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.

The burden for the training and experience requirements in Subparts B and D-H are related as appropriate to the clearance for NRC Form 313, "Application for Material License," and to the NRC Form 313A series of forms for individuals seeking authorization for recognition as authorized users (AU), authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), and radiation safety officers (RSO); which are cleared under 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 to the NRC Form 313A series of forms for recognition as AU, AMP, ANP, and RSO.

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.

Subpart J contained training and experience requirements and associated reporting requirements that were effective during the last reporting period. However, the Subpart J training and experience and any associated reporting expired as of October 24, 2005.

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).

§ 35.13 License amendments

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).

§ 35.14 Notifications

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.

§ 35.41 Procedures for administrations requiring a written directive

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 individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) must meet one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) must complete a structured educational program; or 3) be currently recognized as an authorized user, authorized medical physicist, or authorized nuclear pharmacist, who has experience with the radiation safety aspects of similar types of byproduct material for which the individual has RSO responsibilities. In addition to meeting one of these

requirements, the individual must also obtain written attestation signed by a preceptor RSO, which attests that the individual has satisfactorily completed all applicable training and education requirements, and can function independently as an RSO.

The training and supervised experience and the preceptor statement required by § 35.50 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13, and is cleared under OMB Clearance No. 3150-0120.

§ 35.51 Training for an authorized medical physicist

An individual fulfilling the responsibilities of the authorized medical physicist must meet one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) meet the educational requirements outlined in § 35.51(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements. 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 training and supervised experience and the preceptor statement required by 35.51 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13, and is cleared under OMB Clearance No. 3150-0120.

§ 35.55 Training for an authorized nuclear pharmacist

An individual fulfilling the responsibilities of the authorized nuclear pharmacist must be a pharmacist who meets one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) meet the educational requirements outlined in § 35.55(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized nuclear pharmacist. 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 training and supervised experience and the preceptor statement required by § 35.55 is submitted as part of a licensee's application as required under §§ 35.12 or 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

An individual fulfilling the responsibilities of an authorized user of unsealed byproduct material for uses authorized under § 35.100 must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process includes all of the requirements of § 35.190(a) and whose certification has been recognized by the Commission or an Agreement State, or 2) be an authorized user under §§ 35.290 or 35.390 or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, or 3) meet the training and experience requirements specified in § 35.190(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of unsealed byproduct material for use authorized under §35.100. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for uses under §35.100.

The training and supervised experience and the preceptor statement required by § 35.190 is submitted as part of a licensee's application as required under §§ 35.12 or 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

An individual fulfilling the responsibilities of an authorized user of unsealed byproduct material for uses authorized under §35.200 must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) be an authorized user under §35.390 and meet the requirements in §35.290(c)(1)(ii)(G) or equivalent Agreement State requirements or, before October 24, 2005, meet the requirements in §35.920 or equivalent Agreement State requirements; or 3) complete the training and experience requirements in §35.290(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of unsealed byproduct material for use authorized under §35.200. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user under §35.200.

The training and supervised experience and the preceptor statement required by § 35.290 is submitted as part of a licensee's application as required under §§ 35.12 or 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

An individual fulfilling the responsibilities of an authorized user of unsealed byproduct material for uses authorized under §35.300 must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) complete all the training and supervised experience requirements in §35.390(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of unsealed byproduct material for uses authorized under §35.300. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user under §35.300.

The training and supervised experience and the preceptor statement required by § 35.390 is submitted as part of a licensee's application as required under §§ 35.12 or 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)

An individual fulfilling the responsibilities of an authorized user of unsealed byproduct material 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) must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) be an authorized user in accordance with §35.392(b); or 3) has completed all the training and supervised experience requirements in §35.392(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of unsealed byproduct material 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). 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 administration of sodium iodide I-131.

The training and supervised experience and the preceptor statement required by § 35.392 is submitted as part of a licensee's application as required under §§ 35.12 or 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)

An individual fulfilling the responsibilities of an authorized user of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) be an authorized user in

accordance with §35.394(b); or 3) has completed all the training and supervised experience requirements in §35.394(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). 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 administration of sodium iodide I-131.

