DRAFT SUPPORTING STATEMENT FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL

(3150-0010)

EXTENSION

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 contains the Nuclear Regulatory Commission's (NRC) requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

The recordkeeping requirements of Part 35 are centralized into Subpart L - Records (§§ 35.2024-2655). Cross references to the recordkeeping requirements in Subpart L appear in other related portions of the Part 35 rule, but these cross references do not constitute additional recordkeeping requirements. Reporting requirements are included in multiple subsections throughout Part 35, according to the specific medical use of the material.

In addition to the requirements on licensees, specialty board certification entities desiring to be recognized by the NRC under the requirements of Subparts B and D-H submit a one-time request for recognition and infrequently submit to revise the information.

The burden for the training and experience requirements for individuals in Subparts B and D-H are related as appropriate to the clearance for NRC Form 313, "Application for Material License," and to the NRC Form 313A series of forms for individuals seeking authorization for recognition as authorized users (AU), authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), radiation safety officers (RSO) and associate radiation safety officers (ARSO); which are cleared under the Office of Management and Budget (OMB) Clearance No. 3150-0120. Subsequent references to "NRC Form 313" are intended to refer to NRC Form 313 and to the NRC Form 313A series of forms for recognition as AU, AMP, ANP, RSO and ARSO.

This supporting statement includes burden for all information collection requirements contained in 10 CFR Part 35, including those added or amended in the Final Rule, “10 CFR Parts 30, 32, and 35, Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments” (published July 16, 2017, 83 FR 33046, approved by OMB on July 18, 2018.)

A. JUSTIFICATION

The NRC regulates and licenses the medical use of byproduct materials, as provided by the Atomic Energy Act as amended, and the Energy Reorganization Act of 1974, in order to provide for the radiation safety of workers, the general public, and patients. Licensees must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. Certain specialty board certification entities may request recognition of their certifying processes so that individuals certified by the entity can provide documentation of their board certification as evidence of training and experience. The records required by Part 35 are the least burdensome way for licensees and certification boards to demonstrate compliance with the NRC's requirements.

However, certain events are of such significance that they must be reported to the NRC, to patients or human research subjects, and to referring physicians.

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

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

   The NRC regulates the use of byproduct material in medicine as necessary to provide for the radiation safety of workers and the general public in a risk-informed and performance-based manner. 10 CFR Part 35 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

   The need for each specific requirement is described in Appendix A, “Description of Information Collection Requirements.”

2. Agency Use of Information

   The NRC uses the records and reports required in this part to ascertain that licensees' medical use programs are adequate to protect public health and minimize danger to life and property and that licensees' personnel are aware of and follow up on the information and steps needed to perform licensed activities in a safe manner. The NRC uses the reports made by the specialty boards to determine if their certification process meets the NRC requirements for recognition under the appropriate regulation. The staff makes use of the specialty board and licensee records and reports to determine whether the licensee has individuals with adequate training and experience to safely use byproduct material or radiation from byproduct material to be administered to patients or human research subjects. The staff also makes use of the records and reports to determine whether the licensee has the facilities and equipment necessary to assure protection of public health and safety. The NRC also uses the information to develop reports to inform Congress and the public about the measures taken to provide for the radiation safety of workers, the general public, and patients, and to alert licensees to issues of general concern. Reports of medical events are required to ensure that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or to alert other medical use licensees, to prevent similar events that may have generic implications. In addition, collection of this information enables the NRC to ascertain whether such events are evaluated by the licensee, reported to patients or human research subjects, and referring physicians and that corrective action is taken.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondent to use information technology when it would be beneficial to them.

The NRC has issued Guidance for Electronic Submissions to the NRC which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 25% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

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

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

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

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

Reports made by a specialty board certification entity desiring to be recognized by the NRC under the requirements of Subparts B and D-H are submitted in a one-time request for recognition and infrequently to revise the information.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to OMB's implementing regulation at 5 CFR 1320.5(d), some of the provisions in the revision of Part 35 require licensees to maintain records for more than 3 years or to report information to the NRC or to patients' physicians within less than 30 days following an occurrence.

Paragraph 35.67(e)(2) requires that, in accordance with § 35.3067, a licensee file a report within 5 days if a leakage test reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination. This report is necessary so that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions and to promptly notify other licensees if it appears there may be a generic problem. The NRC allows the licensee up to 5 days to submit the report so that the licensee can review and analyze the leak test result.

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

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

Paragraph 35.645(b)(2) requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing of the results of each spot check. The purpose of this requirement is to ensure that the AMP is aware of any problems noted during the spot check and that the licensee is aware of the performance of the unit so that patients are not administered incorrect doses.

Paragraph 35.2024(a) requires that a record of actions taken by licensee's management in accordance with § 35.24(a) be retained for 5 years to allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

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

Section 35.2026 requires that a record of radiation safety program changes in accordance with § 35.26 be retained for 5 years to allow the NRC to evaluate the nature and appropriateness of such changes during inspections.

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

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

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

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

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

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

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

Section 35.2652 requires that a record of radiation surveys of treatment units made in accordance with § 35.652 be retained for the duration of use of the unit to provide assurance that the source was properly installed or repaired and that the unit did not exceed occupational dose levels with the sources in the shielded position. These records also would be necessary in reconstructing the contributing factors following an incident involving the unit.

