FINAL SUPPORTING STATEMENT
FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)

CLEARANCE EXTENSION WITH BURDEN REVISION

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. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

The recordkeeping and most of the reporting requirements of Part 35 are centralized into two Subparts: Subpart L - Records (§§ 35.2024-2655) and Subpart M - Reports (§§ 35.3045-3067). Cross references to the recordkeeping requirements in Subpart L 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 new training and experience requirements in Subparts B and D-H of the rule. The complete revision to Part 35 allowed use of the current Subpart J, "Training and experience requirements," §§ 35.900 - 35.981, until the new training and experience requirements could be met. Therefore, the Subpart J requirements are included although they are expected to be effective only until October 24, 2004.

The burden for the training and experience requirements in Subparts B and D-H and J are related as appropriate to the clearance for NRC Form 313, "Application for Material License," and NRC Form 313A, "Medical Use Training and Experience and Preceptor Certification," OMB Clearance No. 3150-0120, or to this clearance package for Part 35 requirements. Subsequent references to "NRC Form 313" are intended to refer to NRC Form 313 and NRC Form 313A.

This clearance package also includes the burden (341 hours) for the proposed Amendment to 10 CFR Part 35, "Medical Use of Byproduct Material - Recognition of Specialty Boards." The proposed rule revises the criteria under which NRC and Agreement States will recognize an organization whose certification process constitutes recognized training. Although the final rule is not yet effective, OMB has implemented the burden for the rule. This burden includes 213 hours (49 hours for NRC licensees and 164 hours for Agreement State Licensees) for licensees submitting preceptor statements under 35.14(a) and a one-time burden of 128 hours for certifying boards preparing requests for recognition.

A. Justification

NRC regulates and licenses the medical use of byproduct materials, as provided by the Atomic Energy Act (AEA) as amended, and the Energy Reorganization Act of 1974, in order to provide for the radiation safety of workers, the general public, and patients. Licensees must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. The records required by Part 35 are the least burdensome way for licensees to demonstrate compliance with the NRC's requirements. However, certain events are of such significance that they must be reported to the NRC, to patients or human research subjects, and to referring physicians. Collection of this information enables the NRC to

determine what steps must be taken by other licensees to prevent such events, whether required notifications have been made, and whether corrective actions have been taken. In addition, NRC has the responsibility, pursuant to section 208 of the Energy Reorganization Act of 1974, as amended, to inform Congress and the public of those events constituting "abnormal occurrences" and to also inform NRC medical use licensees of generic issues identified by the NRC review of medical events.

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

§ 35.6 Provisions for the protection of human research subjects

This section requires a licensee whose research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects, prior to conducting research, to obtain review and approval of the research by an “Institutional Review Board (IRB),” as defined and described in the Federal Policy and obtain “informed consent” from the human research subject. This review and approval is needed to ensure the licensee’s compliance with the requirements for the protection of human subjects. Informed consent is needed to ensure that the human research subject is informed of any potential risks and voluntarily agrees to them.

This section also requires a licensee 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 medical use license before conducting such research. The amendment request must include a written commitment that the licensee will, prior to conducting research: (1) obtain review and approval of the research by an “Institutional Review Board,” as defined and described in the Federal Policy; and (2) obtain “informed consent,” as defined and described in the Federal Policy, from the human research subject. This information is needed to ensure the licensee's compliance with the requirements for the protection of human subjects.

§ 35.12 Application for license, amendment, or renewal

Paragraph 35.12(b) requires that an application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by filing an original and one copy of NRC Form 313, "Application for Material License." This includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable. NRC Form 313 requires a description of the applicant’s complete radiation safety program. Under § 35.12(c), an application for license amendment or renewal must be made on NRC Form 313 or by a letter requesting the amendment or renewal, and must include procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable. An application must be signed by the applicant’s or licensee’s management.

The burden for Paragraphs 35.12 (b) and (c) is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

Paragraph 35.12(d), in addition to the requirements in paragraphs (b) and (c) of this section, requires that an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in the requirements of Subparts A

through C of this part. The applicant also is required to provide specific information on: (1) radiation safety precautions and instructions; (2) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (3) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. The applicant or licensee also is 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 that is not specifically addressed in subparts D through H of Part 35.

The burden for new modalities is submitted on NRC Form 313 (OMB Clearance No. 3150-0120).

<u>§ 35.13 License amendments</u>

This section requires that licensees apply for and receive a license amendment before receiving, preparing, or using byproduct material for medical uses that are permitted under Part 35, but are not authorized by the licensee's current license issued under this part; before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license; before changing Radiation Safety Officers (RSO), except as provided in § 35.24(c); before receiving byproduct material in excess of the amount or in a different form than is authorized on the license, or receiving a different radionuclide than is authorized on the license; before adding or otherwise changing areas of use identified in the application or on the license, except for areas where byproduct material is used in accordance with §§ 35.100 and 35.200; before changing the address(es) of use identified in the application or on the license, and before revising procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety. The information is necessary to determine the licensee's ability to control radiation dose to workers, patients, and the public; and for NRC to contact the licensee or conduct an inspection of the licensee's program. The information also is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely, and has the facilities and equipment necessary to ensure protection of public health and safety.

The burden for Section 35.13 is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

<u>§ 35.14 Notifications</u>

Paragraph 35.14(a) requires that licensees provide to the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by a licensee of broad scope, or the permit issued by an NRC master material license broad scope permitee 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 use byproduct material safely.

Paragraph 35.14(b) requires that licensees notify the NRC by letter no later than 30 days after an ANP, AU, AMP, or RSO permanently discontinues performance of duties under the license or has a name change; when the licensee's mailing address changes; when the licensee has a name change that is not a transfer of control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have added to or changed the areas of

use identified in the application or on the license. The report for AU and ANP is required in order to maintain the license file with a current record of individuals authorized to use or prepare byproduct 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 byproduct 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.

§ 35.19 Specific exemptions

Section 35.19 provides that upon application of any interested person or upon its own initiative, the Commission may grant exemptions from the regulations in Part 35 that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Applications for and granting of specific exemptions will allow NRC to make provision for special circumstances outside the purview of the regulations.

§ 35.24 Authority and responsibilities for the radiation protection program

Paragraph 35.24(a) requires a licensee's management to approve in writing (1) requests for license application, renewal, or amendment prior to submittal; (2) any individual, prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and (3) radiation protection program changes that do not require an amendment and are permitted under § 35.26. Management approval is necessary to ensure that actions affecting the radiation protection program have been reviewed by responsible licensee officials.

Paragraph 35.24(b) requires a licensee's management to appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The written agreement from the Radiation Safety Officer (including temporary Radiation Safety Officers) is needed to record the acceptance by the Radiation Safety Officer of all of the obligations of the post.

A licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer, and a licensee may simultaneously appoint more than one temporary Radiation Safety Officer. Paragraph 35.24(c) requires a licensee that appoints a temporary Radiation Safety Officer to notify the Commission in accordance with § 35.14(b). The report of temporary Radiation Safety Officers is required because a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer only for up to 60 days each year.

Paragraph 35.24(e) requires a licensee to establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer, 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) requires licensees who are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The requirement to establish a Radiation Safety Committee to oversee the radiation protection program provides 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(h) requires that a record of actions taken pursuant to paragraphs (a), (b) and (e) 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

Paragraph 35.26(a) allows a licensee to revise its radiation protection program without Commission approval if the revision does not require an amendment under § 35.13; the revision is in compliance with the regulations and the license; the revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and the affected individuals are instructed on the revised program before the changes are implemented. Review and approval by licensee management will allow a licensee to make some changes in their radiation safety program, provided that the changes are in compliance with the regulations and the license.

Paragraph 35.26(b) requires 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) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, Part 35 regulations, and license conditions with respect to the use of byproduct material. This instruction is necessary to provide high confidence that the supervised individual knows and follows all of these procedures, regulations, and license conditions.

Paragraph 35.27(b) requires 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(b)(2) to instruct the supervised individual in the preparation of byproduct material for medical use and require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, radiation protection procedures, Part 35 regulations, and license conditions. This instruction is necessary to provide high confidence that the supervised individual properly prepares byproduct material for medical use.

§ 35.40 Written directives

Paragraph 35.40(a) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage

of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration.

The regulatory text of § 35.40(b) requires:

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

If an oral directive is used because of the emergent nature of the patient's condition, subsection 35.40(a)(1) requires the information in the oral directive to be documented as soon as possible in writing in the patient's record and a written directive must be prepared within 48 hours of the oral directive. Documenting an oral directive is needed to ensure that complete record is made of the administration of byproduct material or radiation from byproduct material.
Paragraph 35.40(c) permits a written revision to an existing written directive if the revision is dated and signed by an authorized user before the administration or the next fractional dose. If an oral revision to an existing written directive is used because of the emergent nature of the patient's condition, the oral revision must be documented as soon as possible in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision. Documenting an oral directive is needed to ensure that complete record is made of the administration of byproduct material or radiation from byproduct material.

Paragraph 35.40(d) requires the licensee to retain a copy of the written directive in accordance with § 35.2040. A description of the record and the need for the record is provided under § 35.2040. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician.

<u>§ 35.41 Procedures for administrations requiring a written directive</u>

Paragraph 35.41(a) requires licensees to develop, implement and maintain written procedures for any administration requiring a written directive to 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.

Paragraph 35.41(c) requires the licensee to retain a copy of the procedures required by § 35.41(a) in accordance with § 35.2041. A description of the record and the need for the record is provided under § 35.2041.

§ 35.50 Training for Radiation Safety Officer

An authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license may be the Radiation Safety Officer (RSO) if he or she has experience with the radiation safety aspects of similar types of byproduct material for which the RSO has responsibilities. Otherwise, § 35.50 requires an RSO to be certified by a specialty board whose certification process satisfies the requirements of § 35.50(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the educational program specified in § 35.50(b)(1). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an RSO.

The certification information required by § 35.50(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies to be the RSO by completing the specified educational program, § 35.50(b)(2) requires the individual to obtain a written certification, signed by a preceptor Radiation Safety Officer, that the educational requirements in paragraph 35.50 (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer for a medical use licensee. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an RSO has met the necessary training and experience requirements in § 35.50.

The certification information required by § 35.50(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.51 Training for an authorized medical physicist

Section 35.51 requires the licensee to require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process includes all of the requirements of § 35.51(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the educational program specified in § 35.51(b)(1). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist.