The training and supervised experience and the preceptor statement required by § 35.394 is submitted as part of a licensee's application as required under §§ 35.12 or 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

An individual fulfilling the responsibilities of an authorized user of a manual brachytherapy source for uses under §35.400 must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or) meet all the supervised training and experience requirements in §35.490(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user for uses under §35.400. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for uses under §35.400.

The training and supervised experience and the preceptor statement required by § 35.490 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.491 Training for ophthalmic use of strontium-90

An individual fulfilling the responsibilities of an authorized user of strontium-90 for opthalmic radiotherapy must be a physician who meets one of the following requirements: 1) is an authorized user in accordance with §35.491(a); or 2) meets all the supervised training and experience requirements in §35.491(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of strontium-90 for ophthalmic uses. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic uses.

The training and supervised experience and the preceptor statement required by § 35.491 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.590 Training for use of sealed sources for diagnosis

An individual fulfilling the responsibilities of an authorized user of diagnostic sealed sources for use in a device authorized under §35.500 must be a physician, dentist, or podiatrist who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2)

meets all the training and experience requirements 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 diagnostic sealed sources for use in a device authorized under §35.500.

The training and experience required by § 35.590 is submitted as part of a licensee's application as required under §§ 35.12 or 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.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

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.

§ 35.630 Dosimetry equipment

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.

§ 35.632 Full calibration measurements on teletherapy units

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.

§ 35.633 Full calibration measurements on remote afterloader units

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

An individual fulfilling the responsibilities of an authorized user of a remote afterloader unit, or teletherapy unit, or gamma stereotactic radiosurgery unit must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or) meet all the supervised training and experience requirements in §35.690(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an authorized user of a remote afterloader unit, or teletherapy unit, or gamma stereotactic radiosurgery unit This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of a remote afterloader unit, or teletherapy unit, or gamma stereotactic radiosurgery unit.

The training and experience required by § 35.590 is submitted as part of a licensee's application as required under §§ 35.12 or 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.

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. The NRC encourages respondent to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. Currently, no responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

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 (e.g., 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

The opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on May 3, 2007 (72 FR 24626). No comments

were received.

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.39(b). However, no information normally considered confidential or proprietary is requested.

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	13,618	50,330
Recordkeeping	237,582	686,234
Total	251,200	736,564
	NRC	251,200
	Agreement States	736,564
	BURDEN GRAND TOTAL	**987,764**

The grand total of the burden for Part 35 is 987,764 hours (251,200 + 736,564). The total cost for Part 35 is the grand total times the cost/hour or (987,764 x $214/hr) = $211,381,496.

Total Responses for NRC and Agreement States licenses are as follows: 259,332 ((NRC: 53,346 + 1,862 recordkeepers = 55,208)(Agreement States: 197,235 + 6,889 recordkeepers = 204,124.))

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be $ 79,079 (923,816 X $214 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 300 hours and $64,200 ($214 per hour x 300 hours). This estimate includes the recurring burden of 300 hours to review event reports. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

15. Reasons for Changes in Burden

Although the overall burden has decreased by 125,453 hours, from 1,113,217 (242,094 NRC Licensees; 871,123 Agreement States) to 987,764 hours (NRC Licensees 251,200 hrs; Agreement States 736,564 hrs), the number of responses increased from 244,086 responses (53,068 NRC Licensees; 191,018 Agreement States) to 259,332 responses (55,208 NRC Licensees; 204,124 Agreement States). The burden reduction is attributable to two causes: (1) the loss of a one-time burden associated with the submission of preceptor statements in accordance with the amended 35.14(a); and (2) one-time activities that specialty boards are required to undertake, in order to become recognized by the NRC as entities capable of certifying licensees' training to effectively carry out duties under Part 35.

The hourly rate has increased from $158/hr to $214/hr.