Section 35.2655 requires that a record of 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 be retained for the duration of use of the unit. This record is required throughout the period of use of the unit to show that the required work was done and to establish a service history that may be used in incident investigations and evaluation of generic equipment

problems.

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

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

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

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

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

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

8. Consultations Outside the Agency

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*.

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

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

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

This supporting statement provides an estimate of the reporting, recordkeeping, and third- party disclosure burden for 10 CFR Part 35 NRC and Agreement States licensees.

Section 274 of the Atomic Energy Act of 1954 provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Act. Licensees operating in these "Agreement States" are referred to in this supporting statement as "Agreement State Licensees." A map of Agreement States and non-Agreement states is located on NRC's website at https://scp.nrc.gov/rulemaking.html. The NRC has established compatibility requirements for Agreement States to implement their own regulations in a manner consistent with NRC regulations.

The NRC does not have data on the number of licensee's subject to Part 35 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. In the last survey, 7.2 times more licensees in Agreement States as there were in states regulated by the NRC. For this clearance, the total number of Agreement State licensees subject to Part 35 was estimated using the ratio of the total number of Agreement State materials licensees to the total of NRC materials licensees. The current ratio is 7.2 (7.2 Agreement State licensees: 1 NRC licensee). Because there are 856 known NRC materials licensees subject to Part 35, staff estimated there are currently 6,163 Agreement States materials licensees subject to Part 35 (865 NRC licenses x 7.2 = 6,163).

The number of NRC record keepers (856) is taken from the NRC's web based licensing system (WBL) and master materials licensee database. The Agreement State record keepers (6,163) is derived from multiplying the number of NRC medical use licenses by the ratio of all NRC materials licenses and all Agreement State material licenses. This ratio is 7.2. The NRC estimates 2 specialty certifying entities

provide updated information per year.

In addition to NRC licensee and Agreement State licensee respondents, the NRC anticipates submission of two applications annually for specialty certifying entities, at 2 hours per application.

The total number of respondents is as follows:

Part 35 Respondents	
NRC licensees	856
- Agreement State licensees	6,163
Specialty certifying entities	2
Total	7,021

The following table summarizes the burden for Part 35.

Part 35 Totals	Burden	Responses	Cost @ $278/hr
Reporting	69,391	292,182	$ 19,290,698
Recordkeeping	1,097,177	7,019	$ 305,015,206
Third Party Disclosure	127	65	$ 35,306
Total	1,166,695	299,266	$ 324,341,210

Detailed tables showing the burden for each information collection requirement in 10 CFR Part 35 are included as a supplementary document to this submission, "Burden Spreadsheet for 10 CFR Part 35 information collections.

The $278 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2019 (84 FR 22331, May 17, 2019).

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Because the recordkeeping burden is estimated to be 1,097,177, the storage cost for this clearance is $ 122,006 (1,097,177 x 0.0004 x $278 (overall hourly fee rate).

14. Estimated Annualized Cost to the Federal Government

For the requested clearance period, the annualized burden and cost to NRC staff for review of submittals made under Part 35 is estimated to be 300 hours and $83,400 ($278 per hour x 300 hours).

15. Reasons for Changes in Burden

The burden for Part 35 increased from 1,104,583 hours to 1,166,695 hours, an increase of 62,111 hours. 58,244 hours of this increase is an increase in recordkeeping burden. The following table summarizes the increase:

Part 35 Burden Totals	Previous submission	Current Request	Change
Reporting	65,571	69,391	3,820
Recordkeeping	1,038,933	1,097,177	58,244
Third Party Disclosure	80	127	47
Total	1,104,583	1,166,694	62,111

The number of estimated respondents decreased slightly from 7,121 to 7,021. Data on the number of NRC licensees is extracted from the Web-Based Licensing system (WBL). NRC staff queried the database to determine the total number of NRC licensees as well as the number of licensees holding licenses authorizing materials used for specific medical purposes. The data were used to estimate respondents on the NRC licensee burden tables. NRC staff anticipates that the number of licensees will remain stable over the course of the clearance period.

The NRC does not have data on the number of licensee's subject to Part 35 who operate in Agreement States; therefore, the number of these licensees must be estimated. Annually, the Agreement States provide the NRC with an estimate of the total number of radioactive materials licensees within their states. In the last survey, 7.2 times more licensees in Agreement States as there were in states regulated by the NRC. This is an increase from the previous renewal, in which the ratio was 6.4. Since the last renewal, Wyoming and Vermont became Agreement States (AS). There are now 39 AS compared to 37 in the last renewal.

In states regulated by the NRC, data is available on both the number of licensees and the particular applications of the material for which they are licensed. As a result, the NRC can determine the specific requirements in the CFR and the specific information collections applicable to each of the licensees regulated by the agency. For AS, the NRC staff only knows the total number of licensees in each state - the specific applications of the material for they are licensed is unknown.

