SUPPORTING STATEMENT
FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)
AND
10 CFR PART 20
STANDARDS FOR PROTECTION AGAINST RADIATION
(3150-0014)

Description of the Information Collection

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

This clearance package covers the requirements for all sections of Part 35. It reflects the elimination of 10 CFR §§ 35.32 and 35.33, previously addressed under OMB 3150-1171, "Quality Management Program and Misadministrations," March 7, 1997. It also incorporates the burden estimated for 10 CFR §35.75, previously addressed under OMB 3150-0010, "Criteria for the Release of Individuals Administered Radioactive Material," January 6, 1997. The recordkeeping and reporting requirements of Part 35 have been centralized into two Subparts: Subpart L - Records (§§ 35.2024-2655) and Subpart M - Reports (§§ 35.3045-3069). Cross references to the recordkeeping requirements appear in other related portions of the Part 35 rule, but these cross references do not constitute separate recordkeeping requirements.

General requirements for radiation protection that are applicable to all NRC licensees are contained in 10 CFR Part 20.

This clearance package covers the revisions to the requirements in 10 CFR §20.1301.

A. Justification

Part of the NRC's function is to license and regulate the use of byproduct materials in order to provide for the radiation safety of workers, the general public, and patients. The NRC requires licensees to perform certain tasks to ensure fulfillment of their

obligations. The records required in this part are the least burdensome way for licensees to demonstrate compliance with NRC's requirements. Occasionally, safety matters are of such significance that personnel need to be aware of the information in order to perform their jobs or work in a safe manner. In such cases, reports are required.

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

Section 35.12 establishes requirements for applications for licenses.

Sections 35.12(b) and (c) require that applicants submit a completed NRC Form 313, "Application for Material License." The form elicits an orderly description of the applicant's complete radiation safety program. Requests for amendments and license renewals may be submitted in a letter format.

Section 35.12(d) requires that applicants for a license for medical use of byproduct material described in §35.900 submit a completed Form 313. Because this license application is for a new medical use, not addressed in Subparts D-H, a licensee is also required to provide additional information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of Part 35. The licensee must also provide specific information necessary for (1) radiation safety precautions and instructions, (2) training and experience of proposed users, (3) methodology for measurement of dosages or doses to be administered to patients or human research subjects, and (4) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. Section 35.12(d) also requires the applicant or licensee to provide any other information requested by the Commission in its review of the application. This section is intended to assist licensees in determining what information is required for the Commission to evaluate a license application for a new medical use of byproduct material.

The burden for Section 35.12 is included in the information collection burden for Form 313. NRC Form 313 has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data. This report is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material.

Section 35.13 requires that licensees apply for and receive a license amendment before receiving or using material for a clinical procedure that is permitted under Part 35, but is not authorized by the licensee's current license under this part; before permitting authorized users, authorized nuclear pharmacists, or authorized medical physicists who do not meet certain requirements to work under the license; before changing Radiation Safety Officers (RSO); before ordering more material or different radionuclide or form than authorized by the license; before changing the area of use, except for areas of use of byproduct material under §§ 35.100 and 35.200; and before changing the addresses of authorized places of use. The triggering events are critical indicators of a potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection of the licensee's program. The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety. The burden for Section 35.13 is included in the information collection burden for Form 313.

Section 35.14 requires that licensees: 1) provide certain information 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); and 2) notify the NRC by letter within 30 days if an ANP, AU, AMP, or RSO ends his association with the licensee or has a name change; when the licensee's mailing address changes; when the licensee has a name change that is not a change in control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have a change in the areas of use. The report

for AU and AMP is required in order to maintain the licensee's file with a current record of individuals authorized to use or prepare radioactive material. The report for changes in "key" workers is required because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure the safety of all licensed users. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use radioactive material safely. The NRC needs to be aware of name and mailing address changes to ensure that the licensee continues receiving correspondence such as information notices, bulletins, and other safety related documents. The NRC needs to be aware of changes of areas of use so that NRC can determine if the facilities are adequate to assure protection of public health and safety.

Section 35.24 establishes the authority and responsibilities for the radiation protection program. Section 35.24(a) requires a licensee's management to approve requests for license application, renewal, or amendment prior to submittal; any individual, prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require an amendment and are permitted under §35.26.

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

Section 35.24(d) requires a licensee to establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer. The statement is needed so that the duties, and responsibilities of the Radiation Safety Officer are clearly defined, and the Radiation Safety Officer is provided sufficient authority to assure that the licensee's radiation

safety activities are being performed in accordance with regulatory requirements.

Section 35.24(f) requires that a record of actions taken pursuant to paragraphs (a) and (d) be retained in accordance with Section 35.2024.

Section 35.26(a) allows a licensee to revise its radiation protection program without Commission approval under certain specified conditions. This section allows a licensee to make some changes in their radiation safety program, provided that the changes do not reduce radiation safety, without submitting an amendment to its licensee. Section 35.26(b) requires a record of each change to be retained in accordance with §35.2026.

Section 35.40 requires licensees, prior to certain specified medical administrations or procedures, to: (1) prepare a written directive containing the patient or human research subject's name and certain specified information pertaining to the administration or procedure, and (2) retain the written directive in accordance with §35.2040.

Section 35.41 requires licensees to develop, maintain, and implement written procedures for any administration requiring a written directive that will provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. These procedures are necessary to ensure that administrations that require a written directive are given as directed by the authorized user physician.

Section 35.50 establishes training and experience requirements for Radiation Safety Officer.

