216-RICR-40-20-9

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING & FACILITIES REGULATION

SUBCHAPTER 20 - RADIATION

PART 9 – MEDICAL USE OF RADIOACTIVE MATERIAL

9.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5(f), as amended.

B. This Part contains the requirements and provisions for the medical use of radioactive material). These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

C. The requirements and provisions of this Part are in addition to, and not in substitution for, other requirements in this Subchapter. The requirements and provisions of this Part apply to applicants and licensees subject to this Subchapter unless specifically exempted.

9.2 Incorporated Material

A. Except as provided in this Part, the requirements of 10 CFR Part 35 (2018) https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/ are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

B. Notwithstanding the provisions of § 9.2(A) of this Part, §§ 35.1, 35.5, 35.6, 35.7, 35.8, 35.10, 35.11, 35.12, 35.13, 35.14, 35.18, 35.19, 35.24, 35.26, 35.27, 35.40, 35.70, 35.75, 35.80, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.206, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35,2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642,35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045 are not incorporated by reference.

C. Effect of incorporation of 10 CFR Part 35. To reconcile differences between this Part and the incorporated sections of 10 CFR Part 35, the following words and phrases shall be substituted for the language in 10 CFR Part 35 as follows:

1. Any reference to NRC or Commission shall be deemed to be a reference to the Agency.

2. Any reference to NRC or agreement state shall be deemed to be a reference to the Agency, NRC or agreement state.

3. Any reference to byproduct material shall be deemed to be a reference to radioactive material.

4. Any reference to a medical event shall be deemed to be a reference to a misadministration.

5. Any notifications, reports or correspondence referenced in the incorporated parts of 10 CFR 35 shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

6. Any reference to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) shall be deemed to be a reference to the Agency's Radiation Advisory Commission.

9.3 Definitions

A. In addition to the definitions contained in 10 CFR § 35.2, whenever used in this Part, the following terms shall be construed as follows:

"Act" means Title 23, Chapter 1.3 of the General Laws of the State of Rhode Island entitled "Radiation Control".

"Agency" means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation - Radiation Control Program, Rhode Island Department of Health.

"Misadministration" means an event that meets the criteria in 9.5.9(A) of this Part.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

"Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

"R.I. Gen. Laws" means the General Laws of Rhode Island, as amended.

"Therapeutic medical unit" means any remote afterloader unit, teletherapy unit, gamma stereotactic radiosurgery unit or similar beam therapy device authorized pursuant to § 9.11.1 of this Part.

9.4 General Requirements

9.4.1 Provisions for Research Involving Human Subjects

A. A licensee may conduct research involving human subjects using radioactive material provided:

1. That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

2. The research involving human subjects authorized in § 9.4.1(A)(1) shall be conducted using radioactive material authorized for medical use in the license; and

3. Nothing in this section relieves licensees from complying with the other requirements in this Part.

9.4.2 FDA, Other Federal and State Requirements

Nothing in this Part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

9.4.3 License Required

A. A person shall manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State, or as allowed by § 9.5.3(A) and § 9.5.3(B) of this Part. A specific license is not needed for an individual who:

1. Receives, possesses, uses, or transfers radioactive material in accordance with this Subchapter under the supervision of an Authorized User as provided in § 9.5.3 of this Part, unless prohibited by license condition; or

2. Prepares unsealed radioactive material for medical use in accordance with this Part under the supervision of an Authorized Nuclear Pharmacist or Authorized User as provided in § 9.5.3 of this Part, unless prohibited by license condition.

B. Human Use of Radioactive Material. In addition to the requirements set forth in § 7.6.2(A) of this Subchapter and other sections of this Part, a specific license for human use of radioactive material will be issued under the following conditions:

1. If the application is for human use sited in a medical institution, only the institution's management may apply. If the application is for human use not cited in a medical institution, the applicant or a person duly authorized to act for and on their behalf may apply.

2. The application includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Authorized User(s), Authorized Medical Physicist(s), and Authorized Nuclear Pharmacist(s).

3. The application includes procedures required by §§ 9.11.2, 9.11.4, 9.11.10, 9.11.11, and 9.11.12 of this Part, as applicable.

4. An application for human use of radioactive material as described in § 9.12.1 of this Part must also include information regarding any radiation safety aspects of the human use of the material that is not addressed in this Part. The applicant shall also provide specific information on:

   a. Radiation safety precautions and instructions;

   b. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

   c. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

9.4.4 Maintenance of Records

Each record required by this Part shall be legible throughout the specified retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

9.4.5 License Amendments

A. A licensee shall apply for and receive a license amendment:

2. Before it receives or uses radioactive material for a type of use that is permitted under this Part, but that is not authorized on the licensee's current license issued pursuant to this Part;

3. Before permitting anyone, except a Visiting Authorized User, Visiting Authorized Medical Physicist or Visiting Authorized Nuclear Pharmacist as described §§ 9.5.3 or 9.5.6 of this Part, to work as an Authorized User, Authorized Medical Physicist or Authorized Nuclear Pharmacist under the license;

4. Before changing a Radiation Safety Officer, except as provided in § 9.5.1(C) of this Part, or Authorized Medical Physicist;

5. Before ordering radioactive material in excess of the amount, or radionuclide or form different than authorized on the license;

6. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license;

7. Before changing statements, representations, and procedures which are incorporated into the license, except as provided for in § 9.5.15 of this Part;

8. Before it releases licensed facilities for unrestricted use.

9. In addition to the requirements specified above, a therapeutic medical unit licensee shall apply for and receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the therapeutic medical unit within the treatment room;

c. Using the therapeutic medical unit in a manner that could result in increased radiation levels in areas outside the treatment room;

d. Relocating the therapeutic medical unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the Authorized Medical Physicist, except as provided in § 9.5.6(B) of this Part.