As a result of the estimation method, the number of licensees in AS may show some variability over time, particularly when states newly join the AS program. For example, before they became AS, the number of licensees subject to each requirement in 10 CFR Part 35 was known for licensees in Wyoming and Vermont, because they were regulated by the NRC and the NRC had their data in the web-based licensing system. After these states became AS, the NRC did not have complete date on these licensees. Instead, NRC staff must estimate the number of licensees in WY and VT that are subject to each information collection requirement.

Further, the method used to estimate respondents assumes that all types of licensees and applications of materials are equally distributed across states, and that the distribution is similar in Agreement States when compared to non-Agreement states. The NRC staff believes that the current method strikes the best balance between accuracy in estimation and burden upon licensees. The current estimation method is the most accurate available without burdening the AS with an annual, comprehensive survey of the specific types of licensees in each Agreement State.

In addition, there was an increase in the overall hourly fee rate from $265/hr to $278/hr.

16. Publication for Statistical Use

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

17. Exceptions to the Certification Statement

Not Applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not Applicable

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APPENDIX A
DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS

§ 35.6 Provisions for the protection of human research subjects

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

This section also requires a licensee whose research is not conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects to apply for and receive approval of a specific amendment to its NRC medical use license before conducting such research. The amendment request must include a written commitment that the licensee will, prior to conducting research: (1) obtain review and approval of the research by an "Institutional Review Board," as defined and described in the Federal Policy; and (2) obtain "informed consent," as defined and described in the Federal Policy, from the human research subject. This information is needed to ensure the licensee's compliance with the requirements for the protection of human subjects.

§ 35.12 Application for license, amendment, or renewal

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

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

Paragraph 35.12(d), in addition to the requirements in paragraphs (b) and (c) of this section, requires that an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in the requirements of Subparts A through C of this part. The applicant also is required to provide specific information on: (1) radiation safety precautions and instructions; (2) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (3) calibration,

maintenance, and repair of instruments and equipment necessary for radiation safety. The applicant or licensee also is required to provide any other information requested by the Commission in its review of the application. This information is needed to enable the Commission to evaluate a license application for a new medical use of byproduct material that is not specifically addressed in subparts D through H of Part 35. The burden for new modalities is submitted on NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.13 License amendments

This section requires that licensees apply for and receive a license amendment before receiving, preparing, or using byproduct material for medical uses that are permitted under Part 35, but are not authorized by the licensee's current license issued under this part; before permitting anyone to work as an AU, ANP, or AMP under the license, except as provided in § 35.14(a); before changing RSOs or ARSOs, except as provided in § 35.24(c); before receiving byproduct material in excess of the amount or in a different form than is authorized on the license, or receiving a different radionuclide than is authorized on the license; before adding or otherwise changing areas of use identified in the application or on the license including areas used in accordance with §§ 35.100 and 35.200 if the change includes addition or relocation of either an area where positron emission tomography (PET) radionuclides are produced or a PET radioactive delivery line from a PET radionuclide/PET radioactive drug production area (other areas of use where byproduct material is used only in accordance with §§ 35.100 and 35.200 are exempt) before changing the address(es) of use identified in the application or on the license, and before revising procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety. The information is necessary to determine the licensee's ability to control radiation dose to workers, patients, and the public; and for NRC to contact the licensee or conduct an inspection of the licensee's program. The information also is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely and has the facilities and equipment necessary to ensure protection of public health and safety.

Paragraph 35.13(d) requires a licensee to apply for and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license. The information is required so that the NRC can determine whether the individual has adequate training and experience (T&E) to serve as an ARSO. The burden for Section 35.13 is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.14 Notifications

Paragraph 35.14(a) requires that licensees provide to the Commission a copy of the board certification and written attestation, the Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by a licensee of broad scope, or the permit issued by an NRC master material license broad scope permit for each individual no later than 30 days after the date the licensee permits the individual to work as an AU, as an ANP, or as an AMP. The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely.

Paragraph 35.14(b) requires that licensees notify the NRC by letter no later than 30 days after an ANP, AU, AMP, RSO or ARSO permanently discontinues performance of duties under the

license or has a name change; when a qualified individual functions as a temporary RSO; when the licensee's mailing address changes; when the licensee has a name change that is not a transfer of control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have added to or changed the areas of use identified in the application or on the license, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. The report for AU and ANP is required in order to maintain the license file with a current record of individuals authorized to use or prepare byproduct material. The report for changes in "key" workers and temporary RSO 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 uses. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use byproduct material safely. The NRC needs to be aware who is temporarily responsible for implementing the radiation safety program. 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 35.14 (b)(1) requires a licensee to notify the Commission within 30 days of when an ARSO discontinues performance of duties under the license or has a name change. The report is required in order to maintain the license file with a current record of individuals responsible for the safe use of byproduct material.

Section 35.14(b)(6) requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee will have to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number for a sealed source listed in the sealed source and device registry (SSDR) used for manual brachytherapy for quantities and isotopes already authorized by the license. The notification is used in lieu of a license amendment requirement which was removed under § 35.13(i). This notification is required in order for the NRC to have an accurate record of sealed sources possessed by a licensee.