Section 35.50(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.50(b)(1) and whose certification has been approved by the Commission. This report is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

Section 35.50(b)(2) requires that an individual obtain a written certification signed by a preceptor Radiation

Safety Officer before the individual can be qualified as a Radiation Safety Officer. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

Section 35.50(b)(3) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge in radiation safety commensurate with the medical uses of byproduct material.

Section 35.51 establishes training and experience requirements for authorized medical physicist.

Section 35.51(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.51(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

Section 35.51(b)(2) requires an individual to obtain a written certification signed by a preceptor authorized medical physicist before the individual can be qualified as a medical physicist. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

Section 35.51(b)(3) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of byproduct material.

Section 35.55 establishes training requirements for authorized nuclear pharmacist.

Section 35.55(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.55(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

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

Section 35.55(b)(3) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of radiopharmaceuticals.

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

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

equipment. Section 35.60(e) requires licensees to retain a record of checks and tests required by Section 35.60(b) in accordance with §35.2060.

Section 35.61 requires licensees to calibrate survey instruments that are used to show compliance with NRC's regulations. Section 35.61(a)(3) 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 were calibrated and operational. Section 35.61(d) requires that licensees retain a record of the survey instrument calibrations in accordance with §35.2061.

Section 35.62 establishes requirements for the possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

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

Section 35.62(c) requires licensees to retain a record of each check and test required by this section in accordance with §35.2060.

Section 35.63(d) requires that licensees retain a record of each radiopharmaceutical dosage determination in accordance with §35.2063.

Section 35.67 establishes requirements for possession of sealed sources and brachytherapy sources.

Section 35.67(a) requires that licensees maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources. These instructions are required so that individuals who handle sources can determine the specific safety

measures appropriate for each kind of source used. The instructions shall be maintained for the duration of source use.

Section 35.67(d) requires that licensees retain a record of sealed source leak tests in accordance with §35.2067.

Section 35.67(e)(2) requires that licensees file a report with the NRC within 5 days if leakage of a sealed source is detected in accordance with §35.3067.

Section 35.67(g) requires that licensees conduct a semi-annual sealed source and brachytherapy source inventory and retain the inventory record in accordance with §35.2067.

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

Section 35.70 requires that licensees survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered. Licensees are also expected to retain a record of each survey in accordance with §35.2070.

Section 35.75 requires that licensees who authorize the release from its control of individuals who have been administered radiopharmaceuticals or implants containing radioactive material take specified actions.

Section 35.75(b) requires that licensees must provide the released individual with instructions on actions recommended to maintain doses to other individuals as

low as is reasonable achievable. The licensees must provide special instructions if the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem).

Section 35.75(c) requires that licensees maintain a record of the basis for authorizing the release of an individual.

Section 35.80 establishes requirements for the provision of mobile services.

Section 35.80(a) 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 of use and delineates the authority and responsibility of each entity. This record is necessary to show that the client's management has permitted this work. This record must be retained for three years after the last provision of service.

Section 35.80(e) requires that mobile service licensees survey all areas of use before leaving a client's address of use and make a record of radiation surveys and retain the record of each survey.

Section 35.80(f) requires that the letter required in §35.80(a) and a record of the surveys required in §35.80(e) be retained in accordance with §35.2080.

Section 35.92(b) requires that licensees retain a record of disposal of waste that was decayed in storage and retain the record in accordance with §35.2092.

Section 35.204(c) requires that licensees measure the molybdenum-99 concentrations in eluates from a molybdenum-99/technetium-99m generator and retain the record in accordance with §35.2204.

Section 35.290 establishes training requirements for authorized users of radiopharmaceuticals for uptake, dilution, or excretion studies.

Section 35.290(a) requires an individual to be certified by a specialty board whose certification

process satisfies the requirements of §35.290(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for uptake, dilution, or excretion studies.

Section 35.290(b)(2) requires an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of a diagnostic radiopharmaceutical for uptake, dilution, or excretion studies. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for uptake, dilution, or excretion studies.

Section 35.290(b)(3) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using radiopharmaceuticals for uptake, dilution, or excretion studies.

Section 35.292 establishes training requirements for authorized users of diagnostic radiopharmaceuticals and generators for imaging and localization studies, except in quantities that require a written directive.

Section 35.292(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.292(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators, except in quantities that require a written directive, for imaging and localization studies.

Section 35.292(b)(2) requires an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of diagnostic radiopharmaceuticals and generators for imaging and localization studies. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators, except in quantities that require a written directive, for imaging and localization studies.

Section 35.292(b)(3) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using diagnostic radiopharmaceuticals and generators for imaging and localization studies.

Section 35.310 requires a licensee, in addition to the requirements of 10 CFR §19.12, to provide radiation safety instruction initially and at least annually to personnel caring for patients or human research subjects who have received radiopharmaceutical therapy and who cannot be released in accordance with §35.75.

Section 35.310(b) requires licensees to retain a record of radiation safety instruction given to personnel who care for radiopharmaceutical therapy patients or human research subjects, in accordance with §35.2310.

Section 35.315 requires licensees to establish safety precautions with respect to patients or human research subjects who have been administered radiopharmaceuticals containing radioactive material and cannot be released in accordance with §35.75.

Section 35.315(a)(2) requires that the licensee post a radiopharmaceutical therapy patient's or human research subject's room with a "Radioactive Materials" sign. This provides notice to hospital workers and the public that there is radioactivity in the room. The section

also requires that the licensee note in the patient's chart how long visitors may stay in the patient's room. This is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules.

Sections 35.315(b) requires that the licensee promptly notify the Radiation Safety Officer, or his designee, if the patient dies or has a medical emergency. This notification is required so that the Radiation Safety Officer or his designee can take whatever actions are necessary to prevent radioactive contamination. The Radiation Safety Officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

Section 35.390 establishes requirements for training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

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

Section 35.390(b)(3) requires an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic radiopharmaceuticals for the uses listed in §35.300. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for therapy.

