specific categories which ave been applied to categorize the requirements in Part 35. A category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. Category "A" designated Agreement State requirements should be essentially identical to those of the NRC. A category "B" designation means the requirement has significant direct transboundary implications. Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplication or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Health and Safety (H&S) Category identifies requirements which are not required for compatibility, but which have particular health

and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program. The Agreement states are encouraged to adopt similar regulations, but are not required to have any degree of uniformity between the NRC regulations and the State regulations. The burden for Agreement State licensees is calculated on the basis of Agreement States having similar regulations for medical use programs.

The total annual burden is estimated to be about 1,171,438 hours per year (about 246 hours per licensee) for the estimated 4,760 licensees covered by equivalent regulations. The details are shown in Tables 3 and 4. The total cost for the Agreement State licensees is estimated at $141,743,998(1,171,438 hours x $121.00 per hour).

Source of Burden and Cost Data and Method of Estimating and Cost

The burden estimates are based on the staff's best estimate of the time required to perform information collection activities. NRC received information on information collection activities during the public workshops and meetings described above. Cost estimates are based on the rate used in NRC's license fee rule.

13. Estimate of Other Additional Costs

None. For licensees under 10 CFR Part 35, it is most likely that purchases of equipment and services were already acquired as part of customary and usual business or private practices.

14. Estimated Annualized Cost to the Federal Government

Application review activities are attributable to and reported under NRC Form 313, "Application for Material Licensee," OMB Clearance No. 3150-0120.

Annual Cost of NRC staff review for activities other than application review (Professional effort is 33,272 hours @ $121.00 per hour) = $4,025,912.

15. Reasons for Changes in Burden and Cost

NRC Licensees:

The revision is a net downward adjustment in burden of XXXXXXXXXX hours as a result of a comprehensive revision of the Part 35 requirements to eliminate prescriptive requirements. XXX reporting requirements, with an estimated burden of XXXXXXXX hours were eliminated as a result of rulemaking since the last burden was calculated. (Sections XXXXXX 35.60(b), 35.61(b), 35.70(d), 35.70(g), 35.315(a)(6), 35.610(a), 35.643(a)(3), 35.643(b), 35.645, and 35.980(b)(2).) Three recordkeeping requirements were eliminated (XXXXX 35.20, 35.22(a)(4) and (5), and 35.32) and numerous other requirements were revised.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

Not Applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

Table 1 - Reporting Requirements
NRC Licensees

Section	Number of Agreement State Licensees	Number of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.6	4,110	1	8	32,880
35.12(b)	OMB Clearance 3150-0120			
35.12(c)	OMB Clearance 3150-0120			
35.12(d)	5	1	4	20
35.13	OMB Clearance 3150-0120			

35.14(a)	OMB Clearance 3150-0120			
35.14(b)	183	1	0.25	46
35.27(a)	4,755	1	1	4,755
35.27(b)	4,755	1	1	4,755
35.67(e)(2)	Burden calculated in 35.3067			
35.75(b)	2,665	24	0.17	10,617
35.315(b)	40	1	1	40
35.415(c)	183	1	1	183
35.642(c)	158	12	0.25	473
35.3045(b)	75	1	0.5	38
35.3045(c)	75	1	8	600
35.3045(d)	75	1	2	150
35.3045(e)	75	1	2	150
35.3046(a)	125	1	4	500
35.3047(a)	3	1	8	20
35.3047(b)	3	1	2	5
35.3047(c)	3	1	0.5	1
35.3047(d)	3	1	8	20
35.3067	5	2	2	20
Appendix A, Part I, Item 12	98	1	120	11,700
Appendix A, Part III, Item 3	98	1	120	11,700
Total:	17,488	56	294	78,672