§ 35.19 Specific exemptions

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

§ 35.24 Authority and responsibilities for the radiation protection program

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

Paragraph 35.24(b) requires that a licensee's management appoint a RSO who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more ARSO to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each ARSO. These duties and tasks are restricted to the types of use for which the ARSO is listed on a license. The RSO may delegate duties and tasks to the ARSO but shall not delegate the authority or responsibilities for implementing the radiation protection program. The recordkeeping burden is captured in § 35.2024(c).

Paragraph 35.24(e) requires a licensee to establish in writing the authority, duties, and responsibilities of the RSO, so that the duties and responsibilities of the RSO are clearly defined, and the RSO is provided sufficient authority to assure that the licensee's radiation safety activities are being performed in accordance with regulatory requirements.

Paragraph 35.24(f) requires licensees who are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The requirement to establish a Radiation Safety Committee to oversee the radiation protection program provides assurance both to the licensees and the NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program.

Paragraph 35.24(h) requires that a record of actions taken pursuant to paragraphs (a), (b) and (e) be retained in accordance with § 35.2024. A description of the contents of the record and the need for the record is provided under § 35.2024.

§ 35.26 Radiation protection program changes

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

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

§ 35.27 Supervision

Paragraph 35.27(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an AU as allowed by § 35.11(b) to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, Part 35 regulations, and license conditions with respect to the use of byproduct material. This instruction is necessary to provide high confidence that the supervised individual knows and follows all of these procedures, regulations, and license

conditions.

Paragraph 35.27(b) requires a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an ANP or physician who is an AU as allowed by § 35.11(b)(2) to instruct the supervised individual in the preparation of byproduct material for medical use and require the supervised individual to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, radiation protection procedures, Part 35 regulations, and license conditions. This instruction is necessary to provide high confidence that the supervised individual properly prepares byproduct material for medical use.

§ 35.40 Written directives

Paragraph 35.40(a) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration. The regulatory text of § 35.40(b) requires:

> (b) The written directive must contain the patient or human research subject's name and the following information—
>
> (1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;
>
> (2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
>
> (3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
>
> (4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
>
> (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
>
> (6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
>
> (i) Before implantation: treatment site, the radionuclide, and dose; and
>
> (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

If an oral directive is used because of the emergent nature of the patient's condition, subsection 35.40(a)(1) requires the information in the oral directive to be documented as soon as possible in writing in the patient's record and a written directive must be prepared within 48 hours of the oral directive. Documenting an oral directive is needed to ensure that complete record is made of the administration of byproduct material or radiation from byproduct material.

Paragraph 35.40(c) permits a written revision to an existing written directive if the revision is dated and signed by an AU before the administration or the next fractional dose. If an oral revision to an existing written directive is used because of the emergent nature of the patient's

condition, the oral revision must be documented as soon as possible in the patient's record and a revised written directive must be signed by the AU within 48 hours of the oral revision. Documenting an oral directive is needed to ensure that a complete record is made of the administration of byproduct material or radiation from byproduct material.

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

§ 35.41 Procedures for administrations requiring a written directive

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

Paragraph 35.41(b)(5) requires licensees to develop, implement, and maintain written procedures for any administration requiring a WD to determine if a medical event, as defined in § 35.3045, has occurred. A licensee will retain a copy of these procedures in accordance with § 35.2041. These written procedures are necessary to provide high confidence that each administration is in accordance with the WD to ensure patient safety.

Paragraph 35.41(b)(6) requires licensees to develop, implement, and maintain written procedures for permanent implant brachytherapy. The procedures must include determining within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD. A licensee will retain a copy of these procedures in accordance with § 35.2041. These written procedures are necessary to provide high confidence that each administration is in accordance with the WD to ensure patient safety.

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

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer

An individual fulfilling the responsibilities of the RSO or an individual assigned duties and tasks as an ARSO, as provided in § 35.24, is an individual who must meet one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) must complete a structured educational program; or 3) be currently recognized as an AU, AMP, or ANP, who has experience with the radiation safety aspects of similar types of byproduct material for which the individual has RSO responsibilities. In addition to meeting one of these requirements, the individual must also obtain written attestation signed by a preceptor RSO or ARSO, which attests that the individual has satisfactorily completed all applicable training and education requirements, and can function independently as an RSO or ARSO.

The training and supervised experience and the preceptor statement required by § 35.50 is

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

If a specialty boards certification process meets the requirements in § 35.50(a) and (c)(1), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate. The procedure for specialty board recognition is available at https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html.

§ 35.51 Training for an authorized medical physicist

An individual fulfilling the responsibilities of the AMP must meet one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) meet the educational requirements outlined in § 35.51(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an AMP. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AMP.

The training and supervised experience and the preceptor statement required by § 35.51 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13, and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.51(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

§ 35.55 Training for an authorized nuclear pharmacist

An individual fulfilling the responsibilities of the ANP must be a pharmacist who meets one of the following requirements: 1) be certified by a specialty board that is recognized by the NRC or an Agreement State; or 2) meet the educational requirements outlined in § 35.55(b)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an ANP. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an ANP.

The training and supervised experience and the preceptor statement required by § 35.55 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.55(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there

are changes to the name of the board, the certification process, or certificate.

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

Paragraph 35.60(c) requires licensees to retain a record of each instrument calibration required by §35.60(b) in accordance with § 35.2060. A description of the contents of the record and the need for the record is provided under § 35.2060.