Section 35.390(b)(4) requires an individual to demonstrate sufficient knowledge in radiation safety by

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

Section 35.404(c) requires a licensee to retain a record of the patient or human research subject surveys required by §§ 35.404(a) and 35.404(b) in accordance with §35.2404.

Section 35.406(c) requires that licensees make a record of brachytherapy source accountability in accordance with §35.2406.

Section 35.410(b) requires that licensees 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.

Section 35.415 requires licensees to establish safety precautions with respect to patients or human research subjects who receive brachytherapy and cannot be released pursuant to §35.75.

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

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

Section 35.432 requires licensees to perform full calibration measurements on brachytherapy sources before the first medical use of the source or the source/applicator configuration, and to retain a record of each calibration in accordance with §35.2432.

Section 35.490 establishes training requirements for authorized users of manual brachytherapy sources for therapeutic medical uses.

> Section 35.490(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.490(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.
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> Section 35.490(b)(3) requires an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of manual brachytherapy sources. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.
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> Section 35.490(b)(4) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using manual brachytherapy.

Section 35.590 establishes training requirements for authorized users of diagnostic sealed sources. These include requiring the authorized user to be a physician, dentist, or podiatrist who has been certified by a specialty board approved by the Commission and has eight hours of classroom and laboratory training that includes basic radionuclide handling techniques specifically applicable to (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use

and measurement of radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested.

Section 35.604(b) requires licensees using sealed sources in devices for therapeutic medical uses immediately after retracting the source from the patient into its shielded position in the device to perform a radiation survey of the patient or human research subject and to retain a record of the survey in accordance with §35.2404.

Section 35.605(d) requires licensees to retain a record of each installation, maintenance, and repair of a therapeutic medical device in accordance with §35.2605.

Section 35.610 establishes requirements for safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.610(a) requires that licensees develop, maintain, and implement specified safety procedures. These procedures are necessary because of the complexity and higher radiation risk associated with these units.

Section 35.610(c) requires that licensees post instructions for individuals who operate the devices at the device console. These instructions are necessary to inform workers of the procedures and to serve as a quick reference in case of emergencies or equipment malfunction.

Section 35.610(e) requires that licensees make a record of initial instruction, refresher training, and practice drills for individuals who operate devices and retain the record in accordance with §35.2310. A record of the training is needed because of the complexity of therapeutic treatment devices.

Section 35.630(c) requires that licensees retain a record of each calibration, intercomparison, and comparison of calibrated dosimetry equipment in accordance with §35.2630.

Section 35.632(g) requires that licensees retain a record of full calibration measurements on teletherapy units in accordance with §35.2632.

Section 35.633(h) requires that licensees retain a record of full calibration measurements on remote afterloaders in accordance with §35.2633.

Section 35.635(g) requires that licensees retain a record of full calibration measurements on gamma stereotactic radiosurgery units in accordance with §35.2635.

Section 35.642 establishes requirements for periodic spot-checks for teletherapy units.

Section 35.642(c) requires that the authorized medical physicist report the results of teletherapy unit output spot- checks promptly to the licensee. This assures the licensee that the results of each spot-check have been reviewed by an expert.

Section 35.642(f) requires that the licensee must retain a copy of each report of monthly teletherapy unit output spot-checks and each monthly teletherapy unit safety spot-checks in accordance with §35.2642.

Section 35.643 establishes requirements for periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.

Section 35.643(b) requires that the licensee have the authorized medical physicist establish procedures for performing periodic spot-checks on high dose-rate and pulsed dose-rate remote afterloaders. This record is necessary to document the procedures and to permit NRC to evaluate the procedures and determine that they are sufficient.

Section 35.643(h) requires that the licensee must retain a copy of each report of weekly and daily spot-checks in accordance with §35.2643.

Section 35.644 establishes requirements for periodic spot-checks for low dose-rate remote afterloaders.

> Section 35.644(c) requires that the licensee shall have the authorized medical physicist establish procedures for performing spot-checks on low dose-rate remote afterloaders prior to each patient treatment and after each source installation. The authorized medical physicist is the most qualified individual to ensure that the procedures are performed in accordance with published protocols approved by nationally recognized bodies.
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> Section 35.644(e) requires that the licensee must retain a copy of each report of spot-checks on low dose-rate remote afterloaders in accordance with §35.2643.

Section 35.645 establishes requirements for periodic spot-checks for gamma stereotactic radiosurgery units.

> Section 35.645(b) requires that the licensee shall have the authorized medical physicist establish procedures for performing spot-checks on gamma stereotactic radiosurgery units monthly and prior to each day of use. The authorized medical physicist is the most qualified individual to ensure that the procedures are performed in accordance with published protocols approved by nationally recognized bodies.
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> Section 35.645(g) requires that the licensee must retain a record of each spot-check in accordance with §35.2645.

Section 35.647(e) requires that the licensee must retain a record of each check of mobile remote afterloaders prior to each change of address of use in accordance with §35.2647.

Section 35.652(b) requires that licensees retain a record of radiation surveys made to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry in accordance with §35.2652.

Section 35.655(c) requires that licensees keep a record of the teletherapy unit and gamma stereotactic radiosurgery unit 5-year inspection and servicing in accordance with §35.2655.

Section 35.690 establishes training requirements for authorized users of therapeutic medical devices.

Section 35.690(a) requires an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.690(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

Section 35.690(b)(4) requires an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic medical device. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

Section 35.690(b)(5) requires an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using therapeutic medical devices.