The certification information required by § 35.51(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, § 35.51(b)(2) requires than an individual obtain a written certification, signed by a preceptor authorized medical physicist, that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist. This written certification is

necessary to ensure that an individual fulfilling the responsibilities of an authorized medical physicist has met the training and experience requirements in § 35.51(b)(1).

The certification information required by § 35.51(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.55 Training for an authorized nuclear pharmacist

Paragraph 35.55(a) requires the licensee to require the authorized nuclear pharmacist to be certified as a nuclear pharmacist by a specialty board whose certification process satisfies the requirements of § 35.55(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the educational program specified in § 35.55(b)(1). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

The certification information required by § 35.55(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, § 35.55(b)(2) requires the individual to obtain a written certification, signed by a preceptor authorized nuclear pharmacist, that the educational requirements in paragraph 35.55 (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized nuclear pharmacist has met the necessary training and experience requirements in § 35.55 (b).

The certification information required by § 35.55(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of byproduct material

Paragraph 35.60(c) requires licensees to retain a record of each instrument calibration 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 of survey instruments

Paragraph 35.61(a) requires 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 are calibrated and operational.

Paragraph 35.61(c) requires that licensees retain a record of each survey instrument calibration in accordance with § 35.2061. A description of the contents of the record and the need for the record is provided under § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use

Paragraph 35.63(a) requires licensees to determine and record the activity of each dosage before medical use. Paragraph 35.63(e) requires licensees to 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(b) requires licensees in possession of certain sealed sources to test the sources for leakage. Paragraph 35.67(d) requires licensees to retain a record of sealed source leak tests in accordance with § 35.2067(a). A description of the contents of the record and the need for the record is provided under § 35.2067(a).

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

Paragraph 35.67(g) requires licensees in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, to conduct a semi-annual physical inventory of all such sources in its possession and retain the inventory record in accordance with § 35.2067. A description of the contents and need for the record is provided under § 35.2067(b).

§ 35.69 Labeling of vials and syringes

Paragraph 35.69 requires that each syringe and vial that contains unsealed byproduct material must be labeled, and that each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. Labeling is needed because review of misadministration/medical event reports has indicated that in many cases misadministrations/medical events are caused by inadvertent transposition of syringes or by drawing a dosage from the wrong vial of byproduct material.

§ 35.70 Surveys for ambient radiation exposure rate

This section requires licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. Licensees are 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 unsealed byproduct material or implants containing byproduct material

Paragraph 35.75(b) requires licensees to provide an individual who has been administered unsealed byproduct material or implants containing byproduct 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 total effective dose equivalent to a nursing 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 as low as reasonably achievable (ALARA).

Paragraph 35.75(c) requires licensees to 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 records and a statement of need for the records is provided under § 35.2075.

Paragraph 35.75(d) requires licensees to 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)(1) requires 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 and delineates the authority and responsibility of the licensee and the client. This record is necessary to show that the client's management has permitted this work and to clearly delineate the authority and responsibilities of each entity.

Paragraph 35.80(a)(4) requires a mobile service licensee to survey all areas of use before leaving a client’s address to ensure compliance with the requirements of Part 20.

Paragraph 35.80(c) requires that the letter required in § 35.80(a)(1) and a record of the surveys required in § 35.80(a)(4) 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 (a) and (b).

§ 35.92 Decay-in-storage

Paragraph 35.92(b) requires licensees to 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.

§ 35.190 Training for uptake, dilution, and excretion studies

Section 35.190 requires the licensee to require the authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements of § 35.190(c) and whose certification has been recognized by the Commission or an Agreement State, or be an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements, or to have been certified as having completed the training and experience specified in § 35.190(c)(1). This requirement 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 certification information required by § 35.190(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, § 35.190(c)(2) requires the individual to obtain a written certification, signed by a preceptor authorized user,

that the individual has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under § 35.100. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user has met the training and experience requirements in § 35.190(c)(1).

The certification information required by § 35.190(c)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.204 Permissible molybdenum-99 concentration

Paragraph 35.204(c) requires that if licensees are required to measure the molybdenum-99 concentrations in eluates from a molybdenum-99/technetium-99m generator, the licensee shall 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 imaging and localization studies

Section 35.290 requires the licensee to require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who has been certified by a specialty board whose certification process satisfies the requirements of § 35.290 (c) and whose certification has been recognized by the Commission or an Agreement State, or be an authorized user under § 35.390 or equivalent Agreement State requirements, or to have been certified as having completed the training and experience specified in § 35.290(c)(1). This requirement is necessary to ensure that the physician has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for the uses authorized under § 35.200.

The certification information required by § 35.290(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, § 35.290(c)(2) requires the individual to obtain a written certification, signed by a preceptor authorized user, that the individual has successfully completed the requirements in § 35.290 (c)(1) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user has met the training and experience requirements in § 35.290.

The certification information required by § 35.290(c)(2) is submitted as part of a licensee's application, as required under §§ 35.12 and 35.13, and is cleared under OMB Clearance No. 3150-0120.

§ 35.310 Safety instruction

Paragraph 35.310(a) requires that licensees provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation

exposure to the public and workers, and (2) the actions to be taken in the event of death or medical emergency.

Paragraph 35.310(b) requires licensees to retain a record of individuals receiving instruction required by § 35.310(a) 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) requires that the licensee post the room of a patient or human research subject who cannot be released in accordance with § 35.75 with a "Radioactive Materials" sign. Paragraph 35.315(a)(3) requires a licensee to note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room. This posting and note are required so that employees and visitors receive information necessary for radiation safety.

Paragraph 35.315(b) requires that the licensee promptly notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient has a medical emergency or dies. This notification is required so that the Radiation Safety Officer, or his or her designee, or authorized user can take whatever actions are necessary for radiation safety.

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required

Section 35.390 requires licensees to require an authorized user of unsealed by product material for the uses authorized under § 35.300 to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the training and experience specified in § 35.390(b)(1). This requirement 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 which a written directive is required.

The certification information required by § 35.390(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, § 35.390(b)(2) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in § 35.390(b)(1) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300, as appropriate. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material for the medical uses authorized under § 35.300(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4) has met the training and experience requirements in § 35.390 (b)(1).

The certification information required by § 35.390(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.392 Training for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

Section 35.392 requires licensees to require an authorized user to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State, or be an authorized user under specified provisions of § 35.390 or equivalent Agreement State requirements, or to have been certified as having completed the training and work experience specified in § 35.392(c)(1) and (2). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

The certification information required by § 35.392(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and work experience, § 35.392(c)(3) requires the individual to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in § 35.392(c)(1) and (c)(2) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material using sodium iodide I-131 and has met the requirements in § 35.392 (c)(1) and (c)(2).

The certification information required by § 35.392(c)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)

Section 35.394 requires an individual to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State, or be an authorized user under specified provisions of § 35.390 or equivalent Agreement State requirements, or to have been certified as having completed the training and work experience specified in §§ 35.394(c)(1) and (2). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

The certification information required by § 35.394(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and work experience, § 35.394(c)(3) requires the individual to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in § 35.394(c)(1) and and (c)(2) and that the individual has achieved a level of competency

sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material using sodium iodide I-131 has met the training and experience requirements in § 35.394 (c)(1) and (c)(2).

The certification information required by § 35.394(c)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.404 Surveys after source implant and removal

Paragraph 35.404(c) requires that, in accordance with § 35.2404, licensees retain a record of surveys to locate and account for all sources that have not been implanted and, after implant removal, to confirm that all sources have been removed. These surveys are required by §§ 35.404(a) and (b). A description of the contents of the record and the need for the record is provided under § 35.2404.

§ 35.406 Brachytherapy sources accountability

Paragraph 35.406(c) requires 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(a) requires licensees to provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released in accordance with § 35.75. This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation exposure to the public and workers and (2) the actions to be taken in the event of death or medical emergency.

Paragraph 35.410(b) requires 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) requires that the licensee post the patient's or human research subject’s room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject’s chart where and how long visitors may stay in the room. This posting provides notice to control radiation exposures to hospital workers and the public.

Paragraph 35.415(c) requires that the licensee notify the Radiation Safety Officer, or his or her designee, and authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the Radiation Safety Officer, or his or her designee, or authorized user can take whatever actions are necessary for radiation safety.

§ 35.432 Calibration measurements of brachytherapy sources

Paragraph 35.432(d) requires licensees to retain a record of calibration measurements made on brachytherapy sealed sources in accordance with § 35.2432. A description of the contents of the record and the need for the record is provided under § 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments

Paragraph 35.433 (b) requires licensees to retain a record of the activity of each strontium-90 source used for opthalmic treatment in accordance with § 35.2433. A description of the contents of the record and the need for the record is provided under § 35.2433.

§ 35.490 Training for use of manual brachytherapy sources

Section 35.490 requires 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 medical specialty board whose certification process includes all the requirements of § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the educational program specified in § 35.490(b)(1). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.400.

The certification information required by § 35.490(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, § 35.490(b)(3) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.490(b)(1) and (2) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user of brachytherapy sources has met the training and experience requirements in § 35.490.

The certification information required by § 35.490(b)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.491 Training for ophthalmic use of strontium-90

If an individual qualifies to be an authorized user of strontium-90 for ophthalmic radiotherapy by completing the training program specified in § 35.491(b)(1) and (2), § 35.491(b)(3) requires the individual to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.491(a) and (b) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user of strontium-90 for ophthalmic use has met the training and experience requirements in § 35.491(b)(1) and (2).

The certification information required by § 35.491(b)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.590 Training for use of sealed sources for diagnosis

Section 35.590 requires 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 medical specialty board whose certification process satisfies the requirements of § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State, or to have completed the training program specified in § 35.590(b). This requirement 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 certification information required by § 35.590(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, the information required by § 35.590(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit

Paragraph 35.604(a) requires licensees who use sealed sources in remote afterloader units, before releasing a patient or human research subject from licensee control, to make a survey of the patient or human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. Paragraph 35.604 (b) requires the licensee to retain a record of the survey required by paragraph 35.604(a) 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, adjustment, and repair

Paragraph 35.605(d) requires licensees to retain a record of each installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units 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 afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Paragraph 35.610(a)(4) requires licensees to develop, implement, and maintain written procedures for responding to an abnormal situation. These procedures are necessary because of the complexity and higher radiation risk associated with therapeutic treatment devices.