§ 35.61 Calibration of survey instruments

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

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

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

Paragraph 35.63(a) requires licensees to determine and record the activity of each dosage before medical use. Paragraph 35.63(e) requires licensees to retain a record of each radiopharmaceutical dosage determination in accordance with § 35.2063. A description of the contents of the record and the need for the record is provided under § 35.2063.

§35.65 Authorization for calibration, transmission, and reference sources

Paragraph 35.65(b)(2) prohibits the bundling or aggregating of single sealed sources to create a sealed source with an activity greater than the maximum activity authorized by § 35.65. Such bundled or aggregated sources will be treated as one single source and the licensee will have to meet all the regulatory requirements for that single source including, if appropriate, listing the source on a specific medical license, leak testing, and satisfying security requirements. This requirement is necessary, so the NRC can ensure that adequate controls for security and radiation safety are applied to these larger sources.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources

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

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

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

under § 35.2067(b).

§ 35.69 Labeling of vials and syringes

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

§ 35.70 Surveys for ambient radiation exposure rate

This section requires licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. Licensees are required to retain a record of each survey in accordance with § 35.2070. A description of the contents of the record and the need for the record is provided under § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material

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

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

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

§ 35.80 Provision of mobile service

Paragraph 35.80(a)(1) requires a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address and delineates the authority and responsibility of the licensee and the client. This record is necessary to show that the client's management has permitted this work and to clearly delineate the authority and responsibilities of each entity.

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

Paragraph 35.80(c) requires that the letter required in § 35.80(a)(1) and a record of the surveys required in § 35.80(a)(4) be retained in accordance with § 35.2080. A description of the contents of the record and the need for the record is provided under § 35.2080 (a) and (b).

§ 35.92 Decay-in-storage

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

§ 35.190 Training for uptake, dilution, and excretion studies

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

The training and supervised experience and the preceptor statement required by § 35.190 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.190(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

§ 35.204 Permissible molybdenum-99 concentration

Paragraph 35.204(d) requires that if a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with § 35.2204.

Section 35.204(e) requires licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and strontium-82 (Sr-82)/rubidium-82 (Rb-82) generators. Although current regulations require licensees to measure Mo-99, Sr-82, and strontium-85 (Sr-85) concentrations and record the results, there is no provision to report when a result exceeds the regulatory limits. Reporting will be in accordance with the reporting and notification requirements in § 35.3204. This reporting requirement will provide information

that will allow the NRC to respond to the potential patient safety issue in a timely manner.

§ 35.290 Training for imaging and localization studies

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

The training and supervised experience and the preceptor statement required by § 35.290 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.290(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

§ 35.310 Safety instruction

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

This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation exposure to the public and workers, and (2) the actions to be taken in the event of death or medical emergency.

Paragraph 35.310(b) requires licensees to retain a record of individuals receiving instruction required by § 35.310(a) in accordance with § 35.2310. A description of the contents of the record and the need for the record are provided under § 35.2310.

§ 35.315 Safety precautions

Paragraph 35.315(a) (2) requires that the licensee post the room of a patient or human research subject who cannot be released in accordance with § 35.75 with a "Radioactive Materials" sign. Paragraph 35.315(a) (3) requires a licensee to note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room. This posting and note are required so that employees and visitors receive information necessary for radiation safety.

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

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

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

The training and supervised experience and the preceptor statement required by §35.390 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.390(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

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

An individual fulfilling the responsibilities of an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) be an AU in accordance with § 35.392(b); or 3) has completed all the training and supervised experience requirements in § 35.392(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AU for the administration of sodium iodide I-131.

The training and supervised experience and the preceptor statement required by §35.392 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.392(a), the board

may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

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

An individual fulfilling the responsibilities of an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) be an AU in accordance with §35.390 for uses listed under 35.390(b)(1)(ii)(G)(2); or 3) has completed all the training and supervised experience requirements in § 35.394(c)(1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AU for the administration of sodium iodide I-131.

The training and supervised experience and the preceptor statement required by § 35.394 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.394(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive

An individual fulfilling the responsibilities of an AU of unsealed byproduct material for parenteral administration requiring a written directive must be a physician who meets one of the following requirements: 1) be an AU under § 35.390 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or 2) be an AU under §§ 35.490, 35.690, or equivalent Agreement State requirements and who has completed all the requirements in § 35.396 (d) of this section which includes obtaining a written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an AU for parenteral administration of unsealed byproduct material requiring a written directive. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AU for the parenteral administration of unsealed byproduct material requiring a written directive.

The training and supervised experience and the preceptor statement required by § 35.396 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.404 Surveys after source implant and removal

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

§ 35.406 Brachytherapy sources accountability

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

§ 35.410 Safety instruction

Paragraph 35.410(a) requires licensees to provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released in accordance with § 35.75. This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation exposure to the public and workers and (2) the actions to be taken in the event of death or medical emergency.

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

§ 35.415 Safety precautions

Paragraph 35.415(a) requires that the licensee post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the room. This posting provides notice to control radiation exposures to hospital workers and the public.