[Insert Subpart J]

Section 35.2024(a) requires that licensees retain a record of actions taken in accordance with §35.24(a) for five years.

For §35.24(a), the record must include a summary of actions and the signature of licensee management for requests for license application, renewal, or amendment; approvals or disapprovals of requests to allow individuals to work as an authorized user,

authorized nuclear pharmacist, or authorized medical physicist; and approval or disapproval of radiation protection program changes that do not require an amendment. This record is needed to document these actions and the basis for them because they are important to the licensee's radiation safety program.

Section 35.2024(b) requires that licensees retain a current copy of the authorities, duties, and responsibilities of the radiation safety officer as required by §35.24(d). The record must include the signature of the radiation safety officer and licensee management. This record is important to show that the ASD 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.

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

Section 35.2040 requires that licensees retain a copy of each written directive as required by §35.40 for three years. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician. Retention of the written directives and records of each administration for 3 years after the date of the administration will allow NRC to ensure that administrations were in accordance with the written directives by reviewing a sample of written directives and records during an NRC inspection.

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

Section 35.2060 requires that licensees retain a record of instrument calibrations performed in accordance with §§ 35.60 and 35.62 for three years. The records must include:

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

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

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

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

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

Section 35.2061 requires that licensees retain a record of radiation survey instrument calibrations required by §35.61 for three years. The record must include:

(1) A description of the calibration procedure; and

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

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

Section 35.2063 requires that licensees retain a record of dosage determinations required by §35.63 for three years. The record must contain the

(1) Radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical, and its lot number;

(2) Patient's or human research subject's name, or identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of determination, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

(4) Date and time of the determination; and

(5) Initials of the individual who made the record.

This record is required for licensees to show that they are maintaining control of the use of radiopharmaceuticals.

Section 35.2067(a) requires that licensees retain records of leak tests required by §35.67(b) for three years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer. This record is required to show that the leak test was done at the appropriate time, and that the source was not leaking. This report also is needed so that NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.2067(b) requires a licensee to 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, a serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer. This inventory record also is needed to show that possession of sealed sources did not exceed the amount authorized by the license.

Section 35.2070 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, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millrem per hour of the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey. The records are needed to document that the surveys were performed, and to document that radiation exposure rates are below the limits set for protection of workers and the public.

Section 35.2075 requires that licensees retain records of the release of individuals containing radiopharmaceuticals or implants in accordance with §35.75 for three years after the date of release. Section 35.2075(b) requires a licensee to retain a record that describes the basis for authorizing the release of individuals if the total effective dose equivalent is calculated by:

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

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

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

(4) Considering the shielding by tissue.

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

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

Section 35.2080(a) requires licensees providing mobile services to retain a copy of the letters signed by the management of each client. The letter must delineate the authority and responsibility of each entity and be retained for 3 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.

Section 35.2080(b) requires that licensees retain a record of each survey required by §35.80(e) for three years. The record

must include the date of the survey, a plan of each area surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey. These records are needed to show that the required surveys were made.

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

Section 35.2204 requires that licensees retain records of molybdenum-99 concentration tests required by §35.204(b) for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials 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.

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

Section 35.2404 requires that licensees retain a record of the radiation surveys of patients and human research subjects

required by §§35.404 and 35.604 for three years. Each record must include the date and results of the survey, an identifier for the patient or the human research subject, and the survey instrument used, and the initials 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.

Section 35.2406 requires that licensees retain 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 storage, the time and date they were removed from storage, the location of use, the number and activity of sources returned to storage, and the time and date they were returned to storage. For permanent implants, the record must include the number and activity of sources removed from storage, the date they were removed from storage, the number and activity of sources returned to storage, the date they were returned to storage, and the number and activity of sources permanently implanted in the patient or human research subject. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

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

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

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

Section 35.2632 requires that licensees retain records of teletherapy full calibrations required by §35.632 for three years. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for the teletherapy unit, the source, and instruments used to calibrate the teletherapy unit; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; an assessment of timer accuracy and linearity; the calculated on-off error; the estimated accuracy of each distance measuring or localization device; and the signature of the medical physicist. 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.

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

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

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

Section 35.2643 requires that licensees retain records of each spot-check for remote afterloaders required by §§35.643 and 35.644 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the rate remote afterloader; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and

intercom, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the periodic spot-check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

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

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

Section 35.2652 requires that licensees retain records of radiation surveys of treatment units made in accordance with §35.2652 for the duration of use of the unit. The record must include the date of the measurements, the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels, and each dose rate measured around the source while the unit is in the off position

and the average of all measurements, and the signature of the Radiation Safety Officer. This record is necessary to show that the surveys were performed and that the units do not exceed occupational dose levels with the sources in the shielded position.

Section 35.2655 requires that licensees retain records of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by §35.655 for the duration of use of the unit. The record must contain the inspector's name, the inspector's radioactive materials license number, the date of inspection, the manufacturer's name and model number and serial number for both the treatment unit and source, a list of components inspected, and a list of components serviced, and the type of service, and the signature of the inspector. This record is needed to document the type of service that was performed and that any required work was done.

Section 35.3045 requires that licensees report an administration of byproduct material or radiation therefrom that meets or exceeds the criteria in §3045(a).

Section 35.3045(b) 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 to promptly take any necessary actions based on the circumstances.

Section 35.3045(c) requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, and to assure that all notifications were made. The report must include the licensee's name; the names of all individuals involved (including the names of the authorized user and the referring physician); a brief description of the event; why the event occurred; the effects on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence; whether the licensee notified the individual or the responsible relative or guardian, and if not, why not; and if there was notification, what information was provided. The

report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed 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.