Paragraph 35.610(b) requires 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) requires licensees to post instructions for individuals who operate the devices at the device console providing the location 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(d) requires licensees to provide initial instruction and annual refresher instruction to all individuals who operate the unit in the procedures identified in § 35.610(a) and the operating procedures for the unit. The initial instruction and refresher instruction are necessary due to the complexity of therapeutic treatment devices.

Paragraph 35.610(e) requires licensees to ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. The drills are necessary because of the complexity and higher radiation risk associated with therapeutic treatment devices.

Paragraph 35.610(f) requires licensees to make a record of initial instruction and refresher training for individuals who operate the units and to 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.

Paragraph 35.610(g) requires licensees to retain a copy of the procedures required by § 35.610(a)(4) and (d)(2) in accordance with § 35.2610. A description of the need for the record is provided under § 35.2610.

<u>§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</u>

Paragraph 35.615(f)(4) requires a licensee to notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the Radiation Safety Officer, or his/her designee, or authorized user can take whatever actions are necessary for radiation safety.

<u>§ 35.630 Dosimetry equipment</u>

Paragraph 35.630(c) requires licensees to retain a record of each calibration, intercomparison, and comparison of 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.

<u>§ 35.632 Full calibration measurements on teletherapy units</u>

Paragraph 35.632(g) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under § 35.2632.

<u>§ 35.633 Full calibration measurements on remote afterloader units</u>

Paragraph 35.633(i) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under §35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units

Paragraph 35.635(g) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units

Paragraph 35.642(b) requires licensees to perform spot check measurements in accordance with written procedures established by the authorized medical physicist. Written procedures are necessary to ensure that the spot-checks are performed correctly and consistently.

Paragraph 35.642(c) requires that the authorized medical physicist review the results of each spot-check and notify the licensee in writing of the results of each spot check. The written notification is needed to ensure that the licensee is aware of the results of each spot-check and aware of the performance of the unit, so that patients are not administered incorrect doses.

Paragraph 35.642(f) requires licensees to retain a record of each spot-check required by § 35.642(a) and (d), and a copy of the spot-check procedures required by § 35.642(b), in accordance with § 35.2642. A description of the contents of these records and the need for the records is provided under § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units

Paragraph 35.643(b) requires licensees to perform spot check measurements in accordance with written procedures established by the authorized medical physicist. Written procedures are necessary to ensure that the spot-checks are performed correctly and consistently.

Paragraph 35.643(c) requires licensees to have the authorized medical physicist review the results of each spot-check required by paragraph (a) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check. The written notification is needed to ensure that the licensee is aware of the results of each spot-check and aware of the performance of the unit, so that patients are not administered incorrect doses.

Paragraph 35.643(f) requires licensees to retain a record of each spot-check required by § 35.643(d), and a copy of the spot-check procedures required by § 35.643(b), in accordance with § 35.2643. A description of the contents of these records and the need for the records is provided under § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units

Paragraph 35.645(b)(1) requires licensees to perform spot-check measurements in accordance with written procedures established by the authorized medical physicist. 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. Written procedures are necessary to ensure that spot-checks are performed correctly and consistently.

Paragraph 35.645(b)(2) requires licensees to have the authorized medical physicist review the results of each spot-check of a gamma stereotactic radiosurgery unit within fifteen days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check. The written notification is needed to ensure that the licensee is aware of the results of

each spot-check and aware of the performance of the unit, so that patients are not administered incorrect doses.

Paragraph 35.645(g) requires licensees to retain a record of each spot-check required by § 35.645(c) and (d), and a copy of the spot-check procedures required by § 35.645(b), in accordance with § 35.2645. A description of the contents of these records and the need for the records is provided under § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloaders

Paragraph 35.647(e) requires licensees to retain a record of each check of mobile remote afterloaders before use at each address of use, as required by § 35.647(b), in accordance with § 35.2547. 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(a) requires licensees to make radiation surveys to ensure that radiation levels do not exceed levels stated in the Sealed Source and Device Registry. Paragraph § 35.652(c) requires licensees 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) requires 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 remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Section 35.690 requires an individual to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.690(b) and whose certification has been recognized by the Commission or an Agreement State, or to have been certified as having completed the educational program and supervised clinical experience specified in § 35.690(b)(1) and (2). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The certification information is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If an individual qualifies by completing the specified educational program and supervised clinical experience, § 35.690(b)(3) requires the individual to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.690(b)(1) and (2) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an

authorized user of therapeutic medical unit(s) has met the training and experience requirements in § 35.690.

The certification information required by § 35.690(b)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.900 Radiation Safety Officer

An authorized user, identified on the licensee's license may be the Radiation Safety Officer (RSO). Otherwise, § 35.900 requires an individual fulfilling the responsibilities of the RSO to be certified by a specialty board whose certification is listed in § 35.900(a), or to have completed the educational program specified in § 35.900(b). This requirement is necessary to ensure that the individual has the training and experience to be an RSO.

The certification information required by § 35.900(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, the information required by § 35.900(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.910 Training for uptake, dilution, and excretion studies

Section 35.910 requires the licensee to require the authorized user of a radiopharmaceuticals in § 35.100(a) to be a physician who is certified by a medical specialty board whose certification is listed in § 35.910(a) or to have completed the training and experience specified in § 35.910(b) or (c). This requirement is necessary to ensure that the individual has the training and experience to be an authorized user for uptake, dilution, and excretion studies.

The certification information required by § 35.910(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, the certification information required by § 35.910(b) or (c) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.920 Training for imaging and localization studies

Section 35.920 requires the licensee to require an authorized user of a radiopharmaceutical, generator, or reagent kit in §35.200(a) to be a physician who has been certified by a specialty board whose certification is listed in § 35.920(a), or to have completed the training and experience specified in § 35.920(b) or (c). This requirement is necessary to ensure that the physician has the training and experience to be an authorized user for the uses authorized under § 35.200.

The certification information required by § 35.920(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, the information required by § 35.920(b) or (c) is submitted as part of a licensee's application, as required under §§ 35.12 and 35.13, and is cleared under OMB Clearance No. 3150-0120.

§ 35.930 Training for Therapeutic use of unsealed byproduct material

Section 35.930 requires licensees to require an authorized user of radiopharmaceuticals in § 35.300 to be a physician certified by a medical specialty board whose certification is listed in § 35.930(a) or to have completed the training and experience specified in § 35.930(b). This requirement is necessary to ensure that the individual has training and experience to be an authorized user of radiopharmacuticals as listed in § 35.300.

The certification information required by § 35.930(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified training and experience, the information required by § 35.930(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.932 Training for Treatment of Hyperthyroidism

Section 35.932 requires licensees to require an authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who satisfies the requirements of § 35.932(a) and (b). This requirement is necessary to ensure that the individual has the training and experience to be an authorized user for the I-131 treatment of hyperthyroidsm.

The information required by § 35.932(a) and (b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.934 Training for the Treatment of Thyroid Carcinoma

Section 35.934 requires an authorized user of only Iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who satisfies the training and work experience of § 35.934(a) and (b). This requirement is necessary to ensure that the individual has the training and work experience for the sodium iodide I-131 treatment of thyroid carcinoma.

The information required by § 35.934(a) and (b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.940 Training for use of brachytherapy sources

Section 35.940 requires licensees to require the authorized user of a brachytherapy source listed in § 35.400 to be a physician certified by a medical specialty board whose certification is listed in § 35.940(a), or has completed the educational program specified in § 35.940(b). This requirement is necessary to ensure that the individual has sufficient training and experience to be an authorized user for the medical uses authorized under § 35.400.

The certification information required by § 35.940(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, the certification information required by § 35.940(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.941 Training for ophthalmic use of strontium-90

Section 35.941 requires the licensee to require the physician authorized only for strontium-90 ophthalmic radiotherapy to have an active practice of therapeutic radiology or ophthalmology and meet the training and work experience specified in § 35.941(a) and (b). This requirement is necessary to ensure that an individual has sufficient training and experience to be an authorized user of strontium-90 for ophthalmic use.

The information required by § 35.941(a) and (b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.950 Training for use of sealed sources for diagnosis

Section 35.950 requires the licensee to require the authorized user of sealed sources in a device listed in § 35.500 to be a physician, dentist, or podiatrist who has been certified by a medical specialty board whose certification is listed in § 35.950(a), or have completed the training program specified in § 35.950(b). This requirement is necessary to ensure that the individual has training and experience to be an authorized user of sealed sources for diagnosis.

The certification information is submitted as part of a licensee's application required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, the information required by § 35.950(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.960 Training for use of therapeutic medical devices

Section 35.960 requires the authorized user of a sealed source listed § 35.600 to be a physician who is certified by a medical specialty board whose certification is listed in § 35.960(a) or has completed the educational program and supervised clinical experience specified in § 35.960(b). This requirement is necessary to ensure that the individual has the training and experience to be an authorized user for therapeutic medical devices.

The certification information is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If an individual qualifies by completing the specified educational program and supervised clinical experience, the information required by § 35.960(b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.961 Training for an authorized medical physicist

Section 35.961 requires the licensee to require the authorized medical physicist to be an individual who is certified by a specialty board whose certification is listed in § 35.961(a) and (b) or to have completed the educational program specified in § 35.961(c). This requirement is necessary to ensure that the individual has achieved a level of training and experience to be an authorized medical physicist.

The certification information required by § 35.961(a) and (b) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, the information required by § 35.961(c) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.980 Training for an authorized nuclear pharmacist

Paragraph 35.980(a) requires the licensee to require the authorized nuclear pharmacist to be a pharmacists certified as a nuclear pharmacist by a specialty board whose certification is listed in § 35.980(a), or to have completed the educational program specified in § 35.980(b)(1). This requirement is necessary to ensure that the individual has the training and experience to be an authorized nuclear pharmacist.

The certification information required by § 35.980(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

If the individual qualifies by completing the specified educational program, § 35.980(b)(2) requires the individual to obtain a written certification, signed by a preceptor authorized nuclear pharmacist, that the educational requirements in paragraph 35.980(b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized nuclear pharmacist has met the necessary training and experience requirements in § 35.980(b).

The certification information required by § 35.980(b) (2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material

Paragraph 35.1000(a) provides that a licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35 if the applicant or licensee has submitted the information required by § 35.12(b) through (d) and has received written approval from the Commission.