9.4.6 Notifications

A. A licensee shall notify the Agency by letter no later than thirty (30) days after:

1. An Authorized User, an Authorized Nuclear Pharmacist, Radiation Safety Officer, or Authorized Medical Physicist permanently discontinues performance of duties under the license or has a name change; or

2. The licensee's mailing address changes; or

3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 7.6.3 (b) of this Subchapter; or

4. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either § 9.7.1 or § 9.7.3 of this Part 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.

9.4.7 Exemptions Regarding Type A Specific Licenses of Broad Scope

For the purpose of this Part, exemptions regarding Type A specific licenses of broad scope are defined by 10 CFR § 35.15.

9.5 General Administrative Requirements

9.5.1 Authority and Responsibilities for the Radiation Protection Program

A. In addition to the radiation protection program requirements of § 1.6 of this Subchapter, a licensee's management shall approve in writing:

1. Requests for a license application, renewal, or amendments before submittal to the Agency;

2. Any individual before allowing that individual to work as a Visiting Authorized User, Visiting Authorized Medical Physicist, or Visiting Authorized Nuclear Pharmacist; and

3. Radiation protection program changes that do not require a license amendment and are permitted under § 9.5.15 of this Part;

B. A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

C. For up to sixty (60) days each year, a licensee may permit an Authorized User or an individual qualified to be a Radiation Safety Officer under § 9.5.10 and § 9.5.14 of this Part, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in § 9.5.1(E) of this Part, if the licensee takes the actions required in §§ 9.5.1(B), (D), (E) and (H) of this Part, and notifies the Agency in accordance with § 9.4.6 of this Part.

D. A licensee may simultaneously appoint more than one temporary Radiation Safety Officer, if needed to ensure that the licensee has a temporary Radiation

Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of use of radioactive material permitted by the license.

E. A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

F. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and,

4. Verify implementation of corrective actions.

G. Licensees that are authorized for two (2) or more different types of uses of radioactive material under §§ 9.8.1, 9.9.1 or 9.11.1 of this Part, or two (2) or more types of units under § 9.11.1 of this Part, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an Authorized User of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an Authorized User nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

H. A licensee shall retain a record of actions taken by the licensee's management in accordance with § 9.5.1(A) of this Part for five (5) years. The record shall include a summary of the actions taken and a signature of licensee management.

I. The licensee shall retain a copy of both authority, duties and responsibilities of the Radiation Safety Officer as required by § 9.5.1(E) of this Part, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 9.5.1(B) of this Part, for the duration of the license. The records shall include the signature of the Radiation Safety Officer and licensee management.

J. A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six (6) months. The licensee shall maintain minutes of each Radiation Safety Committee meeting which shall include the date of the meeting, members present, members absent and a summary of deliberations and discussions.

9.5.2 Duties of Authorized User and Authorized Medical Physicist

A. A licensee shall ensure that only Authorized Users for the type of radioactive material used:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

2. Direct, as specified in § 9.5.3 and § 9.5.4 of this Part, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with §§ 9.4.3(A)(1), 9.4.3(A)(2) and 9.5.3 of this Part.

B. A licensee shall ensure that only Authorized Medical Physicists perform, as applicable:

1. Full calibration measurements as described in §§ 9.11.7, 9.11.8 and 9.11.9 of this Part;

2. Periodic spot-checks as described in §§ 9.11.10, 9.11.11 and 9.11.12 of this Part; and

3. Radiation surveys as described in § 9.11.14 of this Part.

9.5.3 Supervision

A. A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an Authorized User, as allowed by § 9.4.3(A) of this Part, shall:

4. In addition to the requirements in § 2.5 of this Subchapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this Part and license conditions with respect to the use of radioactive material;

5. Require the supervised individual to follow the instructions of the supervising Authorized User for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, this Subchapter, and license conditions with respect to the medical use of radioactive material; and;

6. If the individual is involved in administration of radiation/radioactive materials to humans, ensure that the individual possesses a current license in accordance with Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants [216-RICR-40-05-34], unless the individual is specifically exempted from licensure by said regulations;

B. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an Authorized Nuclear Pharmacist or physician who is an Authorized User, as allowed by § 9.4.3(A)(2) of this Part, shall:

1. In addition to the requirements in § 2.5 of this Subchapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising Authorized User or Authorized Nuclear Pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, this Subchapter, and license conditions.