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

Section 35.3045(e) requires the licensee to furnish a written report of the medical event to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect him/her. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee. Patients need a written report as a record of information furnished to them verbally.

Section 35.3046(a) requires that licensees report precursor events that met the definition in §35.2 by notifying by telephone the NRC Operations Center no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the RSO or AU could lead to a medical event. The licensee also must submit a written report within 15 days after discovery of the precursor event to the appropriate NRC Regional Office. The report must include the licensee's name; the names of all individuals involved (including the names of the authorized user and the referring physician); a brief

description of the event; why the event occurred; the effects on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. This will ensure that NRC is aware of events that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

Section 35.3047 establishes reporting requirements for any administrations of byproduct material or radiation to (1) a pregnant woman, unless the administration received prior approval, exceeding 5mSv effective dose equivalent to an embryo/fetus; (2) breast feeding woman, unless the administration received prior approval, exceeding 5mSv total dose equivalent to a nursing child. If such an administration occurs, §35.3047 requires licensees to notify by telephone the NRC Operation Center within 5 days and to submit a written report of the administration to the appropriate NRC Regional Office within 30 days of the administration. Section 35.3047 specifies that the written report include the licensee's name; the names of all individuals involved (including, the authorized user and referring physician); a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual.

Section 35.3069 requires that licensees report detection of a leaking source by submitting a written report within 5 days after a leakage test reveals the presence of 0.005 microcurie or more of removable contamination. The report is to be filed with the appropriate NRC Regional Office. The report must include the model number and serial number, if assigned, of the leaking source; radionuclide and its estimated activity; the measured activity of each test sample; a description of the method used to measure each test sample, and the date of the test. This will enable NRC to promptly determine if the necessary follow-up actions were taken following discovery of the leaking source.

Appendix A

Appendix A specifies the requirements for an independent organization or entity that submits an application for approval of the Commission to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.290(b)(3), 35.292(b)(3), 35.390(b)(4), 35.490(b)(4), or 35.690(b)(4). Each such organization or entity must furnish NRC with documentation that demonstrates that it:

Appendix A, Part I, item 1 would require the independent organization to make its examination process available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability. This ensures that the independent organization will uphold 10 CFR Part 4, Subpart A -- Regulations Implementing Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974 with respect to prohibiting discriminatory actions.

Appendix A, Part I, item 2 would require the independent organization to have an adequate staff, a viable system for financing its operations, and a policy- and decision-making review board. This provides information to the NRC that the organization will have the resources to maintain an adequate program.

Appendix A, Part I, item 3 would require the independent organization to have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies. The procedures are needed to ensure the independent organization has a program in place for monitoring and enforcing its by-laws and policies. NRC would review the program description to ensure that it includes this element.

Appendix A, Part I, item 4 would require the independent organization to have a committee, whose members can carry out their responsibilities impartially, to review and approve the examination

guidelines and procedures, and to advise the organization's staff in implementing the examination program. This provides information to the NRC that the organization has a mechanism in place for ensuring the technical quality of the examination.

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

Appendix A, Part I, item 6 would require the independent organization to have written procedures describing all aspects of its examination program, maintain records of the current status of each individual's examination and the administration of its examination program. The records are needed by the independent organization to maintain an awareness of an individual's examination results and to record the organization's administration of its certifying or examination program.

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

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

Appendix A, Part I, item 9 would require the independent organization to have procedures for proctoring examinations, including qualifications for proctors. The procedures are needed to help ensure fairness in the examination process. NRC would review the program description to ensure that it includes this element.

Appendix A, Part I, item 10 would require the independent organization to exchange information about examined individuals with the Commission and other independent examining organizations and/or Agreement States and allows periodic review of its examination program and related records. The exchange of information and periodic review are to ensure that all individuals' certifications are current and valid. NRC would review the program description to ensure that it includes this element.

Appendix A, Part I, item 11 would require the independent organization to provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment. The procedures are needed to ensure that the independent certifying organization provides for appropriate examination sites and environments. NRC would review the program description to ensure that it includes this element.

Appendix A, Part II, item 2 would require the independent organization to include procedures in its examination program to ensure that all examination questions are protected from disclosure. The purpose of these procedures is to ensure the fairness of the examination. NRC would review the program description to ensure that it includes this element.

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

2. Agency Use of Information

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

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information, the applications and reports do not lend themselves readily to the use of automated information technology for submission.

4. Effort to Identify Duplication and Use Similar Information

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

and records is the most effective and least burdensome means of obtaining the information.

5. Effort to Reduce Small Business Burden

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

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

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

Applications are only required to be submitted for the initial license, for amendments, and for renewal every 10 years. The application process requires that applicants and licensees perform a comprehensive review of their entire radiation safety program to assure that all activities will be or are being conducted safely and in accordance with NRC regulations. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has the training, experience, equipment, and facilities that are adequate to protect the public health and safety. Other reporting and recordkeeping requirements are occasioned by specific events, such as inventories of licensed material, calibrations and checks of medical devices, medical events, and precursor events. Collection of information at the required frequency from licensees that use byproduct material in the treatment of patients as human research subjects is essential to protect the health and safety of workers and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

Section 35.14 establishes the notification requirements for licensees who are altering their existing license structure. Section 35.14(a) requires licensees provide the Commission with a

copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, pursuant to §35.13(b)(1) through (b)(5).

Contrary to the OMB Guidelines, Section 35.14(b) requires that licensees notify the NRC within 30 days if a (1) an authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change; (2) the licensee's mailing address changes; or (3) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described in §30.34(b); (4) the licensee has added to or changed the areas of use where byproduct material is used in accordance with §§ 35.100 and 35.200 ends his association with the licensee. This prompt report 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 safety. This report will trigger a check of the licensee's file to determine whether the remaining key users are qualified to receive and use material safely.