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

§ 35.432 Calibration measurements of brachytherapy sources

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

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments

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

§ 35.490 Training for use of manual brachytherapy sources

An individual fulfilling the responsibilities of an AU of a manual brachytherapy source for uses under § 35.400 must be a physician who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 2) meet all the supervised training and experience requirements in § 35.490(b) (1). In addition to meeting one of these requirements, the individual must also obtain written attestation that he or she has satisfactorily completed all applicable training and education requirements and can function independently as an AU for uses under § 35.400. This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AU for uses under § 35.400.

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

If a specialty boards certification process meets the requirements in § 35.490(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

§ 35.491 Training for ophthalmic use of strontium-90

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

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

§ 35.590 Training for use of sealed sources for diagnosis

An individual fulfilling the responsibilities of an AU of diagnostic sealed sources for use in a device authorized under § 35.500 must be a physician, dentist, or podiatrist who meets one of the following requirements: 1) be certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State; or 1) meets all the training and experience requirements in § 35.590(b). This requirement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an AU of diagnostic sealed sources for use in a device authorized under § 35.500.

The training and experience required by § 35.590 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.590(a), the board may apply to NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

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

Paragraph 35.604(a) requires licensees who use sealed sources in remote afterloader units, before releasing a patient or human research subject from licensee control, to make a survey of the patient or human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. Paragraph 35.604 (b) requires the licensee to retain a record of the survey required by paragraph 35.604(a) in accordance with § 35.2404. A description of the contents of the record and the need for the record is provided under § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair

Paragraph 35.605(d) requires licensees to retain a record of each installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605. A description of the contents of the record and the need for the record is provided under § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

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

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

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

Paragraph 35.610(d)(1) requires all individuals who will operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. The training must be provided by the device manufacturer or by individuals certified by the device

manufacturer to provide the training. This training is necessary to ensure that operators of these devices have adequate training to protect patient safety.

Paragraph 35.610(d)(2) requires licensees to provide initial instruction and annual refresher instruction to all individuals who operate the unit in the procedures identified in § 35.610(a) and the operating procedures for the unit. The initial instruction and refresher instruction are necessary due to the complexity of therapeutic treatment devices.

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

Paragraph 35.610(f) requires licensees to make a record of initial instruction and refresher training for individuals who operate the units and to retain the record in accordance with § 35.2310. A description of the contents of the record and the need for the record is provided under § 35.2310.

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

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

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

§ 35.630 Dosimetry equipment

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

§ 35.632 Full calibration measurements on teletherapy units

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

§ 35.633 Full calibration measurements on remote afterloader units

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

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units

Paragraph 35.635(g) requires licensees to retain a record of each calibration in accordance

with § 35.2632. A description of the contents of the record and the need for the record is provided under § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units

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

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

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

§ 35.643 Periodic spot-checks for remote afterloader units

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

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

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

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units

Paragraph 35.645(b) (1) requires licensees to perform spot-check measurements in accordance with written procedures established by the AMP. The AMP is the most qualified individual to ensure that the procedures are performed in accordance with published recommendations of nationally recognized bodies. Written procedures are necessary to ensure that spot-checks are performed correctly and consistently.

Paragraph 35.645(b) (2) requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check.

The written notification is needed to ensure that the licensee is aware of the results of each spot-check and aware of the performance of the unit, so that patients are not administered incorrect doses.

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

§ 35.647 Additional technical requirements for mobile remote afterloaders

Paragraph 35.647(e) requires licensees to retain a record of each check of mobile remote afterloaders before use at each address of use, as required by § 35.647(b), in accordance with § 35.2547. A description of the contents of the record and the need for the record is provided under § 35.2647.

§ 35.652 Radiation surveys

Paragraph 35.652(a) requires licensees to make radiation surveys to ensure that radiation levels do not exceed levels stated in the Sealed Source and Device Registry. Paragraph § 35.652(c) requires licensees to retain a record of the radiation surveys in accordance with § 35.2652. A description of the contents of the record and the need for the record is provided under § 35.2652.

§ 35.655 5-year inspection for teletherapy and gamma stereotactic radiosurgery units

Paragraph 35.655(c) requires licensees to keep a record of the teletherapy unit and gamma stereotactic radiosurgery unit 5-year inspection and servicing required by § 35.655(a) in accordance with § 35.2655. A description of the contents of the record and the need for the record is provided under § 35.2655.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

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

The training and experience required by § 35.690 is submitted as part of a licensee's application as required under §§ 35.12 or 35.13 and is cleared under OMB Clearance No. 3150-0120.

If a specialty boards certification process meets the requirements in § 35.690(a), the board may apply to the NRC or an Agreement State to have its certification process recognized and its certified diplomates can use their certification as documentation of training and experience. The board applies once for recognition and infrequently thereafter to update information if there are changes to the name of the board, the certification process, or certificate.

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

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

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

§ 35.2024 Records of authority and responsibilities for radiation protection programs

Paragraph 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. This record must include a summary of actions taken and the signature of licensee management for requests for license application, renewal, or amendment; approvals or disapprovals of requests to allow an individual to work as an AU, ANP, or AMP; and approval or disapproval of radiation protection program changes that do not require an amendment. This record is needed to establish a written record of these actions and the basis for them because it is important to document the licensee's management review and approval of licensing actions and changes to the radiation protection program.