The burden for Paragraphs 35.12 (b) through (d) is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

§ 35.2024 Records of authority and responsibilities for radiation protection programs

Paragraph 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management 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 establish a written record of these actions and the basis for them because it is important to document the licensee's management review and approval of licensing actions and changes to the radiation protection program.

Paragraph 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 34.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management. These records are 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 protection program changes

This section requires licensees to retain a record of each radiation protection program change made in accordance with § 35.26(a) for five years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the 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 requires licensees to retain a copy of each written directive as required by § 35.40 for three years. 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 of administrations during an NRC inspection.

§ 35.2041 Records for procedures for administrations requiring a written directive

This section requires licensees to retain a copy of the procedures for administrations requiring a written directive, required by § 35.41, for the duration of the license. Retention of these procedures for the duration of the license will allow NRC to investigate events where an administered dose or dosage was not in accordance with the written directive.

§ 35.2060 Records of calibrations of instruments to measure the activity of unsealed byproduct material

This section requires licensees to maintain a record of instrument calibrations required by § 35.60 for three years. The records must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual

who performed the calibration. The records of the calibrations required in § 35.60 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 requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for three years. The record must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual who performed the calibration. This survey instrument calibration record 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 requires licensees to maintain a record of dosage determinations required by § 35.63 for three years. The record must contain: the radiopharmaceutical; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); the date and time of the dosage determination; and the name of the individual who determined the dosage. This record is required to demonstrate that the prescribed dosage was obtained for administration to the patient or human research subject.

§ 35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources

Paragraph 35.2067(a) requires licensees to retain records of leak tests required by § 35.67(b) for three years. The records must include the model number and serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; 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) requires 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 by radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory. This inventory record is needed to show that all sealed sources are accounted for.

§ 35.2070 Records of surveys for ambient radiation exposure rate

This section requires a licensee to retain a record of each survey required by § 35.70 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, 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 unsealed byproduct material or implants containing byproduct material

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

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

Paragraph 35.2075(c) requires licensees to retain the records required by paragraphs (a) and (b) of this section for three years after the date of release of the individual. 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.

§ 35.2080 Records of mobile medical services

Paragraph 35.2080(a) requires licensees providing mobile medical services to retain a copy of each letter that permits the use of byproduct material at a client’s address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service. These records are necessary to show that the licensees had permission to use byproduct material at the client's address of use and to document the authority and responsibility of the licensee and the client.

Paragraph 35.2080(b) requires licensees to maintain a record of each survey required by § 35.80(a)(4) for three years. The record must include the date of the survey, the results of the survey, 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 to ensure compliance with the radiation protection requirements of 10 CFR Part 20.

§ 35.2092 Records of decay-in-storage

This section requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for three years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey. These records are needed to show that the radioactivity of the materials that are disposed of as ordinary waste cannot be distinguished from background radiation levels, and that a proper survey was made at the surface of the byproduct material prior to disposal.

§ 35.2204 Records of molybdenum-99 concentrations

This section requires licensees to maintain 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 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or 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 safety instruction

This section requires licensees to maintain records of safety instructions training required by §§ 35.310, 35.410, and 35.610 for three years. The record must include a list of the topics covered, the date of instruction, the name(s) of the attendee(s), 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 and emergency procedures to be used in caring for patients and human research subjects treated with byproduct material or radiation therefrom.

§ 35.2404 Records of surveys after source implant and removal

This section requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for three years. Each record must include the date and results of the survey, 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 accountability

This section requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for three years. For temporary implants, the record must include: the number and activity of sources removed from and returned to storage; the time and dates they were removed from and returned to storage, the name of the individual(s) who removed them from and returned them to storage, and the location of use. For permanent implants, the record must include: the number and activity of sources removed from storage, the dates they were removed from storage, and the name of the individual who removed them from storage; the number and activity of sources not implanted, the date they were returned to storage, and 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 to show that no brachytherapy source is misplaced or missing.

§ 35.2432 Records of calibration measurements of brachytherapy sources

This section requires licensees to maintain a record of calibrations of 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 the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments

This section requires licensees to maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source. The record must include: the initial activity of the source and date; and for each decay calculation, the date and source activity as determined under § 35.433. These records are needed to document that the activity of the strontium-90 sources have been calculated accurately to ensure that adequate radiation safety is maintained.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

This section requires licensees to retain records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for three years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) 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.

§ 35.2610 Records of safety procedures

This section requires licensees to maintain records of procedures required by § 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit. These procedures are needed for as long as the licensee possesses the unit because they are essential to safe operations. These records are needed to show that individuals are aware of the operating procedures for the unit and the safety procedures to be used to respond to abnormal and emergency situations.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

This section requires licensees to 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 manufacturer’s name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630; the correction factor that was determined from the calibration 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, remote afterloader, and gamma stereotactic radiosurgery full calibrations

This section requires licensees to maintain records of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for three years. The record must include: the date of the calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to

calibrate the unit(s); the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; 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, remote afterloader unit, or gamma stereotactic radiosurgery unit.

§ 35.2642 Records of periodic spot-checks for teletherapy units

Paragraph 35.2642(a) requires licensees to 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 of the teletherapy unit, source, and 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 and 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 name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is needed to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

Paragraph 35.2642(c) requires licensees to retain a copy of the written procedures for periodic spot-checks for teletherapy units established by the authorized medical physicist. The procedures must be retained until the licensee no longer possesses the teletherapy unit. This record is necessary to ensure that the procedures remain available for reference by the licensee and the NRC.

§ 35.2643 Records of periodic spot-checks for remote afterloader units

Paragraph 35.2643(a) requires licensees to retain records of each spot-check for remote afterloader units required by §§ 35.643 for three years. The record must include, as applicable: the date of the spot-check; the manufacturer's name, model number, and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

Paragraph 35.2643(c) requires licensees to retain a copy of the written procedures for periodic spot-checks for remote afterloader units established by the authorized medical physicist. The procedures must be retained until the licensee no longer possesses the remote afterloader unit. This record is necessary to ensure that the procedures remain available for reference by the licensee and the NRC.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units

Paragraph 35.2645(a) requires licensees to 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 and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of 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, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

Paragraph 35.2645(c) requires licensees to retain a copy of the written procedures for periodic spot-checks for gamma stereotactic radiosurgery units established by the authorized medical physicist. The procedures must be retained until the licensee no longer possesses the gamma stereotactic radiosurgery unit. This record is necessary to ensure that the procedures remain available for reference by the licensee and the NRC.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units

This section requires licensees to retain records of each check for mobile remote afterloader units 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 of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes and transfer tube applicator interfaces, 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 and related safety equipment are operating correctly.

§ 35.2652 Records of surveys of therapeutic treatment units

This section requires licensees to maintain 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; 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 person who performed the test. 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 requires licensees to maintain a record 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 radioactive materials license number; the date of inspection; the manufacturer's name and model number and serial number of both the treatment unit and source; a list of components inspected and 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 and notification of a medical event

Paragraph 35.3045(a) requires licensees to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose meeting or exceeding specified criteria. The burden associated with this paragraph is addressed under paragraphs (c) and (d) of this section.

Paragraph 35.3045(b) requires licensees to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. The burden associated with this paragraph is addressed under paragraphs (c) and (d) of this section.

Paragraph 35.3045(c) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of the medical event. This reporting requirement is needed to ensure that NRC is aware of medical events and is able promptly to take any necessary actions based on the circumstances.

Paragraph 35.3045(d) requires 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, if any, on the individual(s) who received the administration; what actions, if any, have been taken or are planned to prevent recurrence; certification that the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not. 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(e) requires the licensee to notify the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian, 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. If verbal notification is made, the licensee is required to inform the individual, or responsible relative or guardian, that a written description of the event or may be obtained upon request. The licensee shall provide such a written description, if requested.

Paragraph 35.3045(g) requires the licensee to: (1) annotate a copy of the medical event report provided to the NRC with the: (a) name of the individual who is the subject of the event; and (b) social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and (2) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event. It is necessary to annotate the report to the NRC because the report has no identifying information

regarding the patient. It is necessary to send a copy of the annotated report to the referring physician because the referring physician is responsible for the medical care of the patient and this information is needed for the physician to care for the patient.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child

Paragraph 35.3047(a) requires the licensee to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is the result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. 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 to Congress of unintended radiation exposure.

Paragraph 35.3047(b) requires the licensee to report any dose to a nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician, that is a result of an administration of byproduct material to a breast-feeding individual. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. 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 to Congress reports of unintended radiation exposure.

Paragraph 35.3047(c) requires the licensee to notify by telephone the NRC Operation Center no later than the next calendar day 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) requires the licensee to submit a written report to the appropriate NRC Regional Office no later than 15 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, if any, on the embryo/fetus or the nursing child; what actions, if any, have been taken or are planned to prevent recurrence; and certification that the licensee notified the pregnant individual or mother (or the mother’s or child’s responsible relative or guardian, and if not, why not. The report must not contain the individual's or child’s name or any other information that could lead to identification of the individual or child. 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.

Paragraph 35.3047(e) requires the licensee to notify the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If the referring physician or mother cannot be reached within 24 hours, the licensee is required to make the appropriate notifications as soon as possible thereafter. To meet the requirements of this paragraph, the notification may be made to the mother’s or child’s responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee

shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such written description if requested. This reporting requirement is needed to provide information about the event to the referring physician and the pregnant individual or mother, or the mother's or child's responsible relative or guardian, for appropriate medical care, if needed.

Paragraph 35.3047(f) requires the licensee to: (1) annotate a copy of the report provided to the NRC with the: (a) name of the pregnant individual or the nursing child who is the subject of the event; and (b) social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and (2) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3067 Report of a leaking source

This section requires licensees to report detection of a leaking source by submitting a written report within 5 days after a leakage test required by § 35.67 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 with a copy to the NRC Headquarters Office. The report must include the model and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test, the date of the test, and the action taken. This report is needed to ensure that the NRC is aware of the leaking source and is able promptly to take any necessary actions based on the circumstances.