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

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

Section 35.2024 requires that licensees retain a record of actions taken as required by §§ 35.24(a) and (d) for five years. Section 35.24(a) pertains to management approvals of requests for

license application, renewal, or amendments; to management approvals of individuals prior to their work as a radiation safety officer, authorized user, authorized nuclear pharmacist, or authorized medical physicist; and to radiation protection program changes that do not require a license amendment. Section 35.24(d) pertains to establishment in a written statement of authority, duties, responsibilities, and radiation safety activities for the radiation safety officer. Retention of these records is necessary to document continuing management oversight of the licensee's radiation safety program and to ensure that the licensee's management and the RSO are aware of their responsibilities.

Section 35.2026 requires that licensees retain a record of minor radiation safety program changes for five years. This record is needed to show what radiation safety factors were considered before implementing the minor change. This permits NRC to evaluate the nature and appropriateness of the minor changes during inspections. Maintaining this record for five years provides the NRC with a complete record of the radiation safety program changes for review during inspections and until the changes are incorporated into the license at renewal.

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

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

Section 35.2655 requires that licensees keep a record of five-year inspections for teletherapy and gamma stereotactic radiosurgery units for the duration of use of the unit. This record is required throughout the period of use of the unit to show that the required work was done and to establish a service

history that may be used in incident investigations and evaluation of generic equipment problems.

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

Section 35.3045(c) requires licensees to submit a written report to the approriate NRC Regional Office listed in §30.6 within 15 days after discovery of the medical event. The contents of these reports are specified by §35.3045(c).

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

Section 35.3046 requires that licensees file a report with the NRC within 15 days of any significant precursor event. This report will enable NRC to promptly take any necessary actions based on the circumstances to notify other licensees and to address the root causes of the precursor event.

Section 35.3046(a) requires licenses to notify by telephone the NRC Operations Center no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or authorized user, could lead to a medical event. NRC requires submission of the report no later than the next calendar day so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.3047 establishes reporting requirements for any administrations of byproduct material or radiation to (1) a pregnant woman, unless the administration received prior approval, exceeding 5mSv effective dose equivalent to an embryo/fetus; (2) breast feeding woman, unless the administration received prior approval, exceeding 5mSv total dose equivalent to a nursing child. If such an administration occurs, §35.3047 requires licensees to notify by telephone the NRC Operation Center within 5 days and to submit a written report of the administration to the appropriate NRC Regional Office within 30 days of the administration. Section 35.3047 specifies that the written report include the licensee's name; the names of all individuals involved (including, the authorized user and referring physician); a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual. NRC requires submission of the report within 5 days, with followup written report within 30 days, so that NRC can ensure that appropriate follow-up actions are taken.

Section 35.3067 requires that licensees file a report with the NRC within 5 days if leakage of a sealed source is detected. This report is necessary so that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

8. Consultations Outside the Agency

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards (listed below); putting

background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA and Chicago, IL, held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997 and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

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

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

Interactions with Medical Professional Societies

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

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

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

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:

The total annual burden is estimated to be about 337,165 hours per year (about 177 hours per licensee) for the 1,902 licensees

covered by 10 CFR Part 35. The details are shown in Tables 1 and 2. The total cost for the NRC licensees is estimated at $42,145,625 (337,165 hours x $125.00 per hour).

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

Agreement State Licensees:

Part 35 of Title 10 of the Code of Federal Regulations is a Division III level of compatibility for Agreement States. The Agreement states are encouraged to adopt similar regulations, but are not required to have any degree of uniformity between the NRC regulations and the State regulations. The burden for Agreement State licensees is calculated on the basis of Agreement States having similar regulations for medical use programs.

The total annual burden is estimated to be about 827,540 hours per year (about 174 hours per licensee) for the estimated 4,760 licensees covered by equivalent regulations. The details are shown in Tables 3 and 4. The total cost for the Agreement State licensees is estimated at $103,431,250 (827,450 hours x $125.00 per hour).

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

The estimates are based on the number of licensees, an evaluation of the amount of time to perform individual activities, and the number of times these activities are performed. The burden only includes the time to prepare the report or record, and does not include the time in performing the required activity. Cost to licensees and applicants is calculated at an average rate of $125.00 per hour. This figure includes both salaries and overhead.

13. Estimate of Other Additional Costs

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

14. Estimated Annualized Cost to the Federal Government

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

Annual Cost of NRC staff review for activities other than application review (Professional effort is 239 hours @ $116.00 per hour) = $27,724.

15. Reasons for Changes in Burden and Cost

NRC Licensees:

The revision is a net downward adjustment in burden of 154,413 hours as a result of a comprehensive revision of the Part 35 requirements to eliminate prescriptive requirements. Ten reporting requirements, with an estimated burden of 38,414 hours were eliminated as a result of rulemaking since the last burden was calculated. (Sections 35.60(b), 35.61(b), 35.70(d), 35.70(g), 35.315(a)(6), 35.610(a), 35.643(a)(3), 35.643(b), 35.645, and 35.980(b)(2).) Three recordkeeping requirements were eliminated (35.20, 35.22(a)(4) and (5), and 35.32) and numerous other requirements were revised.