C. A licensee that permits supervised activities under §§ 9.5.3(A) and (B) of this Part is responsible for the acts and omissions of the supervised individual.

9.5.4 Written Directives

A. A written directive shall be dated and signed by an Authorized User prior to administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within forty-eight (48) hours of the oral directive.

B. The written directive shall contain the patient or human research subject's name and the following information:

1. For an administration of a dosage of radioactive drug containing radioactive material: the radioactive drug containing radioactive material, dosage, and route of administration;

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

3. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

4. For high dose rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

5. For all other brachytherapy including low, medium and pulsed dose rate remote afterloaders:

   a. Prior to implantation: treatment site, the radionuclide and dose; and

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

C. A written revision to an existing written directive may be made provided that the revision is dated and signed by an Authorized User prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose.

1. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the Authorized User within forty-eight (48) hours of the oral revision.

D. The licensee shall retain a copy of each written directive for three (3) years.

9.5.5 Procedures for Administrations Requiring a Written Directive

A. For the purpose of this Part, procedures for administrations requiring a written directive are defined by 10 CFR § 35.41.

B. A licensee shall retain a copy of the procedures required under § 9.5.5(A) of this Part for the duration of the license.

9.5.6 Visiting Authorized User, Visiting Authorized Medical Physicist and Visiting Authorized Nuclear Pharmacist

A. A licensee may permit any Visiting Authorized User to use licensed material for medical use under the terms of the licensee's license for sixty (60) days each year if:

1. The Visiting Authorized User has the prior written permission of the licensee's management and Radiation Safety Committee if one is required;

2. The licensee has a copy of an Agency, Agreement State or U.S. Nuclear Regulatory Commission license that identifies the Visiting Authorized User by name as an Authorized User for medical use; and

3. Only those procedures for which the Visiting Authorized User is specifically authorized by an Agency, Agreement State or U.S. Nuclear Regulatory Commission license are performed by that individual.

B. A licensee may permit a medical physicist to act as a Visiting Authorized Medical Physicist, and perform the duties of a medical physicist under the terms of the licensee's license for sixty (60) days each calendar year if:

1. The medical physicist is registered with the Agency, under the provisions of § 3.6 of this Subchapter, as a provider of Radiation Physics Services in the area of calibration and compliance surveys of therapeutic medical units; and

2. The Visiting Authorized Medical Physicist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

3. The licensee has a copy of:

a. An Agency, NRC or Agreement State license that identifies the individual as an Authorized Medical Physicist; or

b. A permit issued by an Agency, NRC or Agreement State specific license of broad scope that identifies the medical physicist by name as an Authorized Medical Physicist.

C. A licensee may permit a nuclear pharmacist to act as a Visiting Authorized Nuclear Pharmacist, and to perform the duties of a nuclear pharmacist under the terms of the licensee's license for sixty (60) days each calendar year if:

1. The nuclear pharmacist possesses a current license as a pharmacist in accordance with Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [216-RICR-40-15-1]; and

2. The visiting Authorized Nuclear Pharmacist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

3. The licensee has a copy of:

a. An Agency, NRC or Agreement State license that identifies the individual as an Authorized Nuclear Pharmacist; or

b. A permit issued by an Agency, NRC or Agreement State specific license of broad scope that identifies the nuclear pharmacist by name as an Authorized Nuclear Pharmacist.

D. A licensee need not apply for a license amendment in order to permit:

1. A Visiting Authorized User to use licensed material as described in § 9.5.6(A) of this Part;

2. A Visiting Authorized Medical Physicist to perform licensed duties as described in § 9.5.6(B) of this Part;

3. A Visiting Authorized Nuclear Pharmacist to perform licensed duties as described in § 9.5.6(B) of this Part.

E. A licensee shall retain copies of the records specified in §§ 9.5.6(A), 9.5.6(B) and 9.5.6(C) of this Part for three (3) years from the date of the last visit.

9.5.7 Requirements for Suppliers of Sealed Sources or Devices for Medical Use

For the purpose of this Part, requirements for suppliers of sealed sources or devices for medical use are defined by 10 CFR § 35.49.

9.5.8 Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. The licensee shall conduct quality control procedures in accordance with written procedures.

9.5.9 Report and Notification of a Misadministration

A. Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

a. The total dose delivered differs from the prescribed dose by twenty percent (20%) or more;

b. The total dosage delivered differs from the prescribed dosage by twenty percent (20%) or more or falls outside the prescribed dosage range; or

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent (50%) or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

a. An administration of a wrong radioactive drug;

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or

e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and fifty percent (50%) or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

C. A licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

1. All required notifications shall use Agency contact information specified in § 1.4 of this Subchapter.

D. The licensee shall submit a written report to the Agency within fifteen (15) days after discovery of the misadministration.

1. The written report shall include:

a. The licensee's name;

b. The prescribing physician's name;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual(s) who received the administration;

f. What actions, if any, have been taken, or are planned, to prevent recurrence;

g. Verification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report shall not contain the individual's name or other information that could lead to identification of the individual.

E. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the licensee either that he/she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or affected individual cannot be reached within twenty-four (24) hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, individuals affected by the misadministration, or that individual's responsible relatives or guardians.

G. A licensee shall retain a record of misadministrations reported in accordance with this section for three (3) years. The record shall contain:

1. The licensee's name;

2. Names of the individuals involved;

3. The social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration;

4. A brief description of the event; why it occurred; the effect, if any, on the individual;

5. The actions, if any, taken, or planned, to prevent recurrence; and

6. Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

H. The licensee shall provide a copy of the record required by § 9.5.9(G) of this Part to the referring physician, if other than the licensee, no later than fifteen (15) days after the discovery of the misadministration.

9.5.10 Training for a Radiation Safety Officer

For the purpose of this Part, training requirements for a radiation safety officer are defined by 10 CFR § 35.50.

9.5.11 Training for an Authorized Medical Physicist

A. For the purpose of this Part, training requirements for an Authorized Medical Physicist are defined by 10 CFR § 35.51.

B. In addition to the requirements in § 9.5.11 of this Part, an Authorized Medical Physicist must be registered with the Agency, under the provisions of § 3.6 of this Subchapter, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist.

9.5.12 Training for an Authorized Nuclear Pharmacist

A. For the purpose of this Part, training requirements for an Authorized Nuclear Pharmacist are defined by 10 CFR § 35.55.

B. In addition to the requirements in § 9.5.12(A) of this Part, an Authorized Nuclear Pharmacist must possess a current license as a pharmacist in accordance with Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [216-RICR-40-15-1].

9.5.13 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

A. For the purpose of this Part, training requirements for an experienced Radiation Safety Officer, teletherapy or medical physicist, Authorized Medical Physicist, Authorized User, nuclear pharmacist, and Authorized Nuclear Pharmacist are defined by 10 CFR § 35.57.

B. An individual who does not qualify as an experienced medical physicist pursuant to § 9.5.13(A) of this Part, but has, prior to 24 October 2004, registered with the Agency, under the provisions of § 3.6 of this Subchapter, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist need not comply with the training requirements of § 9.5.11 of this Part. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

9.5.14 Recentness of Training.

For the purpose of this Part, training requirements regarding recentness of training are defined by 10 CFR § 35.59.

9.5.15 Radiation Protection Program Changes.

A. A licensee may revise its radiation protection program without prior Agency approval if:

1. The revision does not require an amendment under § 9.4.5 of this Part;

2. The revision is in compliance with this Subchapter and the license;

3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

4. The affected individuals are instructed on the revised program before the changes are implemented.

B. A licensee shall retain a record of each change for five (5) years. The record shall include the effective date of the change, a copy of the old and new procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change and the signature of the licensee management representative that reviewed and approved the change.

C. A copy of the record required by § 9.5.15(B) of this Part shall be submitted to the Agency within thirty (30) days of adopting said change(s).

9.5.16 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material

A. A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

1. NRC NUREG 1556-Vol. 9 "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

B. For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the consequences, if any, of failure to follow the guidance.

C. For patients administered radioactive material for which a written directive is required, the licensee shall maintain a record, for three (3) years after the date of release, of the basis for authorizing the release of an individual.

D. The licensee shall maintain a record, for three (3) years after the date of release, that instructions required by § 9.5.16(B) of this Part were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 1 mSv (0.1 rem).

E. The licensee shall immediately notify the Agency in accordance with § 9.5.17 of this Part if a patient departs prior to an authorized release.

F. The licensee shall notify the Agency in accordance with § 9.5.19 of this Part:

1. When they are aware that a patient containing radioactive material and who has been released in accordance with § 9.6.9 of this Part dies; and

2. If it is possible that any individual could receive an effective dose equivalent in excess of 5 mSv (0.5 rem) as a result of the deceased's body.]

9.5.17 Reports of Patient Departure Prior to Authorized Release

A. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under § 9.5.16(A) of this Part.

B. The licensee shall submit a written report to the Agency within thirty (30) days after discovery of the unauthorized departure. The written report must include:

1. The licensee's name;

2. The date and time of the unauthorized departure;

3. The projected date and time when release would have occurred;

4. The address of the patient's or human research subject's home or anticipated destination following departure;

5. The radionuclide, chemical and physical form and calculated activity at time of release;

6. The apparent reason(s) for the departure prior to authorized release; and

7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

9.5.18 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

For the purpose of this Part, training requirements for report and notification of a dose to an embryo/fetus or a nursing child are defined by 10 CFR § 35.3047.

9.5.19 Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material

A. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive an effective dose equivalent in excess of § 1.8.1 of this Subchapter as a result of the deceased's body.

B. The licensee shall submit a written report to the Agency within thirty (30) days after discovery that the patient or human research subject referenced in § 9.5.18 of this Part has died. The written report shall include:

1. The licensee's name;

2. The date of death;

3. The radionuclide, chemical and physical form and calculated activity at time of death; and,

4. The names (or titles) and address(es) of known individuals who might have received a TEDE exceeding 5 mSv (0.5 rem).

9.6 General Technical Requirements

9.6.1 Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

For the purpose of this Part, requirements for possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material are defined by 10 CFR § 35.60.