§ 35.50 Training for Radiation Safety Officer,
§ 35.51 Training for an authorized medical physicist,
§ 35.55 Training for an authorized nuclear pharmacist,
§ 35.190 Training for uptake, dilution, and excretion studies,
§ 35.290 Training for imaging and localization studies,
§ 35.390 Training for use of unsealed byproduct material for which a written directive is required,
§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries),
§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries),
§ 35.490 Training for use of manual brachytherapy sources,
§ 35.491 Training for ophthalmic use of strontium-90,
§ 35.590 Training fo use of sealed sources for diagnosis, and
§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Each of these sections implicitly requires a medical specialty certifying board or similar organization providing training to prepare and submit a letter demonstrating to NRC that the board's certification process includes all of the requirements for training and experience specified for an authorized user for the medical use of byproduct material addressed in that section. Based on the contents of the letter, NRC will or will not recognize the certification process of that medical board. A licensee may, under these sections, require an authorized user under the particular section to be an individual certified by a medical board whose certification process has been recognized by NRC (or an Agreement State). Medical certification boards are expected in many, but not necessarily all, cases to seek recognition under more than one of these sections by means of the same letter. This is expected to be a

one-time submission. The reporting requirements for this one-time submission are estimated in Item 14. below. This submission is necessary to ensure that NRC can ascertain that an individual certified by a particular medical specialty certifying board for a particular medical use of byproduct material has achieved a level of competency sufficient to function independently as an authorized user.

2. Agency Use of Information

The NRC uses the records and reports required in this part to ascertain that licensees' medical use programs are adequate to protect public health and minimize danger to life and property and that licensees' personnel are aware of and follow up on the information and steps needed to perform licensed activities in a safe manner. The staff makes use of the records and reports to determine whether the licensee has individuals with adequate training and experience to safely use byproduct material or radiation from byproduct material to be administered to patients or human research subjects, 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 Congress and 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 are required to ensure that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or to alert other medical use licensees, to prevent similar events that may have generic implications. In addition, collection of this information enables the NRC to ascertain whether such events are evaluated by the licensee, reported to patients or human research subjects, and referring physicians, and that corrective action is taken.

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 provides 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 for medical use 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 byproduct material are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures while maintaining the required level of safety.

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 not be in a position to assess whether this category of licensee is operating within the specific radiation safety requirements applicable to the medical use, possession, or transfer of byproduct material for medical use. In addition, NRC will not be able to report to Congress and evaluate those medical events constituting "abnormal occurrences" or to ensure that patients, human research subjects, and referring physicians are informed of "medical events."

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

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to OMB's implementing regulation at 5 CFR 1320.5(d), some of the provisions in the revision of Part 35 require licensees to maintain records for more than three years or to report information to the NRC or to patients' physicians within less than 30 days following an occurrence.

Paragraph 35.67(e)(2) requires that, in accordance with § 35.3067, a licensee file a report within five days if a leakage test 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 and to promptly notify other licensees if it appears there may be a generic problem. NRC allows the licensee up to five days to submit the report so that the licensee can review and analyze the leak test result.

Paragraph 35.642(c) requires that an authorized medical physicist review the results of each spot-check of a teletherapy unit and notify the licensee as soon as possible in writing of the results of each spot-check. The purpose of this requirement is to ensure that the authorized medical physicist is aware of any problems noted during the spot-check and that the licensee is aware of the performance of the unit so that patients are not administered incorrect doses.

Paragraph 35.643(c) requires that an authorized medical physicist review the results of each spot-check of a remote afterloader unit and notify the licensee as soon as possible in writing of the results of each spot-check. The purpose of this requirement is to ensure that the authorized medical physicist is aware of any problems noted during the spot-check and that the licensee is aware of the performance of the unit so that patients are not administered incorrect doses.

Paragraph 35.645(b)(2) requires licensees to have the authorized medical physicist review the results of each spot-check of a gamma stereotactic radiosurgery unit within fifteen days of each spot-check and to notify the licensee as soon as possible in writing of the results of each spot

check. The purpose of this requirement is to ensure that the authorized medical physicist is aware of any problems noted during the spot check and that the licensee is aware of the performance of the unit so that patients are not administered incorrect doses.

Paragraph 35.2024(a) requires that a record of actions taken by licensee's management in accordance with § 35.24(a) be retained for five years to allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Paragraph 35.2024(b) requires that a copy of both the authority, duties, and responsibilities of the Radiation Safety Officer (RSO), and the RSO's signed agreement to such responsibilities, in accordance with § 35.24(e), be maintained by the licensee for the duration of the license. The purpose of this requirement is to ensure that they remain available for reference and to allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2026 requires that a record of radiation safety program changes in accordance with § 35.26 be retained for five years to allow the NRC to evaluate the nature and appropriateness of such changes during inspections.

Section 35.2041 requires that a copy of the procedures for administrations requiring a written directive, required by § 35.41, be retained for the duration of the license. Retention of these procedures for the duration of the license will allow NRC to investigate medical events where an administered dose or dosage was not in accordance with the written directive.

Section 35.2433 requires that records of the calculated activity of a strontium-90 source in accordance with § 35.433 be retained for the life of the source to ensure that they remain available for reference by the licensee and the NRC and to show throughout the life of the source that its activity was properly calculated.

Section 35.2610 requires that operating procedures and procedures for responding to abnormal situations, required by § 35.610(a)(4) and (d)(2), be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit to ensure that these procedures remain available for reference by the licensee and the NRC. These procedures are needed for as long as the licensee possesses the unit because they are essential to safe operations.

Section 35.2630 requires that a record of each calibration, intercomparison, and comparison of dosimetry equipment done in accordance with § 35.630 be retained for the duration of the license to show throughout the period of use of the equipment that calibrations of medical devices were made with properly calibrated equipment.

Paragraph 35.2642(c) requires that a copy of the written procedures for periodic spot-checks for teletherapy units established by the authorized medical physicist be retained until the licensee no longer possesses the teletherapy unit to ensure that the procedures remain available for reference by the licensee and the NRC.

Paragraph 35.2643(c) requires that a copy of the written procedures for periodic spot-checks for remote afterloader units established by the authorized medical physicist be retained until the licensee no longer possesses the remote afterloader unit to ensure that the procedures remain available for reference by the licensee and the NRC.

Paragraph 35.2645(c) requires that a copy of the written procedures for periodic spot-checks for gamma stereotactic radiosurgery units established by the authorized medical physicist be retained until the licensee no longer possesses the gamma stereotactic radiosurgery unit to ensure that the procedures remain available for reference by the licensee and the NRC.

Section 35.2652 requires that a record of radiation surveys of treatment units made in accordance with § 35.652 be retained for the duration 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. These records also would be necessary in reconstructing the contributing factors following an incident involving the unit.

Section 35.2655 requires that a record of five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 be retained 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.

Paragraph 35.3045(d) requires that licensees submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 calendar days after discovery of a medical event. This requirement balances the time required for the licensee to evaluate the event and prepare a written report against the needs of the NRC to take timely action, as necessary, to address the medical event.

Paragraph 35.3045(e) requires that if an individual affected by a medical event has been notified verbally about the medical event, the licensee must furnish a written report of the medical event to the individual upon request. This requirement ensures that complete written information will be furnished to an individual upon request so that adequate follow-up medical care can be provided, if needed.

Paragraph 35.3045(g) requires a licensee to provide a copy of the annotated medical event report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event. This requirement balances the time required for the licensee to evaluate the event and prepare a written report against the needs of the referring physician to provide timely follow-up medical care, if needed.

Paragraph 35.3047(e) requires the licensee to provide notification of the event to the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of § 35.3047, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. This requirement ensures that verbal notice is supplied promptly to the referring physician and the pregnant individual or mother so that adequate follow-up medical care can be provided, if necessary.

Paragraph 35.3047(f) requires a licensee to provide a copy of the annotated event report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event. This requirement balances the time required for the licensee to evaluate the event and prepare a written report against the needs of the referring physician to provide timely follow-up medical care.

Section 35.3067 requires 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 and to promptly notify other licensees if it appears there may be a generic problem. NRC allows the licensee up to five days to submit the report so that the licensee can review and analyze the leak test result.

8. Consultations Outside the Agency

OMB Terms of Clearance

In the September, 18, 2001, Notice of Office of Management and Budget Action approving the revision of an information collection received on March 14, 2001 for 10 CFR Part 35, “Medical Use of Byproduct Material,” OMB directed NRC to ensure that each of the recordkeeping and reporting requirements contained in 10 CFR 35 have practical utility, that requirements for recordkeeping and reporting are the least burdensome necessary, and that the reporting threshold for a "medical event" ensures that all such reports have practical utility.

PRACTICAL UTILITY

When determining that each of the recordkeeping and reporting requirements contained in 10 CFR 35 have practical utility, NRC was asked to consider any new information regarding: a) the risks posed by the medical use of reactor byproduct materials, b) the burden imposed by the information collection requirements, and c) the costs and efficacy of alternative strategies for assuring safe use of these materials--including reliance on existing professional standards and State and Federal medical and pharmaceutical laws. These points were discussed in depth in the April 24, 2002 publication of the final rule for 10 CFR Part 35 (67 FR 20252-20259).

NRC’s regulations are risk-informed and performance-based but not risk-based. The new 10 CFR Part 35, which became effective October 24, 2002, significantly reduced the recordkeeping and reporting requirements, as well as the burden imposed by information collection requirements for the two lowest risk medical uses. These medical uses are described in 10 CFR Subpart D, “Unsealed byproduct material - written directive not required,” and 10 CFR Subpart G, “Sealed sources for diagnosis.”

When the NRC promulgated the new Part 35, it reviewed each recordkeeping and reporting requirement and considered the risks posed by the medical use of reactor byproduct materials and the burden imposed by the information collection requirements to assure the practical utility of the information collected. The NRC reviewed the information collection burden contained in the rule again when it prepared and filed its February 11, 2002,"Report to Congress Regarding the Revised 10 CFR Part 35” (attached). As the NRC made clear in its Report and specifically stated in the section entitled "Executive Summary," the burden for low risk uses was reduced to the minimum and regulatory requirements were retained only where such requirements are necessary to assure radiation safety for workers and the public, including patients and human research subjects and to meet NRC’s statutory responsibilities. See Report, pages 11 through 15. NRC recognizes that although physicians have primary responsibility for the protection of their patients, NRC has a necessary role and is required by statute to maintain the radiation safety of workers and the public, including patients.