16. Publication for Statistical Use

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

17. Reason for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

Not Applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

Table 1: Reporting Requirements - NRC Licensees

Section	No. of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.12(b)	OMB Clearance 3150-0120		
35.12(c)	OMB Clearance 3150-0120		
35.12(d)	2	4	8
35.13	OMB Clearance 3150-0120		
35.14	221	0.5	111
35.50(a)	48	0.5	24
35.50(b)(2)	53	1	53
35.50(b)(3)	114	0.25	100
35.51(a)	48	0.5	24
35.51(b)(2)	53	1	53
35.51(b)(3)	53	0.25	93
35.55(a)	2	0.5	1
35.55(b)(2)	2	1	2
35.55(b)(3)	2	0.25	0.5
35.69(e)(2)	Burden calculated in 35.3069		
35.75(b)	25,429	0.166	4,238
35.290(a)	283	0.5	141
35.290(b)(2)	314	1	314
35.290(b)(3)	31	0.25	8
35.292(a)	283	0.5	141
35.292(b)(2)	314	1	314
35.292(b)(3)	31	0.25	8
35.315(a)(2)	3,200	0.2	640

Table 1: Reporting Requirements - NRC Licensees (continued)

Section	No. of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.315(b)	16	1	16
35.390(a)	332	0.5	166
35.390(b)(3)	369	1	369
35.390(b)(4)	37	0.25	9
35.415(a)	8,700	0.2	1,740
35.415(c)	73	1	73
35.490(a)	39	0.5	19
35.490(b)(3)	43	1	43
35.490(b)(4)	43	0.25	11
35.590	324	0.5	162
35.642(c)	756	0.25	189
35.690(a)	39	0.5	19
35.690(b)(4)	43	1	43
35.690(b)(5)	43	0.25	11
35.3045(b)	30	0.5	15
35.3045(c)	30	8	240
35.3045(d)	30	2	60
35.3045(e)	30	2	60
35.3046(a)	476	4	1,904
35.4047	1	8	8
35.3067	2	2	4
Appendix A	39	120	4,680
Total:	41,978	168.316	16,114.5

Table 2: Recordkeeping Requirements - NRC Licensees

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.24(f)	Burden calculated in 35.2024			
35.26(b)	Burden calculated in 35.2026			
35.60(d)	Burden calculated in 35.2060			
35.61(a)(3)	1,902	0.03	57	Equipment duration
35.61(c)	Burden calculated in 35.2061			
35.62(c)	Burden calculated in 35.2060			
35.63(d)	Burden calculated in 35.2063			
35.67(a)	1,885	0.5	942	Source duration
35.67(d)	Burden calculated in 35.2069(a)			
35.67(g)	Burden calculated in 35.2069(b)			
35.69	1,707	1	1,707	
35.70	Burden calculated in 35.2070			
35.75(c)	Burden calculated in 35.2075			
35.75(d)	Burden calculated in 35.2075			
35.80(a)	40	20	800	3 years after last service
35.80(e)	Burden calculated in 35.2080			
35.92(b)	Burden calculated in 35.2092			
35.204(c)	Burden calculated in 35.2204			
35.310(b)	Burden calculated in 35.2310			
35.404(c)	Burden calculated in 35.2404			
35.406(b)	Burden calculated in 35.2406			
35.410(b)	Burden calculated in 35.2301			
35.432	Burden calculated in 35.2432			

Table 2: Recordkeeping Requirements - NRC Licensees (continued)

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.604(b)	Burden calculated in 35.2404			
35.605(d)	Burden calculated in 35.2605			
35.610(c)	195	0.5	90	Duration of use of unit
35.610(e)	Burden calculated in 35.2310			
35.630(c)	Burden calculated in 35.2630			
35.632(g)	Burden calculated in 35.2632			
35.633(h)	Burden calculated in 35.2633			
35.635(g)	Burden calculated in 35.2635			
35.642(c)	Burden calculated in 35.2642			
35.643(g)	Burden calculated in 35.2643			
35.644(e)	Burden calculated in 35.2643			
35.645(g)	Burden calculated in 35.2645			
35.647(e)	Burden calculated in 35.2647			
35.652(b)	Burden calculated in 35.2652			
35.655(c)	Burden calculated in 35.2655			
35.2024(b)	1,216	1	1,216	5 years
35.2026	1,902	1	1,902	5 years
35.2040	1,902	1	1,902	3 years
35.2045	1,902	1	1,902	3 years
35.2060	55	0.2	11	3 years
35.2061	1,902	0.5	951	3 years
35.2063	1,757	47	82,579	3 years
35.2067(a)	1,885	2	3,770	3 years

Table 2: Recordkeeping Requirements - NRC Licensees (continued)

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.2067(b)	1,885	0.16	59	3 years
35.2070	1,885	66	124,410	3 years
35.2075	4,914	0.13	638	3 years
35.2080	40	130	5,200	3 years
35.2092	1,757	14	24,598	3 years
35.2204	674	1	674	3 years
35.2310	1,902	2	3,804	3 years
35.2404	18,286	0.25	4,571	3 years
35.2406	18,286	0.5	9,143	3 years
35.2432	63	1	63	3 years
35.2605	195	2	390	3 years
35.2630	521	0.5	260.5	3 years
35.2632	63	4	252	3 years
35.2633	143	4	572	3 years
35.2635	9	4	36	3 years
35.2642	63	12	1068	3 years
35.2643	143	312	44,616	3 years
35.2645	9	272	2,448	3 years
35.2647	0	0	0	3 years
35.2652	208	2	416	Duration of use of unit
35.2655	65	0.05	3	Duration of use of unit
Total:	69,361	903.3	321,051	