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. 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)
35.6(b)	164	1	164	4
35.6(c)	41	1	41	4
35.12(b), (c), & (d)	OMB Clearance 3150-0120			
35.13	OMB Clearance 3150-0120			
35.14(a) & (b)	559	2	1118	0.25
35.19	16	1	16	1
35.24(c)	20	1	20	1
35.67(e)(2)	Burden covered in 35.3067			
35.75(b)	498	24	11952	0.17
35.315(b)	12	1	12	1
35.415(c)	60	1	60	1
35.615(f)(4)	21	1	21	1
35.642(c)	2	12	24	0.25
35.643(c)	218	155	33790	0.25
35.645(b)(2)	23	260	5980	0.25
35.1000	OMB Clearance 3150-0120			
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)			
35.3045(c)	35	1	35	0.5
35.3045(d)	35	1	35	8
35.3045(e)	35	1	35	2
35.3045(g)	35	1	35	0.5
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)			
35.3047(c)	2	1	2	0.5
35.3047(d)	2	1	2	8
35.3047(e)	2	1	2	2
35.3047(f)	2	1	2	0.5
35.3067	0	2	0	2
Total			53,346	

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 @ $214
35.24(a)	1,862	5	0.5	4,655	996,170

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

35.24(b)	372	2	0.25	186	39,804
35.24(e)	Burden covered in 35.2024				
35.24(f)	344	1	0.5	172	36,808
35.24(h)	Burden covered in 35.2024				
35.26(a)(3)&(4)	1,862	1	0.5	931	199,234
35.26(b)	Burden covered in 35.2026				
35.27(a)	1,862	1	1	1,862	398,468
35.27(b)	494	1	1	494	105,716
35.40(a)(1)	916	7	0.25	1,603	343,042
35.40(c)(1)	916	10	0.25	2,290	490,060
35.40(d)	Burden covered in 35.2040				
35.41(a)	916	1	0.5	458	98,012
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)	1,862	1	0.03	56	11,984
35.61(c)	Burden covered in 35.2061				
35.63(e)	Burden covered in 35.2063				
Subtotal				12,707	2,719,298
35.67(d)	Burden covered in 35.2067				
35.67(g)	Burden covered in 35.2067				
35.69	1,610	2126	0.02	68,457	14,649,79
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)	143	20	1	2,860	612,040
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				

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

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)	64	1	1	64	13,696
35.310(b)	Burden covered in 35.2310				
35.315(a)(3)	64	18	0.1	115	24,610
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				
Subtotal				71,496	15,300,14
35.404(c)	Burden covered in 35.2404				
35.406(c)	Burden covered in 35.2406				
35.410(a)	240	1	1	240	51,360
35.410(b)	Burden covered in 35.2310				
35.415(a)(3)	240	5	0.1	120	25,680
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)	218	1	1	218	46,652
35.610(b)	218	1	0.03	7	1,498
35.610(c)	218	1	0.5	109	23,326
35.610(d)	218	1	1	218	46,652
35.610(e)	218	1	0.5	109	23,326
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				

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

35.633(i)	Burden covered in 35.2632				
36.635(g)	Burden covered in 35.2632				
Subtotal				1,021	218,494
35.642(b)	2	1	4	8	1,712
35.642(c)	2	12	0.25	6	1,284
35.642(f)	Burden covered in 35.2642				
35.643(b)	218	1	4	872	186,608
35.643(c)	218	155	0.25	8,448	1,807,87
35.643(f)	Burden covered in 35.2643				
35.645(b)(1)	23	1	4	92	19,688
35.645(b)(2)	23	260	0.25	1,495	319,930
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				
35.2024(a)	1,862	5	0.25	2,328	498,192
35.2024(b)	1,862	1	0.1	186	39,804
35.2026	1,862	1	0.25	466	99,724
35.2040	916	52	0.05	2,382	509,748
35.2041	916	1	0.05	46	9,844
35.2060	494	255	0.02	2,519	539,066
Subtotal				18,848	4,033,47
35.2061	1,862	1.5	0.25	698	149,372
35.2063	1,610	2126	0.02	68,457	14,649,79
35.2067(a)	1,862	3	0.06	335	71,690
35.2067(b)	1,862	2	0.06	223	47,722
35.2070	498	55	0.02	548	117,272
35.2075(a)	498	6	.25	747	159,858
35.2075(b)	498	2	.2	199	42,586
35.2080(a)	143	20	0.03	86	18,404
35.2080(b)	143	260	0.1	3,718	795,652
35.2092	1,862	52	0.02	1,936	414,304
35.2204	80	52	0.08	333	71,262