10 CFR Part 35 requirements are, for the most part, performance-based and state the objective to be achieved. This permits the licensee to select from various nationally recognized standards and existing professional standards to meet these objectives in lieu of past prescriptive requirements. Professional standards do not exist for all medical uses in 10 CFR Part 35, such as emerging technologies and some of the diagnostic uses of sealed sources. At this time, State and Federal medical and pharmaceutical laws do not address the radiation safety provisions in the medical use of byproduct material that are subject to the 10 CFR Part 35 information collection requirements. NRC has received no new information or public comments since its Report to Congress on the risks posed by the medical use of reactor byproduct materials, the burden imposed by the information collection requirements, or costs and efficacy of alternative strategies for assuring safe use of these materials.

RECORDKEEPING AND REPORTING BURDEN.

When determining that the requirements for recordkeeping and reporting are the least burdensome necessary, NRC was asked to consider whether (a) alternatives, including the use of a third-party accrediting organization, would achieve the same purpose in a less burdensome way, (b) records and reports related to the radiation safety program and its management would be sufficient to ensure safety without requiring retention of program records and written procedures, and (c) the retention period for records can be shortened without damaging the NRC's ability to fulfill its purpose in these regulations. These points were discussed in the April 24, 2002 publication of the final rule for 10 CFR Part 35 (67 FR 20258-20259 and 20322-20330).

Although there are a number of third-party accrediting organizations, such as the Joint Committee on the Accreditation of Healthcare Organizations (JCAHO), that on a voluntary basis review some health care organizations and programs, no single third party organization or aggregate of organizations accredit all the types of medical use licensees or types of medical uses NRC regulates. Further, the focus of these organizations is currently on practice of medicine issues and evaluations that NRC does not regulate. At this time, NRC requirements provide the most uniform approach to maintaining radiation safety for workers, patients, and the public and thus, are the least burdensome for licensees.

NRC's use of information in the required records and reports is discussed in Item 2, "Agency use of information," in NRC's supporting statement for OMB clearance. The procedures used by a licensee to take radiation measurements, to monitor radiation safety aspects of patient treatment, and to make radiation safety decisions are an integral part of the records and reports associated with radiation safety programs. It is necessary to retain program records and written procedures to interpret the records and reports when evaluating the licensee's performance and reconstructing past activities. These documents are also invaluable for ensuring safety when there is turnover of individuals key to the licensee's radiation safety program. 10 CFR Part 35 no longer requires most procedures to be submitted to NRC. This was done in an effort to reduce the regulatory burden and provide greater flexibility for licensees to revise their programs.

When Part 35 was revised, the retention period of each record was evaluated to determine whether it needed to be kept for the life of the license, the period the licensee possesses a therapy device, or a shorter period. As a result of this evaluation, the

shortest possible retention times were used. A three-year retention period is needed for records because of NRC's three-year inspection frequency for most medical licensees. Justification for retention of records for more than three years is discussed in greater detail in item 7 of NRC's supporting statement, "Circumstances which justify variation from OMB guidelines."

REPORTING THRESHOLD FOR "MEDICAL EVENT"

When determining that the reporting threshold for a "medical event" ensures the reports have practical utility, NRC was asked to examine any new information regarding the risks posed by variation from the prescribed doses and examine whether a different threshold would better satisfy the requirements for practical utility and are the least burdensome. These points were discussed in the April 24, 2002 publication of the final rule for 10 CFR Part 35 (67 FR 20329-20331).

NRC thresholds set in 1992 for radioactive drugs ensured only significant nuclear medicine events would be reported. As a result of those changes the number of NRC "misadministrations/reportable medical events" dropped from over 400 per year to under 40 per year. The current dose thresholds added in 2002 for patient intervention and wrong treatment site ensure that significant events are reported and that therapy events with low doses do not have to be reported. Even though the new thresholds reduced the types of medical events that need to be reported, the number of NRC reportable medical events has remained essentially constant because of both the increased number of medical use licensees and the increase in the number of licensees involved in therapeutic medical uses most likely to result in reportable medical events. The NRC did not conduct a survey of licensees, other stakeholders, and Agreement States as indicated in OMB's Terms of Clearance for its approval of the information collection requirements contained in the Revised Part 35,because under the new regulations only significant events are required to be reported and so few events are reportable. Further, the total burden to licensees is 1,726 hours for the estimated 166 medical event reports for all licensees (36 for NRC licensees and 130 for Agreement State licensees) which is an insignificant portion (only 0.15 percent) of the entire burden for Part 35.

The general uses of information obtained from reported medical events is discussed in more detail in Item 2, "Agency use of information." However, the practical utility of the information obtained for these new increased thresholds is confirmed by reviewing recent medical event reports. These reports have identified a manufacturer's mislabeling the activities for brachytherapy sources, design errors in therapeutic devices, inadequate labeling of incompatible component parts, and other mechanical and human factor errors associated with administration of therapy dosages and doses. Medical use licensees are informed of such medical events in Information Notices, the Nuclear Materials and Safeguards News Letter, and other communications to provide them with greater awareness of how to avoid similar events. Heightened awareness of medical events due to device design and use weaknesses has resulted in manufacturer's improvements in design, operator instructions, and training programs.

The opportunity for public comment was published in the Federal Register on May 14, 2004 (69 FR 26899). No comments were received.

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

The information in this section summarizes the burden information in Tables 1-4 for licensees and the one-time and annual burden to certifying boards.

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

	NRC Licensees (hrs/yr)	Agreement State Licensees (hrs/yr)
Reporting	13,041	46,945
Recordkeeping	228,940	823,950
Total	241,981	870,895

In addition to the above burden for NRC and Agreement State licensees, there is an additional burden of 341 hours for the proposed Amendment to 10 CFR Part 35, “Medical Use of Byproduct Material - Recognition of Specialty Boards.” This burden includes 213 hours (49 hours NRC licensees and 164 hours Agreement State Licensees) for licensees submitting preceptor statements under 35.14(a) and a one-time annualized burden of 128 hours for certifying boards preparing requests for recognition under the proposed revision of Part 35. The proposed rule revises the criteria in Subparts B, D, E, F, G, and H under which NRC and Agreement States will recognize an organization whose certification process constitutes recognized training. OMB has approved and implemented the burden for this proposed amendment.

Therefore, the total NRC licensee burden is 242,030 hours (241,981 + 49 hours), and the total Agreement State burden is 871,059 hours (870,895 + 165 hours). There is a one-time burden to certifying boards of 128 hours.

The total burden and cost for Part 35 is 1,113,217 hours (242,030 + 871,059 hours) and $175,888,286 (1,113,217 x $158/hr).

TOTAL RESPONSES: 244,086 (NRC: 51,309 + 1,759 recordkeepers; and Agreement States: 184,686 + 6,332 recordkeepers)

13. Estimate of Other Additional Costs

NRC has determined that the storage and equipment costs per foot are approximately $45. The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be $ 66,543 (1,052,890 X $158 X .0004).

14. Estimated Annualized Cost to the Federal Government

For the requested clearance period the annualized burden and cost to NRC staff for review of submittals made under Part 35 is estimated to be 392 hours and $61,936 ($158 per hour x 392 hours). This estimate includes the recurring burden to review event reports (300 hours), and an annualized one-time burden of 92 hours for review of applications for certifying organizations (23 requests for recognition x 4 hours per request, as described in the following table). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

Total NRC Burden for Recognition of Certifying Boards and
Total Burden for Medical Speciality Certifying Boards to Prepare Requests for Recognition

Section	Number of medical boards seeking recognition by NRC	NRC Burden Per Recognition Request (Hours)	Total NRC Recognition Burden (Hours)
35.50(a)	5	4	20
35.51(a)	2	4	8
35.55(a)	2	4	8
35.190(a)	5	4	20
35.290(a)	Same as 35.190	–	0
35.390(a)	1	4	4
35.392(a)	2	4	8
35.394(a)	Same as 35.392	–	0
35.490(a)	3	4	12
35.491	None	–	0
35.590(a)	Counted under other sections	–	0
35.690(a)	3	4	12
Total Board Applications:	23	4	92

15. Reasons for Changes in Burden

Although the number of NRC medical use licensees has increased from 1,655 to 1,759 for the clearance renewal period, the NRC licensee burden has decreased by 12,049 hours, from 254,079 hours during the last clearance period to 242,030 hours, based primarily on a better estimate of the number of licensees subject to certain requirements.

NRC also revised its method of counting NRC licensees by including the number of NRC Master Materials Licensee permittees as well as individual NRC licensees. This more accurately reflects the number of and burden on licensees required to comply with NRC regulations.

There are currently a total of 17,109 Agreement State licensees and 4,818 NRC licensees. Therefore, there are approximately 3.6 Agreement State licensees to each NRC licensee (4818 X 3.6 = 17,345). During the last clearance period this ratio was 2.5 Agreement State licensees to each NRC licensee. Therefore, using this new ratio, the burden for the Agreement States has increased by 235,364 hours from 635,695 to 871,059 hours because of the increase in the number of licensees, although the burden per respondent/recordkeeper has, for the most part remained unchanged.

In addition to the burden changes because of the increase in the number of licensees, the burden for several sections has been re-estimated based on experience. The burden in § 35.2060 associated with direct measurement of dosages required in § 35.60 was significantly reduced (-29.9K hours) because most licensees receive unit doses from commercial nuclear pharmacies and few are required to make the direct measurements. The burden in § 35.2433 was also significantly reduced (-25.6K hours) due to a lower estimate in the number of decay calculations required by § 35.433. The burden estimate for § 35.2632 significantly increased (11.3K hours) because the number of licensees with remote afterloaders has increased and most remote afterloaders require more frequent calibrations. The slight decrease in NRC licensee burden for § 35.2643 reflects an increase in the number of licensees with remote afterloaders but a reduction of the average number of patients treated per licensee. However, as indicated above, because the revised Agreement State ratio significantly increases the number of Agreement State licensees, the total burden for this section results in a 30K burden hour increase.

Overall, the burden for Part 35 has increased by a total of 222,781 hours, from 890,095 to 1,113,217 hours, resulting in a burden increase of more than 25%.