9.6.2 Calibration of Survey Instruments

A. For the purpose of this Part, requirements for calibration of survey instruments are defined by 10 CFR § 35.61.

B. The licensee shall retain a record of each calibration required in § 9.6.2(A) of this Part for three (3) years. The record shall include:

1. The model and serial number of the instrument;
2. The results of the calibration;
3. The name of the individual who performed the calibration; and
4. The date of calibration.

9.6.3 Determination of Dosages of Unsealed Radioactive Materials for Medical Use

A. For the purpose of this Part, requirements for determination of dosages of unsealed radioactive materials for medical use are defined by 10 CFR § 35.63.

B. Retain a record of the dosage determinations required by § 9.6.3(A) of this Part for three (3) years. To satisfy this requirement, the record shall contain:

1. The radiopharmaceutical;
2. Patient's or human research subject's name, and identification number if one has been assigned;
3. Prescribed dosage and determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);
4. Date and time of the dosage determination; and
5. Name of the individual who determined the dosage

9.6.4 Authorization for Calibration, Transmission and Reference Sources

For the purpose of this Part, authorization for calibration, transmission and reference sources is defined by 10 CFR § 35.65.

9.6.5 Requirements for Possession of Sealed Sources and Brachytherapy Sources

A. For the purpose of this Part, requirements for possession of sealed sources and brachytherapy sources are defined by 10 CFR § 35.67.

B. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all such sources at intervals not to exceed six (6) months.

1. The licensee shall retain each inventory record for three (3) years.

2. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer or the individual who performed the inventory.

9.6.6 Vial Shields

A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

9.6.7 Labeling of Vials and Syringes

For the purpose of this Part, requirements for labeling of vials and syringes are defined by 10 CFR § 35.69.

9.6.8 Surveys for Contamination and Ambient Radiation Dose Rate

A. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material were prepared for use or administered.

B. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs containing radioactive material or radioactive wastes are stored.

C. A licensee shall conduct the surveys required by §§ 9.6.8(A) and (B) of this Part so as to able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

D. A licensee shall establish dose rate action levels for the surveys required by §§ 9.6.8(A) and (B) of this Part and shall require that the individual performing the

survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

E. A licensee shall survey for removable contamination at least once each week all areas where generators and radioactive drugs containing radioactive material are prepared for use or administered or radioactive materials are stored.

F. A licensee shall conduct the surveys required by § 9.6.8(E) of this Part so as to be able to detect contamination on each wipe sample 33.3 Bq (2000 dpm).

G. A licensee shall establish removable contamination action levels for the surveys required by § 9.6.8(E) of this Part and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

H. A licensee does not need to perform the surveys required by § 9.6.8(A) of this Part in an area(s) where patients or human research subjects are confined when they cannot be released pursuant to § 9.6.9 of this Part.

I. A licensee shall retain a record of each survey for three (3) years. The record shall 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.

9.6.9 Mobile Nuclear Medicine Service Requirements

A. The Agency shall license mobile nuclear medicine services or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

B. A licensee providing mobile nuclear medicine service shall:

1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the mobile nuclear medicine service and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile nuclear medicine service;

2. Inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

3. Maintain all records required by this Part and Parts 1 and 2 of this Subchapter at a location within the Agency's jurisdiction that is:

a. A single address of use:

(1) Identified as the records retention location; and

(2) Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

b. When no address of use is identified on the license for records retention, the mobile unit:

(1) Identified in the license; and

(2) Whose current client's address schedule and location schedule is reported to the Agency.

4. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, this check for proper function shall include a constancy check;

5. Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

6. Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

7. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

8. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

9. Check survey instruments for consistent response with a dedicated check source before use at each client's address;

10. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with the requirements in Parts 1 and 2 of this Subchapter;

11. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency pursuant to § 9.7.6 of this Part; and,

C. A mobile nuclear medical service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a

license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

D. A licensee providing mobile nuclear medical services shall retain a copy of each letter required by § 9.6.9(B)(1) of this Part. Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three (3) years after the last provision of service.

E. A licensee providing mobile nuclear medical services shall retain the record of each survey required by § 9.6.9(B)(8) of this Part for three (3) years. The record shall 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.

F. A licensee providing mobile nuclear medical services shall, at a minimum, maintain the following documents on each mobile unit:

1. The current operating and emergency procedures;

2. A copy of the license;

3. Copies of the letter(s) required by § 9.6.9(B)(1) of this Part;

4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding thirty (30) calendar days.

9.6.10 Decay in Storage

A. For the purpose of this Part, requirements for decay in storage are defined by 10 CFR § 35.92(a).

B. For radioactive material disposed in accordance with § 9.6.10(A) of this Part, the licensee shall retain a record of each disposal for three (3) years. The record shall include the date of the disposal, the model and serial number of 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.