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

35.2310	522	1	0.1	52	11,128
35.2404	559	61	0.02	682	145,948
35.2406	240	15	0.2	720	154,080
35.2432	240	15	0.2	720	154,080
35.2433	34	100	0.5	1,700	363,800
35.2605	243	4.5	2	2,187	468,018
35.2610	243	2	0.05	24	5,136
35.2630	243	1	0.5	122	26,108
35.2632	243	3.7	4	3,596	769,544
Subtotal				87,083	18,635,76
35.2642(a)	3	12	0.5	18	3,852
35.2642(c)	3	1	0.05	0	0
35.2643(a)	218	155	1	33,790	7,231,06
35.2643(c)	218	1	0.05	11	2,354
35.2645(a)	23	260	2	11,960	2,559,44
35.2645(c)	23	1	0.05	1	214
35.2647	4	260	0.5	520	111,280
35.2652	243	1	0.5	122	26,108
35.2655	25	0.2	1	5	1,070
Subtotal				46,427	9,935,37
Total				237,582	50,842,54

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 @ $214/Hr
35.6(b)	606	1	606	4	2,424	518,736
35.6(c)	151	1	151	4	604	129,256
35.12(b), (c), & (d)	OMB Clearance 3150-0120					
35.13	OMB Clearance 3150-0120					
35.14(a) & (b)	2,068	2	4,136	0.25	1,034	221,276
35.19	59	1	59	1	59	12,626
35.24(c)	74	1	74	1	74	15,836
35.67(e)(2)	Burden covered in 35.3067					
35.75(b)	1,842	24	44,208	0.17	7,515	1,608,210
35.315(b)	44	1	44	1	44	9,416
35.415(c)	222	1	222	1	222	47,508
35.615(f)(4)	77	1	77	1	77	16,478
35.642(c)	7	12	84	0.25	21	4,494
35.643(c)	806	155	124,930	0.25	31,233	6,683,862
35.645(b)(2)	85	260	22,100	0.25	5,525	1,182,350
35.1000	OMB Clearance 3150-0120					
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)					
35.3045(c)	129	1	129	0.5	65	13,910
35.3045(d)	129	1	129	8	1,032	220,848
35.3045(e)	129	1	129	2	258	55,212
35.3045(g)	129	1	129	0.5	65	13,910
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)					
35.3047(c)	7	1	7	0.5	4	856

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

35.3047(d)	7	1	7	8	56	11,984
35.3047(e)	7	1	7	2	14	2,996
35.3047(f)	7	1	7	0.5	4	856
35.3067	0	2	0	2	0	0
Training and Experience Requirements: See Item 12	One-time burden for application for recognition of certifying groups					
Total			197,235		50,330	10,770,620

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

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Burden Hours per Record	Total Annual Burden Hours	Cost @$214/Hr	Record Retention Period
35.24(a)	6889	5	0.5	17,223	3,685,722	5 years
35.24(b)	1376	2	0.25	688	147,232	
35.24(e)	Burden covered in 35.2024					
35.24(f)	1273	1	0.5	637	136,318	Industry practice
35.24(h)	Burden covered in 35.2024					
35.26(a)(3)&(4)	6889	1	0.5	3,445	737,230	5 years
35.26(b)	Burden covered in 35.2026					
35.27(a)	6889	1	1	6,889	1,474,246	
35.27(b)	1828	1	1	1,828	391,192	
35.40(a)(1)	3389	7	0.25	5,931	1,269,234	3 years
35.40(c)(1)	3389	10	0.25	8,473	1,813,222	3 years
35.40(d)	Burden covered in 35.2040					
35.41(a)	3389	1	0.5	1,695	362,730	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)	6889	1	0.03	207	44,298	Equipment duration
35.61(c)	Burden covered in 35.2061					
35.63(e)	Burden covered in 35.2063					