Paragraph 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO as required by § 35.24(e), and a signed copy of each RSOs agreement to be responsible for implementing the radiation safety program, as required by § 34.24(b), for the duration of the license. The records must include the signature of the RSO and licensee management. These records are important to show that the RSO has sufficient authority, time, resources, and management prerogative to ensure that radiation safety activities are being performed in accordance with licensee- approved procedures and regulatory requirements.

Section 35.2024(c) requires the licensee to keep the written documents signed by the licensee's management for each ARSO appointed under § 35.24(b) for 5 years after the ARSO is removed from the license. These records are important to show that the ARSO had sufficient authority, time, resources, and management prerogative to ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements.

§ 35.2026 Records of radiation protection program changes

This section requires licensees to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. This record facilitates the Commission's evaluation of the nature and appropriateness of the minor changes during inspections prior to renewal and provides the licensee with a complete record of the radiation safety program changes until the changes are incorporated into the license when renewed.

§ 35.2040 Records of written directives

This section requires licensees to retain a copy of each written directive as required by § 35.40 for 3 years. 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 of administrations during an NRC inspection.

§ 35.2041 Records for procedures for administrations requiring a written directive

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

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

This section requires licensees to maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual who performed the calibration. The records of the calibrations required in § 35.60 are necessary to demonstrate that the instruments used to measure the activity of alpha-, beta-, and photon-emitting radionuclides are functioning correctly and are capable of accurately measuring dosages; to establish trends in equipment performance; and to show compliance with regulatory requirements.

§ 35.2061 Records of radiation survey instrument calibrations

This section requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual who performed the calibration. This survey instrument calibration record is required to show that survey instruments were calibrated and are functioning correctly.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use

This section requires licensees to maintain a record of dosage determinations required by § 35.63 for 3 years. The record must contain: the radiopharmaceutical; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); the date and time of the dosage determination; and the name of the individual who determined the dosage. This record is required to demonstrate that the prescribed dosage was obtained for administration to the patient or human research subject.

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

Paragraph 35.2067(a) requires licensees to retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number and serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its

estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test. This record is required to demonstrate that the leak test was done as required, and that the source was not leaking.

Paragraph 35.2067(b) requires that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number, if one has been assigned; the identity of each source by radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory. This inventory record is needed to show that all sealed sources are accounted for.

§ 35.2070 Records of surveys for ambient radiation exposure rate

This section requires a licensee to retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey. The records are needed to document that the surveys were performed, and that the ambient radiation exposure rates are below the limits set for protection of workers and the public.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material

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

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

Paragraph 35.2075(c) requires licensees to retain the records required by paragraphs (a) and (b) of this section for 3 years after the date of release of the individual. Retention of the release records for 3 years after the date of the release will allow the NRC to ensure that releases were in accordance with the criteria for release by reviewing a sample of the records during an NRC inspection.

§ 35.2080 Records of mobile medical services

Paragraph 35.2080(a) requires licensees providing mobile medical services to retain a copy of each letter that permits the use of byproduct material at a client’s address, as required by § 35.80(a) (1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 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 and to document the authority and responsibility of the licensee and the client.

Paragraph 35.2080(b) requires licensees to maintain a record of each survey required by § 35.80(a) (4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey. These records are needed to show that the required surveys were made to ensure compliance with the radiation protection requirements of 10 CFR Part 20.

§ 35.2092 Records of decay-in-storage

This section requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey. These records are needed to show that the radioactivity of the materials that are disposed of as ordinary waste cannot be distinguished from background radiation levels, and that a proper survey was made at the surface of the byproduct material prior to disposal.

§ 35.2204 Records of molybdenum-99 concentrations

This section requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

§ 35.2310 Records of safety instruction

This section requires licensees to maintain a record of safety instructions required by §§ 35.310 and 35.410 and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction. This record is needed to show that the required initial and refresher training was given and that the drills were performed so that individuals are aware of the safety and emergency procedures to be used in caring for patients and human research subjects treated with byproduct material or radiation therefrom.

§ 35.2404 Records of surveys after source implant and removal

This section requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced.

§ 35.2406 Records of brachytherapy source accountability

This section requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for 3 years. For temporary implants, the record must include: the number and activity of sources removed from and returned to storage; the time and dates they

were removed from and returned to storage, the name of the individual(s) who removed them from and returned them to storage, and the location of use. For permanent implants, the record must include: the number and activity of sources removed from storage, the dates they were removed from storage, and the name of the individual who removed them from storage; the number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and the number and activity of sources permanently implanted in the patient or human research subject. This record is required to show that no brachytherapy source is misplaced or missing.

§ 35.2432 Records of calibration measurements of brachytherapy sources

This section requires licensees to maintain a record of calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source. The record must include: the date of calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the AMP. These records are needed to document that the brachytherapy sources have been calibrated.

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

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

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

This section requires licensees to retain records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to show that the devices are properly installed, maintained, and repaired, to establish trends in device performance, and to establish a service history that may be used in evaluation of generic equipment problems.