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 – Annual Reporting Requirements
NRC Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $158/Hr
35.6(b)	164	1	164	4	656	103,648
35.6(c)	41	1	41	4	164	25,912
35.12(b), (c), & (d)	OMB Clearance 3150-0120					
35.13	OMB Clearance 3150-0120					
35.14(a) & (b)	530	2	1060	0.25	265	41,870
35.19	16	1	16	1	16	2,528
35.24(c)	20	1	20	1	20	3,160
35.67(e)(2)	Burden covered in 35.3067					
35.75(b)	550	24	13200	0.17	2,244	354,552
35.315(b)	12	1	12	1	12	1,896
35.415(c)	70	1	70	1	70	11,060
35.615(f)(4)	20	1	20	1	20	3,160
35.642(c)	3	12	36	0.25	9	1,422
35.643(c)	202	155	31310	0.25	7,827	1,236,666
35.645(b)(2)	20	260	5200	0.25	1,300	205,400
35.1000	OMB Clearance 3150-0120					
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)					
35.3045(c)	36	1	36	0.5	18	2,844
35.3045(d)	36	1	36	8	288	45,504
35.3045(e)	36	1	36	2	72	11,376
35.3045(g)	36	1	36	0.5	18	2,844

Table 1 – Annual Reporting Requirements
NRC Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $158/Hr
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)					
35.3047(c)	3	1	3	0.5	2	316
35.3047(d)	3	1	3	8	24	3,792
35.3047(e)	3	1	3	2	6	948
35.3047(f)	3	1	3	0.5	2	316
35.3067	2	2	4	2	8	1,264
Training and Experience Requirements: See Item 12	One-time burden for application for recognition of certifying groups					
Total			51,309		13,041	2,060,478

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.24(a)	1,759	5	0.5	4,398	694,884	5 years
35.24(b)	350	2	0.25	175	27,650	
35.24(e)	Burden covered in 35.2024					
35.24(f)	400	1	0.5	200	31,600	Industry practice
35.24(h)	Burden covered in 35.2024					
35.26(a)(3)&(4)	1,759	1	0.5	880	139,040	5 years
35.26(b)	Burden covered in 35.2026					
35.27(a)	1,759	1	1	1,759	277,922	
35.27(b)	490	1	1	490	77,420	
35.40(a)(1)	1,071	7	0.25	1,874	296,092	3 years
35.40(c)(1)	1,071	10	0.25	2,677	422,966	3 years
35.40(d)	Burden covered in 35.2040					
35.41(a)	1,071	1	0.5	535	84,530	Duration of license
35.41(c)	Burden covered in 35.2041					
35.50(a)	OMB Clearance 3150-0120					
35.50(b)(2)	OMB Clearance 3150-0120					
35.51(a)	OMB Clearance 3150-0120					
35.51(b)(2)	OMB Clearance 3150-0120					
35.55(a)	OMB Clearance 3150-0120					
35.55(b)(2)	OMB Clearance 3150-0120					
35.60(c)	Burden covered in 35.2060					
35.61(a)(3)	1,759	1	0.03	53	8,374	Equipment duration
35.61(c)	Burden covered in 35.2061					
35.63(e)	Burden covered in 35.2063					
35.67(d)	Burden covered in 35.2067					
35.67(g)	Burden covered in 35.2067					
35.69	1,577	2126	0.02	67,054	10,594,532	Equipment duration

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.70(c)	Burden covered in 35.2070					
35.75(c)	Burden covered in 35.2075(a)					
35.75(d)	Burden covered in 35.2075(b)					
35.80(a)(1)	44	20	1	880	139,040	3 years after last service
35.80(c)	Burden covered in 35.2080					
35.92(b)	Burden covered in 35.2092					
35.190(a)	OMB Clearance 3150-0120					
35.190(c)(2)	OMB Clearance 3150-0120					
35.204(c)	Burden covered in 35.2204					
35.290(a)	OMB Clearance 3150-0120					
35.290(c)(2)	OMB Clearance 3150-0120					
35.310(a)	700	1	1	700	110,600	Annual
35.310(b)	Burden covered in 35.2310					
35.315(a)(3)	700	18	0.1	1,260	199,080	Duration of treatment
35.390(a)	OMB Clearance 3150-0120					
35.390(b)(2)	OMB Clearance 3150-0120					
35.392(a)	OMB Clearance 3150-0120					
35.392(c)(3)	OMB Clearance 3150-0120					
35.394(a)	OMB Clearance 3150-0120					
35.394(c)(3)	OMB Clearance 3150-0120					
35.404(c)	Burden covered in 35.2404					
35.406(c)	Burden covered in 35.2406					
35.410(a)	390	1	1	390	61,620	
35.410(b)	Burden covered in 35.2310					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.415(a)(3)	280	5	0.1	140	22,120	Duration of treatment
35.432(d)	Burden covered in 35.2432					
35.433(b)	Burden covered in 35.2433					
35.490(a)	OMB Clearance 3150-0120					
35.490(b)(3)	OMB Clearance 3150-0120					
35.491 (c)	OMB Clearance 3150-0120					
35.590(a)	OMB Clearance 3150-0120					
35.604(b)	Burden covered in 35.2404					
35.605(d)	Burden covered in 35.2605					
35.610(a)(4)	224	1	1	224	35,392	Possession of unit
35.610(b)	224	1	0.03	7	1,106	Possession of unit
35.610(c)	224	1	0.5	112	17,696	Possession of unit
35.610(d)	224	1	1	224	35,392	Possession of unit
35.610(e)	224	1	0.5	112	17,696	
35.610(f)	Burden covered in 35.2310					
35.610(g)	Burden covered in 35.2610					
35.630(c)	Burden covered in 35.2630					
35.632(g)	Burden covered in 35.2632					
35.633(i)	Burden covered in 35.2632					
36.635(g)	Burden covered in 35.2632					
35.642(b)	3	1	4	12	1,896	Possession of unit
35.642(c)	3	12	0.25	9	1,422	3 years
35.642(f)	Burden covered in 35.2642					
35.643(b)	202	1	4	808	127,664	Possession of unit

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.643(c)	202	155	0.25	7,828	1,236,824	3 years
35.643(f)	Burden covered in 35.2643					
35.645(b)(1)	20	1	4	80	12,640	Possession of unit
35.645(b)(2)	20	260	0.25	1,300	205,400	3 years
35.645(g)	Burden covered in 35.2645					
35.647(e)	Burden covered in 35.2647					
35.652(c)	Burden covered in 35.2652					
35.655(c)	Burden covered in 35.2655					
35.690(a)	OMB Clearance 3150-0120					
35.690(b)(3)	OMB Clearance 3150-0120					
35.900(a)	OMB Clearance 3150-0120					
35.900(b)	OMB Clearance 3150-0120					
35.910(a)	OMB Clearance 3150-0120					
35.910(b)	OMB Clearance 3150-0120					
35.910(c)	OMB Clearance 3150-0120					
35.920(a)	OMB Clearance 3150-0120					
35.920(b)	OMB Clearance 3150-0120					
35.920(c)	OMB Clearance 3150-0120					
35.930(a)	OMB Clearance 3150-0120					
35.930(b)	OMB Clearance 3150-0120					
35.932(a)	OMB Clearance 3150-0120					
35.932(b)	OMB Clearance 3150-0120					
35.934(a)	OMB Clearance 3150-0120					
25.934(b)	OMB Clearance 3150-0120					
35.940(a)	OMB Clearance 3150-0120					
35.940(b)	OMB Clearance 3150-0120					
35.941(a)&(b)	OMB Clearance 3150-0120					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.950(a)	OMB Clearance 3150-0120					
35.950(b)	OMB Clearance 3150-0120					
35.960(a)	OMB Clearance 3150-0120					
35.960(b)	OMB Clearance 3150-0120					
35.961(a)	OMB Clearance 3150-0120					
35.961(b)	OMB Clearance 3150-0120					
35.961(c)	OMB Clearance 3150-0120					
35.980(a)	OMB Clearance 3150-0120					
35.980(b)	OMB Clearance 3150-0120					
35.2024(a)	1,759	5	0.25	2,199	347,442	5 years
35.2024(b)	1,759	1	0.1	176	27,808	Duration of license
35.2026	1,759	1	0.25	440	69,520	5 years
35.2040	1,071	52	0.05	2,785	440,030	3 years
35.2041	1,071	1	0.05	53	8,374	Duration of license
35.2060	490	255	0.02	2,499	394,842	3 years
35.2061	1,759	1.5	0.25	660	104,280	3 years
35.2063	1,600	2126	0.02	68,032	10,749,056	3 years
35.2067(a)	1,759	3	0.06	316	49,928	3 years
35.2067(b)	1,759	2	0.06	211	33,338	3 years
35.2070	550	55	0.02	605	95,590	3 years
35.2075(a)	550	6	.25	825	130,350	3 years
35.2075(b)	550	2	.2	220	34,760	3 years
35.2080(a)	48	20	0.03	29	4,582	3 years after last service

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @ $158/HR	Record Retention Period
35.2080(b)	48	260	0.1	1,248	197,184	3 years
35.2092	1759	52	0.02	1,829	288,982	3 years
35.2204	80	52	0.08	333	52,614	3 years
35.2310	574	1	0.1	57	9,006	3 years
35.2404	591	61	0.02	721	113,918	3 years
35.2406	390	15	0.2	1,170	184,860	3 years
35.2432	390	15	0.2	1,170	184,860	3 years
35.2433	19	100	0.5	950	150,100	Life of source
35.2605	224	4.5	2	2,016	318,528	3 years
35.2610	224	2	0.05	22	3,476	Possession of unit
35.2630	224	1	0.5	111	17,538	3 years
35.2632	224	3.7	4	3,315	523,770	3 years
35.2642(a)	3	12	0.5	18	2,844	3 years
35.2642(c)	3	1	0.05	1	158	Possession of unit
35.2643(a)	202	155	1	31,310	4,946,980	3 years
35.2643(c)	202	1	0.05	10	1,580	Possession of unit
35.2645(a)	20	260	2	10,400	1,643,200	3 years
35.2645(c)	20	1	0.05	1	158	Possession of unit
35.2647	7	260	0.5	910	143,780	3 years
35.2652	224	1	0.5	112	17,696	Duration of use of unit
35.2655	23	0.2	1	5	790	Duration of use of unit
Total				228,940	36,172,520	