9.6.11 Survey Instruments

A. Licensees authorized for radioactive material use under §§ 9.7.1, 9.7.3, 9.8.1, 9.9.1 and/or 9.11.1 of this Part shall possess an operable survey instrument that has been calibrated in accordance with § 9.6.2 of this Part and meets the following criteria:

AUTHORIZED USE	SURVEY INSTRUMENT
9.7.1 - Uptake, dilution, and excretion studies	Portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour
9.7.3 - Imaging & localization studies; or 9.8.1 - Unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required; or 9.9.1 - Manual brachytherapy	Portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour; and Portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour.
9.11.1- Remote afterloader unit, teletherapy unit and/or gamma stereotactic radiosurgery unit	Portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour.

B. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes pursuant to § 9.10.1 of this Part shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with § 9.6.2 of this Part.

9.7 Unsealed Radioactive Material - Written Directive Not Required

9.7.1 Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive is Not Required

For the purpose of this Part, requirements for use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required are defined by 10 CFR § 35.100.

9.7.2 Training for Uptake, Dilution, and Excretion Studies

For the purpose of this Part, training requirements for uptake, dilution, and excretion studies are defined by 10 CFR § 35.190.

9.7.3 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required

A. For the purpose of this Part, requirements for use of unsealed radioactive material for imaging and localization studies for which a written directive is not required are defined by 10 CFR § 35.200.

B. Provided the conditions of § 9.7.6 of this Part are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

C. Technetium-99m pertechnetate as an aerosol for lung function studies is not subject to the restrictions in § 9.7.3(B) of this Part.

9.7.4 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

A. For the purpose of this Part, permissible Molybdenum-99, Strontium-82, and Strontium-85 concentrations are defined by 10 CFR § 35.204(a)-(c).

B. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for three (3) years. The record shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

C. A licensee shall report immediately to the Agency each occurrence of radio-nuclide contaminant concentration exceeding the limits specified in § 9.7.4(A) of this Part.

9.7.5 Training for Imaging and Localization Studies

For the purpose of this Part, training requirements for imaging and localization studies are defined by 10 CFR § 35.190.

9.7.6 Control and Storage of Volatiles, Aerosols and Gases

A. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by § 1.7.1 and § 1.8.1 of this Subchapter.

B. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

C. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

D. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in § 1.18 of this Subchapter. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

E. A licensee shall post the time calculated in § 9.7.6(D) of this Part at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

F. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six (6) months. Records of these checks and measurements shall be maintained for three (3) years.

G. A copy of the calculations required in § 9.7.6(D) of this Part shall be recorded and retained for the duration of the license.

H. A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.

I. A licensee shall store and use a multidose container in a properly functioning fume hood.

9.8 Unsealed Radioactive Material - Written Directive Required

9.8.1 Use of Unsealed Radioactive Material for Which a Written Directive is Required

For the purpose of this Part, requirements for use of unsealed radioactive material for which a written directive is required are defined by 10 CFR § 35.300.

9.8.2 Safety Instruction

A. For the purpose of this Part, requirements for safety instruction are defined by 10 CFR § 35.310(a).

B. A licensee shall keep a record of individuals receiving instruction required by in § 9.8.2(A) of this Part for three (3) years. The record shall include a list of the topic(s) covered, the date of instruction or training the name(s) of the attendees, and the name(s) of the individual(s) who provided the instruction.

9.8.3 Safety Precautions

For the purpose of this Part, requirements for safety precautions are defined by 10 CFR § 35.315.

9.8.4 Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required

For the purpose of this Part, training requirements for use of unsealed radioactive material for which a written directive is required are defined by 10 CFR § 35.390.

9.8.5 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 gigabecquerels (33 millicuries)

For the purpose of this Part, training requirements 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) are defined by 10 CFR § 35.392.

9.8.6 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 gigabecquerels (33 millicuries)

For the purpose of this Part, training requirements for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) are defined by 10 CFR § 35.394.

9.8.7 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive

For the purpose of this Part, training requirements for the parenteral administration of unsealed radioactive material requiring a written directive are defined by 10 CFR § 35.396.

9.9 Manual Brachytherapy

9.9.1 Use of Sources for Manual Brachytherapy

For the purpose of this Part, requirements for use of sources for manual brachytherapy are defined by 10 CFR § 35.400.

9.9.2 Surveys after Source Implant and Removal

A. For the purpose of this Part, requirements for surveys after source implant and removal are defined by 10 CFR §§ 35.404(a) and (b).

B. A licensee shall retain a record of the surveys required by § 9.9.2(A) of this Part for three (3) years. Each record shall include the date and results of the survey, the serial number and the model number of the survey instrument used, and the name of the individual who made the survey.

9.9.3 Brachytherapy Sources Accountability

C. For the purpose of this Part, requirements for brachytherapy sources accountability are defined by 10 CFR §§ 35.406(a) and (b).

D. A licensee shall maintain a record of the brachytherapy source accountability as follows:

1. For temporary implants, the record shall include:

   a. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;

   b. The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

   c. The number and activity of sources temporarily implanted in the patient or human research subject.

2. For permanent implants, the record shall include:

   a. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

   b. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

   c. The number and activity of sources permanently implanted in the patient or human research subject.