Table 2 - Recordkeeping Requirements
NRC Licensees

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record-keeping Hours	Record Retention Period
35.24(a)	3,040	5	0.5	7,600	5 years
35.24(b)	3,193	1	0.5	1,596	Duration of license
35.24(d)	3,040	1	0.5	1,520	Duration of license
35.24(f)	Burden calculated in 35.2024				
35.26(a)(3)+(4)	4,755	1	0.5	2,378	5 years
35.26(b)	Burden calculated in 35.2026				
35.27(c)	4,755	1	0.5	2,378	Duration of

					license
35.40	Burden calculated in 34.2040				
35.41	4,755	1	0.5	2,378	Duration of license
35.50(a)	Not effective during clearance period.				
35.50(b)(2)	Not effective during clearance period.				
35.50(b)(3)	Not effective during clearance period.				
35.51(a)	Not effective during clearance period.				
35.51(b)(2)	Not effective during clearance period.				
35.51(b)(3)	Not effective during clearance period.				
35.55(a)	Not effective during clearance period.				
35.55(b)(2)	Not effective during clearance period.				
35.55(b)(3)	Not effective during clearance period.				
35.57(c)	Not effective during clearance period.				
35.60(b)	4,755	1	1	4,755	Equipment duration
35.60(e)	Burden calculated in 35.2060				
35.61(a)(3)	4,755	1	0.03	143	Equipment duration
35.61(b)	4,755	1	0.03	143	Equipment duration
35.61(d)	Burden calculated in 35.2061				
35.62(b)	130	1	0.5	65	Equipment duration
35.62(d)	Burden calculated in 35.2060				
35.63(e)	Burden calculated in 35.2063				
35.67(a)	3,365	1	0.5	1,683	Source duration
35.67(d)	Burden calculated in 35.2067(a)				
35.67(g)	Burden calculated in 35.2067(b)				
35.69	4,268	1	0.5	2,134	Duration of license
35.70	Burden calculated in 35.2070				
35.75(c)	Burden calculated in 35.2075(a)				
35.75(d)	Burden calculated in 35.2075(b)				

35.80(a)	100	20	1	2,000	3 years after last service
35.80(e)	Burden calculated in 35.2080				
35.80(f)	Burden calculated in 35.2080				
35.92(b)	Burden calculated in 35.2092				
35.204(c)	Burden calculated in 35.2204				
35.290(a)	Not effective during clearance period.				
35.290(b)(2)	Not effective during clearance period.				
35.290(b)(3)	Not effective during clearance period.				
35.292(a)	Not effective during clearance period.				
35.292(b)(2)	Not effective during clearance period.				
35.292(b)(3)	Not effective during clearance period.				
35.310(b)	Burden calculated in 35.2310				
35.315(a)(2)	2,665	3	0.2	1,599	Duration of treatment
35.390(a)	Not effective during clearance period.				
35.390(b)(3)	Not effective during clearance period.				
35.390(b)(4)	Not effective during clearance period.				
35.404(c)	Burden calculated in 35.2404				
35.406(c)	Burden calculated in 35.2406				
35.410(b)	Burden calculated in 35.2301				
35.415(a)	1,135	18	0.2	4,086	Duration of treatment
35.432(f)	Burden calculated in 35.2432				
35.490(a)	Not effective during clearance period.				
35.490(b)(3)	Not effective during clearance period.				
35.490(b)(4)	Not effective during clearance period.				
35.590	Not effective during clearance period.				
35.604(b)	Burden calculated in 35.2404				
35.605(d)	Burden calculated in 35.2605				
35.610(a)	488	1	0.5	244	Duration of use of unit
35.610(b)	488	1	0.03	15	Duration of use of

					unit
35.610(c)	488	1	0.5	244	Duration of use of unit
35.610(e)	Burden calculated in 35.2310				
35.630(c)	Burden calculated in 35.2630				
35.632(g)	Burden calculated in 35.2632				
35.633(h)	Burden calculated in 35.2633				
35.635(g)	Burden calculated in 35.2635				
35.642(c)	158	12	0.25	473	Duration of use of unit
35.642(f)	Burden calculated in 35.2642				
35.643(b)	285	1	0.5	143	Duration of use of unit
35.643(h)	Burden calculated in 35.2643				
35.644(c)	73	1	0.5	36	Duration of use of unit
35.644(e)	Burden calculated in 35.2643				
35.645(b)(1)	23	1	0.5	9	Duration of use of unit
35.645(b)(2)	23	260	0.25	1,463	Duration of use of unit
35.645(g)	Burden calculated in 35.2645				
35.647(e)	Burden calculated in 35.2647				
35.652(c)	Burden calculated in 35.2652				
35.655(c)	Burden calculated in 35.2655				
35.690(a)	Not effective during clearance period.				
35.690(b)(4)	Not effective during clearance period.				
35.690(b)(5)	Not effective during clearance period.				
35.900(a)	132	1	0.5	66	
35.910(a)	793	1	0.5	397	
35.920(a)	793	1	0.5	397	
35.930(a)	900	1	0.5	450	
35.932(a)	10	1	0.5	5	
35.934(a)	10	1	0.5	5	
35.940(a)	107	1	0.5	54	
35.941(a)	5	1	0.5	2.5	
35.950(a)	900	1	0.5	450	
35.960(a)	107	1	0.5	54	
35.961(a)	132	1	0.5	66	