Table 3: Reporting Requirements - Agreement State Licensees

Section	No. of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.12(b)	OMB Clearance 3150-0120		
35.12(c)	OMB Clearance 3150-0120		
35.13	OMB Clearance 3150-0120		
35.14	1,178	0.5	589
35.50(a)	120	0.5	60
35.50(b)(2)	133	1	133
35.50(b)(3)	286	0.25	72
35.51(a)	120	0.5	60
35.51(b)(2)	133	1	133
35.51(b)(3)	133	0.25	33
35.55(a)	3	0.5	1.5
35.55(b)(2)	3	1	3
35.55(b)(3)	3	0.25	.75
35.69(e)(2)	Burden calculated under 35.3069		
35.75(b)	63,673	0.166	10,553
35.290(a)	707	0.5	354
35.290(b)(2)	785	1	785
35.290(b)(3)	78	0.25	19.5
35.292(a)	707	0.5	354
35.292(b)(2)	785	1	785
35.292(b)(3)	78	0.25	19.5
35.315(a)(2)	8,000	0.2	1,600
35.315(b)	40	1	40

Table 3: Reporting Requirements - Agreement State Licensees (continued)

Section	No. of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.390(a)	830	0.5	415
35.390(b)(3)	923	1	923
35.390(b)(4)	93	0.25	23
35.415(a)	21,750	0.25	5,437.5
35.415(c)	183	1	183
35.490(a)	97	0.5	49
35.490(b)(3)	107	1	107
35.490(b)(4)	107	0.25	27
35.590	810	0.5	405
35.642(c)	1,896	0.25	474
35.690(a)	97	0.5	49
35.690(b)(4)	107	1	107
35.690(b)(5)	107	0.25	27
35.3045(b)	75	0.5	38
35.3045(c)	75	8	600
35.3045(d)	75	2	150
35.3045(e)	75	2	150
35.3046(a)	1,189	4	4,756
35.4047	1	8	8
35.3067	4	2	8
Appendix A	N/A	N/A	N/A
Total:	104,703	44.366	29,531.75

Table 4: Recordkeeping Requirements - Agreement State Licensees

Section	No. of Agreement State Recordkeepers (2.5 x No. NRC licensees)	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.24(f)	Burden calculated in 35.2624			
35.26(b)	Burden calculated in 35.2026			
35.40	Historically part of patient records.			
35.60(d)	Burden calculated in 35.2060			
35.61(a)(3)	4,760	0.03	143	Equipment duration
35.61(c)	Burden calculated in 35.2061			
35.62(c)	Burden calculated in 35.2060			
35.63(d)	Burden calculated in 35.2063			
35.67(a)	4,713	0.5	2,356	Source duration
35.67(d)	Burden calculated in 35.2069(a)			
35.67(g)	Burden calculated in 35.2069(b)			
35.69	4,267	1	4,267	
35.70	Burden calculated in 35.2070			
35.75(c)	Burden calculated in 35.2075			
35.75(d)	Burden calculated in 35.2075			
35.80(a)	100	20	2,000	3 years after last service
35.80(e)	Burden calculated in 35.2080			
35.92(b)	Burden calculated in 35.2092			
35.204(c)	Burden calculated in 35.2204			
35.310(b)	Burden calculated in 35.2310			
35.404(c)	Burden calculated in 35.2404			
35.406(b)	Burden calculated in 35.2406			
35.410(b)	Burden calculated in 35.2310			
35.432	Burden calculated in 35.2432			

Table 4: Recordkeeping Requirements - Agreement State Licensees (continued)

Section	No. of Agreement State Recordkeepers (2.5 x No. NRC licensees)	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.604(b)	Burden calculated in 35.2404			
35.605(d)	Burden calculated in 35.2605			
35.610(c)	494	0.5	225	Equipment duration
35.610(e)	Burden calculated in 35.2310			
35.630(c)	Burden calculated in 35.2630			
35.632(g)	Burden calculated in 35.2632			
35.633(g)	Burden calculated in 35.2633			
35.635(g)	Burden calculated in 35.2635			
35.642(c)	Burden calculated in 35.2642			
35.643(g)	Burden calculated in 35.2643			
35.644(e)	Burden calculated in 35.2643			
35.645(f)	Burden calculated in 35.2645			
35.647(d)	Burden calculated in 35.2647			
35.650(c)	Burden calculated in 35.2650			
35.652(b)	Burden calculated in 35.2652			
35.655(c)	Burden calculated in 35.2655			
35.660	Burden calculated in 35.2316			
35.2024	3,040	1	3,040	5 years
35.2026	4,760	1	4,760	3 years
35.2040	Historically part of patient record			
35.2045	4,760	1	4,760	3 years
35.2060	138	0.2	28	
35.2061	4,760	0.5	2,380	3 years
35.2063	4,392	47	206,424	3 years

Table 4: Recordkeeping Requirements - Agreement State Licensees (continued)

Section	No. of Agreement State Recordkeepers (2.5 x No. NRC licensees)	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.2067(a)	4,713	2	9,426	3 years
35.2067(b)	4,713	0.16	754	3 years
35.2070	4,713	66	311,058	3 years
35.2075	12,285	.13	1,597	3 years
35.2080	100	130	13,000	3 years
35.2092	4,392	14	61,495	3 years
35.2204	1,685	1	1,685	3 years
35.2310	4,760	2	9,520	3 years
35.2404	45,714	0.25	11,428	3 years
35.2406	45,714	0.5	22,857	3 years
35.2432	158	1	158	
35.2605	494	2	988	3 years
35.2630	208	0.5	104	3 years
35.2632	158	4	632	3 years
35.2633	357	4	1,428	3 years
35.2635	21	4	84	3 years
35.2642	158	12	1,896	3 years
35.2643	357	312	111,384	3 years
35.2645	21	272	6,300	3 years
35.2647	3	260	780	3 years
35.2652	522	2	1,044	Duration of use of unit
35.2655	165	0.05	8	Duration of use of unit
Total:	167,595	1,162.32	798,009	