E. A licensee shall maintain the records required in § 9.9.3(B) of this Part for three (3) years.

9.9.4 Safety Instruction

A. For the purpose of this Part, requirements for safety instruction are defined by 10 CFR § 35.410(a).

B. A licensee shall keep a record of individuals receiving instruction required by in § 9.9.4(A) of this Part for three (3) years. The record shall include a list of the topic(s) covered, the date of instruction or training the name(s) of the attendees, and the name(s) of the individual(s) who provided the instruction.

9.9.5 Safety Precautions

For the purpose of this Part, requirements for safety precautions are defined by 10 CFR § 35.415.

9.9.6 Calibration Measurements of Brachytherapy Sources

A. For the purpose of this Part, requirements for calibration measurements of brachytherapy sources are defined by 10 CFR § 35.432.

B. A licensee shall retain a record of each calibration of brachytherapy sources required by § 9.9.6(A) of this Part for three (3) years after the last use of the source. The record shall include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

3. The source output or activity;

4. Source positioning accuracy within applicators;

5. The signature of the Authorized Medical Physicist; and

6. For surface applicators where the calibration was performed by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists, a complete copy of all calibration measurements provided for that source.

9.9.7 Decay of Strontium-90 Sources for Ophthalmic Treatments

A. For the purpose of this Part, requirements for decay of Strontium-90 sources for ophthalmic treatments are defined by 10 CFR § 35.433.

B. A licensee shall retain a record of decay calculations required by § 9.9.7(A) of this Part for 3 years after the last use of the source. The record shall include:

1. The date and initial source output or activity as determined under § 9.9.6(A) of this Part;

2. For each decay calculation, the date and the source output or activity as determined under § 9.9.7(A) of this Part; and

3. The signature of the Authorized Medical Physicist.

9.9.8 Therapy-related Computer Systems

A. For the purpose of this Part, requirements for acceptance testing on the treatment planning system of therapy-related computer systems are defined by 10 CFR § 35.437.

B. In addition to the requirements of § 9.9.8(A) of this Part, acceptance testing shall include verification of the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

9.9.9 Training for Use of Manual Brachytherapy Sources

For the purpose of this Part, training requirements for use of manual brachytherapy sources are defined by 10 CFR § 35.490.

9.9.10 Training for Ophthalmic Use of Strontium-90

For the purpose of this Part, training requirements for ophthalmic use of Strontium-90 are defined by 10 CFR § 35.491.

9.10 Sealed Sources for Diagnosis

9.10.1 Use of Sealed Sources for Diagnosis

For the purpose of this Part, requirements for use of sealed sources for diagnosis are defined by 10 CFR § 35.500.

9.10.2 Training for Use of Sealed Sources for Diagnosis

For the purpose of this Part, training requirements for use of sealed sources for diagnosis are defined by 10 CFR § 35.590.

9.11 Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

9.11.1 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

For the purpose of this Part, requirements for use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit are defined by 10 CFR § 35.600.

9.11.2 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit

A. For the purpose of this Part, requirements for surveys of patients and human research subjects treated with a remote afterloader unit are defined by 10 CFR § 35.604.

B. A licensee shall retain a record of the surveys required by § 9.11.2(A) of this Part for three (3) years. Each record shall include the date and results of the survey, the serial number and the model number of the survey instrument used, and the name of the individual who made the survey.

9.11.3 Installation, Maintenance, Adjustment, and Repair

A. For the purpose of this Part, requirements for installation, maintenance, adjustment, and repair are defined by 10 CFR § 35.605.

B. A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for three (3) years. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

9.11.4 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

A. For the purpose of this Part, requirements for safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units are defined by 10 CFR § 35.610.

B. A licensee shall retain a copy of the procedures required by § 9.11.4(A) of this Part until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

C. A licensee shall retain a record of the surveys required by § 9.11.4(A) of this Part for three (3) years. Each record shall include the date and results of the survey, the serial number and the model number of the survey instrument used, and the name of the individual who made the survey.

9.11.5 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

For the purpose of this Part, requirements for safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units are defined by 10 CFR § 35.615.

9.11.6 Dosimetry Equipment

A. For the purpose of this Part, requirements for dosimetry equipment are defined by 10 CFR § 35.630.

B. The licensee shall maintain a record of each calibration, intercomparison, and comparison of its dosimetry equipment for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

1. The date;

2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by §§ 9.11.6(A) & (B) of this Part;

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

4. The names of the individuals who performed the calibration, inter-comparison, or comparison, and evidence that the intercomparison was performed by or under the direct supervision of an Authorized Medical Physicist.

9.11.7 Full Calibration Measurements on Teletherapy Units

A. For the purpose of this Part, requirements for full calibration measurements on teletherapy units are defined by 10 CFR § 35.632.

B. A licensee shall maintain a record of each calibration for three (3) years. The record shall include:

1. The date of the calibration;

2. The manufacturer's name, model number and serial number for both the teletherapy unit and the source, and the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit;

3. The results and assessments of the full calibrations; and

4. The signature of the Authorized Medical Physicist who reviewed or performed the full calibration.

9.11.8 Full Calibration Measurements on Remote Afterloader Units

A. For the purpose of this Part, requirements for full calibration measurements on remote afterloader units are defined by 10 CFR § 35.633.