35.980(a)	3	1	0.5	2	
35.2024(a)	3,040	5	0.25	3,800	5 years
35.2024(b)	3,040	1	0.08	243	Duration of license
35.2026	4,755	1	0.25	1,189	5 years
35.2040	4,755	21	0.16	15,977	3 years
35.2045	75	1	0.25	19	3 years
35.2060	4,755	400	0.2	380,400	3 years
35.2061	4,755	1.5	0.5	3,566	3 years
35.2063	4,393	290	0.16	203,812	3 years
35.2067(a)	3,365	2	0.16	1,077	3 years
35.2067(b)	3,365	2	0.5	3,365	3 years
35.2070	4,393	260	0.25	285,513	3 years
35.2075(a)	2,665	24	0.08	5,117	3 years
35.2075(b)	2,665	3	0.16	1,279	3 years
35.2075(c)	2,665	2	0.13	693	3 years
35.2080(a)	100	20	0.03	60	3 years after last service
35.2080(b)	100	20	6.5	13,000	3 years
35.2092	4,393	88	0.16	61,846	3 years
35.2204	1,685	52	0.08	7,010	3 years
35.2310	2,665	1	0.25	666	3 years
35.2404	1,553	29	0.25	11,256	3 years
35.2406	1,135	25	0.16	4,540	3 years
35.2432	1,135	25	0.16	4,540	3 years
35.2605	1,303	1	2	2,605	3 years
35.2630	1,303	1	0.5	651	3 years
35.2632	158	1.5	4	945	3 years
35.2633	358	3	4	4,290	3 years
35.2635	23	1.2	4	108	3 years
35.2642	158	12	0.5	945	3 years
35.2643	358	260	1	92,950	3 years
35.2645	23	260	1	5,850	3 years
35.2647	0	0	0	0	3 years
35.2652	488	1	0.5	244	Duration of use of unit
35.2655	163	0.2	2	65	Duration of use of unit
Appendix A, Part I, Item 1	N/A				

Appendix A, Part I, Item 2	N/A				
Appendix A, Part I, Item 3	N/A				
Appendix A, Part I, Item 4	N/A				
Appendix A, Part I, Item 5	N/A				
Appendix A, Part I, Item 6	N/A				
Appendix A, Part I, Item 7	N/A				
Appendix A, Part I, Item 8	N/A				
Appendix A, Part I, Item 9	N/A				
Appendix A, Part I, Item 10	N/A				
Appendix A, Part I, Item 11	N/A				
Appendix A, Part II, Item 2	N/A				
Appendix A, Part III, Item 2	N/A				
Total:	121,160	2,161	46	1,156,646	

Table 3 - Reporting Requirements
Agreement State Licensees

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.50(a)+(b)	185	1	1	185
35.51(a)+(b)	185	1	1	185
35.55(a)+(b)	5	1	1	5
35.290(a)+(b)	110	1	1	110
35.292(a)+(b)	110	1	1	110
35.390(a)+(b)	1,290	1	1	1,290
35.490(a)+(b)	150	1	1	150
35.690(a)+(b)	150	1	1	150
Total:	2,185	8	8	2,185

Table 4 - Recordkeeping Requirements
Agreement State Licensees

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.50(a)	167	1	1	167

35.51(a)	167	1	1	167
35.55(a)	5	1	1	5
35.290(a)	99	1	1	99
35.292(a)	99	1	1	99
35.390(a)	1,161	1	1	1,161
35.490(a)	135	1	1	135
35.690(a)	135	1	1	135
Total:	1,967	8	8	1,967