Table 3 – Annual Reporting Requirements
Agreement State Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $158/Hr
35.6(b)	590	1	590	4	2,360	372,880
35.6(c)	148	1	148	4	592	93,536
35.12(b), (c), & (d)	OMB Clearance 3150-0120					
35.13	OMB Clearance 3150-0120					
35.14(a) & (b)	1908	2	3816	0.25	954	170,732
35.19	58	1	58	1	58	9,164
35.24(c)	72	1	72	1	72	11,376
35.67(e)(2)	Burden covered in 35.3067					
35.75(b)	1980	24	47520	0.17	8,078	1,276,324
35.315(b)	43	1	43	1	43	6,794
35.415(c)	252	1	252	1	252	39,816
35.615(f)(4)	72	1	72	1	72	11,376
35.642(c)	11	12	132	0.25	33	5,214
35.643(c)	727	155	112685	0.25	28171	4,451,018
35.645(b)(2)	72	260	18720	0.25	4,680	739,440
35.1000	OMB Clearance 3150-0120					
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)					
35.3045(c)	130	1	130	0.5	65	10,270
35.3045(d)	130	1	130	8	1,040	164,320
35.3045(e)	130	1	130	2	260	41,080
35.3045(g)	130	1	130	0.5	65	10,270

Table 3 – Annual Reporting Requirements
Agreement State Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $158/Hr
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)					
35.3047(c)	11	1	11	0.5	6	948
35.3047(d)	11	1	11	8	88	13,904
35.3047(e)	11	1	11	2	22	3,476
35.3047(f)	11	1	11	0.5	6	948
35.3067	7	2	14	2	28	4,424
Training and Experience Requirements: See Item 12	One-time burden for application for recognition of certifying groups					
Total			184,686		46,945	7,417,310

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.24(a)	6332	5	0.5	15,830	2,501,140	5 years
35.24(b)	1260	2	0.25	630	99,540	
35.24(e)	Burden covered in 35.2024					
35.24(f)	1440	1	0.5	720	113,760	Industry practice
35.24(h)	Burden covered in 35.2024					
35.26(a)(3)&(4)	6332	1	0.5	3,166	500,228	5 years
35.26(b)	Burden covered in 35.2026					
35.27(a)	6332	1	1	6,332	1,000,456	
35.27(b)	1764	1	1	1,764	278,712	
35.40(a)(1)	3856	7	0.25	6,748	1,066,184	3 years
35.40(c)(1)	3856	10	0.25	9,640	1,523,120	3 years
35.40(d)	Burden covered in 35.2040					
35.41(a)	3856	1	0.5	1,928	304,624	Duration of license
35.41(c)	Burden covered in 35.2041					
35.50(a)	OMB Clearance 3150-0120					
35.50(b)(2)	OMB Clearance 3150-0120					
35.51(a)	OMB Clearance 3150-0120					
35.51(b)(2)	OMB Clearance 3150-0120					
35.55(a)	OMB Clearance 3150-0120					
35.55(b)(2)	OMB Clearance 3150-0120					
35.60(c)	Burden covered in 35.2060					
35.61(a)(3)	6332	1	0.03	190	30,020	Equipment duration
35.61(c)	Burden covered in 35.2061					
35.63(e)	Burden covered in 35.2063					
35.67(d)	Burden covered in 35.2067					
35.67(g)	Burden covered in 35.2067					
35.69	5677	2126	0.02	241,386	38,138,988	Equipment duration
35.70(c)	Burden covered in 35.2070					

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.75(c)	Burden covered in 35.2075(a)					
35.75(d)	Burden covered in 35.2075(b)					
35.80(a)(1)	158	20	1	3,160	499,280	3 years after last service
35.80(c)	Burden covered in 35.2080					
35.92(b)	Burden covered in 35.2092					
35.190(a)	OMB Clearance 3150-0120					
35.190(c)(2)	OMB Clearance 3150-0120					
35.204(c)	Burden covered in 35.2204					
35.290(a)	OMB Clearance 3150-0120					
35.290(c)(2)	OMB Clearance 3150-0120					
35.310(a)	2520	1	1	2,520	398,160	Annual
35.310(b)	Burden covered in 35.2310					
35.315(a)(3)	2520	18	0.1	4,536	716,688	Duration of treatment
35.390(a)	OMB Clearance 3150-0120					
35.390(b)(2)	OMB Clearance 3150-0120					
35.392(a)	OMB Clearance 3150-0120					
35.392(c)(3)	OMB Clearance 3150-0120					
35.394(a)	OMB Clearance 3150-0120					
35.394(c)(3)	OMB Clearance 3150-0120					
35.404(c)	Burden covered in 35.2404					
35.406(c)	Burden covered in 35.2406					
35.410(a)	1404	1	1	1,404	221,832	
35.410(b)	Burden covered in 35.2310					
35.415(a)(3)	1008	5	0.1	504	79,632	Duration of treatment
35.432(d)	Burden covered in 35.2432					
35.433(b)	Burden covered in 35.2433					
35.490(a)	OMB Clearance 3150-0120					

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.490(b)(3)	OMB Clearance 3150-0120					
35.491 (c)	OMB Clearance 3150-0120					
35.590(a)	OMB Clearance 3150-0120					
35.604(b)	Burden covered in 35.2404					
35.605(d)	Burden covered in 35.2605					
35.610(a)(4)	806	1	1	806	127,348	Possession of unit
35.610(b)	806	1	0.03	24	3,792	Possession of unit
35.610(c)	806	1	0.5	403	63,674	Possession of unit
35.610(d)	806	1	1	806	127,348	Possession of unit
35.610(e)	806	1	0.5	403	63,674	
35.610(f)	Burden covered in 35.2310					
35.610(g)	Burden covered in 35.2610					
35.630(c)	Burden covered in 35.2630					
35.632(g)	Burden covered in 35.2632					
35.633(i)	Burden covered in 35.2632					
36.635(g)	Burden covered in 35.2632					
35.642(b)	11	1	4	44	6,952	Possession of unit
35.642(c)	11	12	0.25	33	5,214	3 years
35.642(f)	Burden covered in 35.2642					
35.643(b)	727	1	4	2,908	459,464	Possession of unit
65.643(c)	727	155	0.25	28,171	4,451,018	3 years
35.643(f)	Burden covered in 35.2643					
35.645(b)(1)	72	1	4	288	45,504	Possession of unit
35.645(b)(2)	72	260	0.25	4,680	739,440	3 years
35.645(g)	Burden covered in 35.2645					
35.647(e)	Burden covered in 35.2647					
35.652(c)	Burden covered in 35.2652					

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.655(c)	Burden covered in 35.2655					
35.690(a)	OMB Clearance 3150-0120					
35.690(b)(3)	OMB Clearance 3150-0120					
35.900(a)	OMB Clearance 3150-0120					
35.900(b)	OMB Clearance 3150-0120					
35.910(a)	OMB Clearance 3150-0120					
35.910(b)	OMB Clearance 3150-0120					
35.910(c)	OMB Clearance 3150-0120					
35.920(a)	OMB Clearance 3150-0120					
35.920(b)	OMB Clearance 3150-0120					
35.920(c)	OMB Clearance 3150-0120					
35.930(a)	OMB Clearance 3150-0120					
35.930(b)	OMB Clearance 3150-0120					
35.932(a)	OMB Clearance 3150-0120					
35.932(b)	OMB Clearance 3150-0120					
35.934(a)	OMB Clearance 3150-0120					
25.934(b)	OMB Clearance 3150-0120					
35.940(a)	OMB Clearance 3150-0120					
35.940(b)	OMB Clearance 3150-0120					
35.941(a)&(b)	OMB Clearance 3150-0120					
35.950(a)	OMB Clearance 3150-0120					
35.950(b)	OMB Clearance 3150-0120					
35.960(a)	OMB Clearance 3150-0120					
35.960(b)	OMB Clearance 3150-0120					
35.961(a)	OMB Clearance 3150-0120					
35.961(b)	OMB Clearance 3150-0120					
35.961(c)	OMB Clearance 3150-0120					

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.980(a)	OMB Clearance 3150-0120					
35.980(b)	OMB Clearance 3150-0120					
35.2024(a)	6,332	5	0.25	7,915	1,250,570	5 years
35.2024(b)	6,332	1	0.08	506	79,948	Duration of license
35.2026	6,332	1	0.25	1,583	250,114	5 years
35.2040	3,855	52	0.05	10,023	1,583,634	3 years
35.2041	3,855	1	0.05	193	30,494	Duration of license
35.2060	1,764	255	0.02	8,996	1,421,368	3 years
35.2061	6,332	1.5	0.25	2,375	375,250	3 years
35.2063	5760	2126	0.02	244,915	38,696,570	3 years
35.2067(a)	6,332	3	0.06	1,140	180,120	3 years
35.2067(b)	6,332	2	0.06	760	120,080	3 years
35.2070	1,980	55	0.02	2,178	344,124	3 years
35.2075(a)	1,980	6	0.25	2,970	469,260	3 years
35.2075(b)	1,980	2	0.2	792	125,136	3 years
35.2080(a)	173	20	0.03	104	16,432	3 years after last service
35.2080(b)	173	260	0.1	4,498	710,684	3 years
35.2092	6,332	52	0.02	6,585	1,040,430	3 years
35.2204	288	52	0.08	1,198	189,284	3 years
35.2310	2,066	1	0.1	207	32,706	3 years
35.2404	2,128	61	0.02	2,596	410,168	3 years
35.2406	1,404	15	0.2	4,212	665,496	3 years
35.2432	1,404	15	0.2	4,212	665,496	3 years
35.2433	68	100	0.5	3,400	537,200	Life of source
35.2605	806	4.5	2	7,254	1,146,132	3 years
35.2610	806	2	0.05	81	12,798	Possession of unit
35.2630	806	1	0.5	403	63,674	3 years

Table 4 – Annual Recordkeeping Requirements
Agreement State Licensees (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Hours per Record	Total Record-keeping Hours	Cost @$158/Hr	Record Retention Period
35.2632	806	3.7	4	11,928	1,884,624	3 years
35.2642(a)	11	12	0.5	66	10,428	3 years
35.2642(c)	11	1	0.05	1	158	Possession of unit
35.2643(a)	727	155	1	112,685	17,804,230	3 years
35.2643(c)	727	1	0.05	36	5,688	Possession of unit
35.2645(a)	72	260	2	37,440	5,915,520	3 years
35.2645(c)	72	1	0.05	4	632	Possession of unit
35.2647	25	260	0.5	3,250	513,500	3 years
35.2652	806	1	0.5	403	63,674	Duration of use of unit
35.2655	83	0.2	1	17	2,686	Duration of use of unit
Total				823,950	130,184,100	