B. A licensee shall retain a record of each calibration for three (3) years. The record shall include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for both the remote afterloader unit and the source(s), and the model number and serial number of the instrument used to calibrate the unit;

3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the Authorized Medical Physicist who reviewed or performed the full calibration.

9.11.9 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

A. For the purpose of this Part, requirements for full calibration measurements on gamma stereotactic radiosurgery units are defined by 10 CFR § 35.635.

B. A licensee shall retain a record of each calibration for three (3) years. The record shall include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for both the gamma stereotactic radiosurgery unit and the sources, and the model number and serial number of the instrument used to calibrate the unit;

3. The results and assessments of the full calibrations; and

4. The signature of the Authorized Medical Physicist who reviewed or performed the full calibration.

9.11.10 Periodic Spot-checks on Teletherapy Units

A. For the purpose of this Part, requirements for periodic spot-checks on teletherapy units are defined by 10 CFR § 35.642.

B. A licensee shall maintain a record of each spot-check and a copy of the procedures required by § 9.11.10(A) of this Part for three (3) years. The record shall include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and the instrument used to measure the output of the teletherapy unit;

3. An assessment of timer constancy and linearity;

4. The calculated "on-off" error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring or localization device

7. The difference between the anticipated output and the measured output;

8. 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

9. The signature of the individual who performed the periodic spot-check, and the signature of the Authorized Medical Physicist who reviewed the record of the spot-check.

9.11.11 Periodic Spot-checks on Remote Afterloader Units

A. For the purpose of this Part, requirements for periodic spot-checks on remote afterloader units are defined by 10 CFR § 35.643.

B. A licensee shall retain a record of each check and a copy of the procedures required by § 9.11.11(A) of this Part for three (3) years. The record shall include, as applicable:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

4. 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

5. The signature of the individual who performed the periodic spot-check, and the signature of the Authorized Medical Physicist who reviewed the record of the spot-check.

9.11.12 Periodic Spot-checks on Gamma Stereotactic Radiosurgery Units

A. For the purpose of this Part, requirements for periodic spot-checks on gamma stereotactic radiosurgery units are defined by 10 CFR § 35.645.

B. A licensee shall retain a record of each check and a copy of the procedures required by § 9.11.12(A) of this Part for three (3) years. The record shall include:

1. The date of the spot-check;

2. 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;

3. An assessment of timer linearity and accuracy;

4. The calculated on-off error;

5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;

7. An assessment of source output against computer calculations;

8. 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

9. The signature of the individual who performed the periodic spot-check, and the signature of the Authorized Medical Physicist who reviewed the record of the spot-check.

9.11.13 Additional Technical Requirements for Mobile Remote Afterloader Units

A. For the purpose of this Part, additional technical requirements for mobile remote afterloader units are defined by 10 CFR § 35.647.

B. A licensee shall retain a record of each check required by § 9.11.13(A) of this Part for three (3) years. The record shall include:

1. The date of the check;

2. The manufacturer's name, model number, and serial number of the remote afterloader unit;

3. Notations accounting for all sources before the licensee departs from a facility;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

5. The signature of the individual who performed the check.

9.11.14 Radiation Surveys

A. For the purpose of this Part, requirements for radiation surveys are defined by 10 CFR § 35.652.

B. A licensee shall maintain a record of the surveys required by § 9.11.14(A) of this Part for the duration of the license. The record shall include:

1. The date of the measurements;,

2. The manufacturer's name, model number and serial number of the treatment unit, the source, and the instrument used to measure radiation levels;

3. Each dose rate measured around the source while in the "off" position and the average of all measurements, and

4. The signature of the Authorized Medical Physicist who reviewed or performed the survey.

9.11.15 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

A. For the purpose of this Part, requirements for five-year inspection for teletherapy and gamma stereotactic radiosurgery units are defined by 10 CFR § 35.655.

B. A licensee shall maintain a record of the inspection and servicing for the duration of use of the unit. The record shall contain:

1. The inspector's name;

2. The inspector's radioactive materials license number;

3. The date of inspection;

4. The manufacturer's name and model number and serial number for both the treatment unit and source;

5. A list of components inspected and serviced, and the type of service; and

6. The signature of the inspector.

9.11.16 Therapy-related Computer Systems

For the purpose of this Part, requirements for acceptance testing on the treatment planning system of therapy-related computer systems are defined by 10 CFR § 35.657.

9.11.17 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

For the purpose of this Part, training requirements for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units are defined by 10 CFR § 35.690.

9.12 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

9.12.1 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

A. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed elsewhere in this Part if:

1. The applicant or licensee has submitted:

a. Information regarding any radiation safety aspects of the medical use of the material that is not addressed elsewhere in this Part; and

b. Specific information on:

(1) Radiation safety precautions and instructions;

(2) Training and experience of proposed users;

(3) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(4) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

c. Any other information requested by the Agency in its review of the application; and

2. The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with this Subchapter and specific conditions the Agency considers necessary for the medical use of the material.