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

35.67(d)	Burden covered in 35.2067					
35.67(g)	Burden covered in 35.2067					
35.69	1610	2126	0.02	68,457	14,649,798	Equipment duration
Subtotal				115,473	24,711,222	
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)	143	20	1	2,860	612,040	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)	237	1	1	237	50,718	Annual
35.310(b)	Burden covered in 35.2310					
35.315(a)(3)	64	18	0.1	115	24,610	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					

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

35.410(a)	888	1	1	888	190,032	
35.410(b)	Burden covered in 35.2310					
35.415(a)(3)	888	5	0.1	444	95,016	Duration of treatment
35.432(d)	Burden covered in 35.2432					0
Subtotal				4,544	972,416	
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)	807	1	1	807	172,698	Possession of unit
35.610(b)	807	1	0.03	24	5,136	Possession of unit
35.610(c)	807	1	0.5	404	86,456	Possession of unit
35.610(d)	807	1	1	807	172,698	Possession of unit
35.610(e)	807	1	0.5	404	86,456	
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)	7	1	4	28	5,992	Possession of unit
35.642(c)	7	12	0.25	21	4,494	3 years
35.642(f)	Burden covered in 35.2642					

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

35.643(b)	807	1	4	3,228	690,792	Possession of unit
65.643(c)	807	155	0.25	31,271	6,691,994	3 years
35.643(f)	Burden covered in 35.2643					
35.645(b)(1)	85	1	4	340	72,760	Possession of unit
35.645(b)(2)	85	260	0.25	5525	1,182,350	3 years
Subtotal				42,859	9,171,826	
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					
35.2024(a)	6,889	5	0.25	8,611	1,842,754	5 years
35.2024(b)	6,889	1	0.1	689	147,446	Duration of license
35.2026	6,889	1	0.25	1,722	368,508	5 years
35.2040	3,389	52	0.05	8,811	1,885,554	3 years
35.2041	3,389	1	0.05	169	36,166	Duration of license
35.2060	1,828	255	0.02	9,323	1,995,122	3 years
35.2061	6,889	1.5	0.25	2,583	552,762	3 years
35.2063	5,957	2126	0.02	253,292	54,204,488	3 years
35.2067(a)	6,889	3	0.06	1,240	265,360	3 years
35.2067(b)	6,889	2	0.06	827	176,978	3 years
35.2070	1,843	55	0.02	2,027	433,778	3 years
35.2075(a)	1,843	6	0.25	2,765	591,710	3 years
35.2075(b)	1,843	2	0.2	737	157,718	3 years
35.2080(a)	529	20	0.03	317	67,838	3 years after last service

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

35.2080(b)	529	260	0.1	13,754	2,943,356	3 years
35.2092	6,889	52	0.02	7,165	1,533,310	3 years
35.2204	296	52	0.08	1,231	263,434	3 years
35.2310	1,931	1	0.1	193	41,302	3 years
35.2404	2,068	61	0.02	2,523	539,922	3 years
Subtotal				317,979	68,047,506	
35.2406	888	15	0.2	2,664	570,096	3 years
35.2432	888	15	0.2	2,664	570,096	3 years
35.2433	126	100	0.5	6,300	1,348,200	Life of source
35.2605	899	4.5	2	8,091	1,731,474	3 years
35.2610	899	2	0.05	90	19,260	Possession of unit
35.2630	899	1	0.5	450	96,193	3 years
35.2632	899	3.7	4	13,305	2,847,300	3 years
35.2642(a)	11	12	0.5	66	14,270	3 years
35.2642(c)	11	1	0.05	1	214	Possession of unit
35.2643(a)	807	155	1	125,085	26,768,190	3 years
35.2643(c)	807	1	0.05	40	8,560	Possession of unit
35.2645(a)	85	260	2	44,200	9,458,800	3 years
35.2645(c)	85	1	0.05	4	856	Possession of unit
35.2647	15	260	0.5	1,950	417,300	3 years
35.2652	899	1	0.5	450	96,300	Duration of use of unit
35.2655	93	0.2	1	19	4,066	Duration of use of unit
Subtotal				205,379	43,951,106	
Total				686,234	146,854,076	