§ 35.2610 Records of safety procedures

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

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

This section requires licensees to retain a record of the calibration, intercomparison, and

comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. For each calibration, intercomparison, or comparison, the record must include: the date; the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630; the correction factor that was determined from the calibration or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison. This record is needed to show that calibrations of medical devices were made with properly calibrated instruments.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations

This section requires licensees to maintain records of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years. The record must include: the date of the calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s); the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the AMP who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the teletherapy unit, remote afterloader unit, or gamma stereotactic radiosurgery unit.

§ 35.2642 Records of periodic spot-checks for teletherapy units

Paragraph 35.2642(a) requires licensees to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. The record must include: the date of the spot-check; the manufacturer's name, model number, and serial number of the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and the name of the individual who performed the periodic spot-check and the signature of the AMP who reviewed the record of the spot check. This record is needed to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

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

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

Paragraph 35.2643(a) requires licensees to retain records of each spot-check for remote afterloader units required by §§ 35.643 for 3 years. The record must include, as applicable: the date of the spot-check; the manufacturer's name, model number, and serial number for the

remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and the name of the individual who performed the periodic spot-check and the signature of the AMP who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

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

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

Paragraph 35.2645(a) requires licensees to retain records of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. The record must include: the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and the name of the individual who performed the periodic spot-check and the signature of the AMP who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units and related safety equipment are operating correctly.

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

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

This section requires licensees to retain records of each check for mobile remote afterloader units required by § 35.647 for 3 years. The record must include: the date of the check; the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes and transfer tube applicator interfaces, and source positioning accuracy; and the signature of the individual who performed the check. This record is necessary to show that the checks were performed and that the units and related safety equipment are operating correctly.

§ 35.2652 Records of surveys of therapeutic treatment units

This section requires licensees to maintain records of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit. The record must include: the date of the measurements; the manufacturer's name, model number, and serial number of the treatment unit, source, and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the person who performed the test. This record is necessary to show that the surveys were performed and that the units do not exceed occupational dose levels with the sources in the shielded position.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units

This section requires licensees to maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit. The record must contain: the inspector's radioactive materials license number; the date of inspection; the manufacturer's name and model number and serial number of both the treatment unit and source; a list of components inspected and serviced, and the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed and that any required work was done.

§ 35.3045 Reports and notification of a medical event

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

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

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

Paragraph 35.3045(d) requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event. The report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any, on the individual(s) who received the administration; what actions, if any, have been taken or are planned to prevent recurrence; certification that the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it

appears the precipitating event might be generic.

Paragraph 35.3045(e) requires the licensee to notify the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician cannot be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs. If verbal notification is made, the licensee is required to inform the individual or responsible relative or guardian that a written description of the event may be obtained upon request. The licensee shall provide such a written description, if requested.

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

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

Paragraph 35.3047(a) requires the licensee to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is the result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the AU. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. This report is needed so that NRC can comply with the legislative intent of section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports to Congress of unintended radiation exposure.

Paragraph 35.3047(b) requires the licensee to report any dose to a nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician, that is a result of an administration of byproduct material to a breast-feeding individual. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. This report is needed so that NRC can comply with the legislative intent of section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit to Congress reports of unintended radiation exposure.

Paragraph 35.3047(c) requires the licensee to notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Paragraph 35.3047(d) requires the licensee to submit a written report to the appropriate NRC Regional Office no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b). The written report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why

the event occurred; the effect, if any, on the embryo/fetus or the nursing child; what actions, if any, have been taken or are planned to prevent recurrence; and certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian, and if not, why not. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Paragraph 35.3047(e) requires the licensee to notify the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If the referring physician or mother cannot be reached within 24 hours, the licensee is required to make the appropriate notifications as soon as possible thereafter. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such written description if requested. This reporting requirement is needed to provide information about the event to the referring physician and the pregnant individual or mother, or the mothers or child's responsible relative or guardian, for appropriate medical care, if needed.

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

§ 35.3067 Report of a leaking source

This section requires licensees to report detection of a leaking source by submitting a written report within 5 days after a leakage test required by § 35.67 reveal the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office with a copy to the NRC Headquarters Office. The report must include the model and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test, the date of the test, and the action taken. This report is needed to ensure that the NRC is aware of the leaking source and is able promptly to take any necessary actions based on the circumstances.

§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations

Paragraph 35.3204(a) requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the distributor of the generator by telephone within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). Breakthrough of Mo-99 and contamination of Sr-82 and Sr-85 can lead to unnecessary exposure to radiation to patients. This notification requirement will allow the NRC to assess the situation so that appropriate actions may be taken to avoid unwarranted radiation

exposure to patients.

Paragraph 35.3204(b) requires radiopharmacy and medical use licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 30 days after discovery of an eluate exceeding the permissible concentration listed in § 35.204(a). This report is a follow up on the requirement under § 35.3204(a) to notify the NRC within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This reporting requirement will allow the NRC to determine appropriate actions to take to avoid unwarranted radiation exposure to patients.

GUIDANCE DOCUMENTS FOR INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL

3150-0010

Title	Accession number
Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)	ML19256C219
Regulatory Guide 8.39 Release of Patients Administered Radioactive Materials	ML083300045