902 KAR 100:072. Use of radionuclides in the health arts.

RELATES TO: KRS 211.842 - 211.852, 211.990(4), 10 C.F.R. 35, 45 C.F.R. 46
STATUTORY AUTHORITY: KRS 194A.050, 211.090, 211.844, 10 C.F.R. 35
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to promulgate administrative regulations for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes requirements and provisions for the use of radioactive material in the healing arts, for issuance of licenses authorizing the medical use of radioactive material and for specific licensees to possess, use, and transfer radioactive material for medical uses.

Section 1. Implementation. (1) A licensee shall implement the provisions in this administrative regulation on or before October 24, 2005, with the exception of the requirements listed in subsection (2) of this section.

(2) A licensee shall implement the training requirements in Sections 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, and 77 of this administrative regulation on or before October 25, 2007.

(3) Prior to October 25, 2007, a licensee shall satisfy the training requirements of this administrative regulation for a radiation safety officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(a) The appropriate training requirements in Sections 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, and 77 of this administrative regulation; or

(b) The appropriate training requirements in Section 78 of this administrative regulation.

(4) If a license condition exempted a licensee from a provision of this administrative regulation on October 24, 2005, then the license condition continues to exempt the licensee from the provision of 902 KAR 100:072.

(5) If a requirement in this administrative regulation differs from the requirement in an existing license condition, the requirement in this administrative regulation shall govern.

(6) A licensee shall continue to comply with any license condition that requires it to implement procedures required by Sections 49, 55, 56, and 57 of this administrative regulation until there is a license amendment or renewal that modifies the license condition.

Section 2. License Required. (1) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the cabinet, the U.S. Nuclear Regulatory Commission, or another agreement state, or as allowed in subsection (2)(a) or (b) of this section.

(2) A specific license is not required for an individual who:

(a) Receives, possesses, uses, or transfers radioactive material in accordance with the administrative regulations in this chapter under the supervision of an authorized user as provided in Section 12 of this administrative regulation unless prohibited by license condition; or

(b) Prepares unsealed radioactive material for medical use in accordance with the administrative regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Section 12 of this administrative regulation unless prohibited by license condition.

Section 3. Maintenance of Records. Each record required by this administrative regulation shall be legible throughout the retention period specified by each section. The record shall be the original or 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.

Section 4. Application for License, Amendment, or Renewal. (1) An application shall be signed by the applicant's or licensee's management.

(2) An application for a license for medical use of radioactive material as described in Sections 30, 31, 33, 37, 45, 46 and 62 of this administrative regulation and shall be made by:

(a) Filing an original and one (1) copy of Form RPS-7, Application for Radioactive Material License, that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist; and

(b) Submitting procedures required by Sections 49, 55, 56, and 57, of this administrative regulation as applicable.

(3) A request for a license amendment or renewal shall be made by:

(a) Submitting an original and one (1) copy of either:

1. Form RPS-7, Application for Radioactive Material License; or

2. A letter requesting the amendment or renewal; and

(b) Submitting procedures required by Sections 49, 55, 56, and 57 of this administrative regulation as applicable.

(4) In addition to the requirements in subsections (2) and (3) of this section, an application for a license or amendment for medical use of radioactive material as described in Section 62 of this administrative regulation shall also include information regarding any radiation safety aspects of the medical use of the material that is unique to the evolving technology.

(a) The applicant shall also 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.

(b) The applicant or licensee shall provide information requested by the cabinet as necessary to complete its review of the application.

(5) An applicant that satisfies the requirements specified in 902 KAR 100:052 of this chapter may apply for a Type A specific license of broad scope.

Section 5. License Amendments. A licensee shall apply for and receive a license amendment:

(1) Before the licensee receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter;

(2) Before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except:

(a) For an authorized user, an individual who meets the requirements in Sections 63, 68(1), 69(1), 70(1), 71(1), 72(1), 74(1), 76(1), 77(1), 78(2)(a), 78(3)(a), 78(4)(a), 78(7)(a), 78(9)(a), and 78(10)(a) of this administrative regulation;

(b) For an authorized nuclear pharmacist, an individual who meets the requirements in Sections 63 and 66(1) or 78(12)(a);

(c) For an authorized medical physicist, an individual who meets the requirements in Sections 63 and 65(1) or 78(11)(a) or (b) of this administrative regulation;

(d) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

1. On a cabinet, an agreement state, or U.S. Nuclear Regulatory Commission license or other equivalent permit or license recognized by the cabinet that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

2. On a permit issued by the cabinet, an agreement state, or U.S. Nuclear Regulatory Commission specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

3. On a permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

4. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(3) Before it changes radiation safety officers, except as provided in Section 10(3) of this administrative regulation;

(4) Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(5) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either Section 30 or 31 of this administrative regulation;

(6) Before it changes the address of use identified in the application or on the license; or

(7) Before it revises procedures required by Sections 49, 55, 56 and 57 of this administrative regulation as applicable, where the revision reduces radiation safety; and

(8) Before conducting research involving human research subjects using radioactive material.

Section 6. Notifications. (1) A licensee shall provide the cabinet a copy of the board certification, the cabinet, U.S. Nuclear Regulatory Commission or agreement state license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state licensee of broad scope, or the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee for each individual no later than thirty (30) days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist under Section 5(2)(a) through (d) of this administrative regulation.

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

(a) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes; (c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 902 KAR 100:040, Section 6(2) of this chapter; or

(d) The licensee has added to or changed the areas of use identified in the application or on the license if radioactive material is used in accordance with either Section 30 or 31 of this administrative regulation.

(3) The licensee shall mail the documents required in this section to the Cabinet for Health and Family Services, Radiation Health Branch, Manager, 275 East Main
Street, Mailstop HS1C-A, Frankfort, Kentucky 40621.

Section 7. Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a Type A specific license of broad scope for medical use, issued under 902 KAR 100:052 of this chapter, is exempt from:

(1) Section 4(4) of this administrative regulation regarding the need to file an amendment to the license for medical use of radioactive material, as described in Section 62 of this administrative regulation;

(2) The provisions of Section 5(2) of this administrative regulation;

(3) The provisions of Section 5(5) of this administrative regulation regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(4) The provisions of Section 6(1) of this administrative regulation;

(5) The provisions of Section 6(2)(a) of this administrative regulation for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(6) The provisions of Section 6(2)(d) of this administrative regulation regarding additions to or changes in the areas of use identified in the application or on the license if radioactive material is used in accordance with either Section 30 or 31 of this administrative regulation; and

(7) The provisions of Section 36(1) of this administrative regulation.

Section 8. License Issuance. (1) The cabinet shall issue a license for the medical use of radioactive material if:

(a) The applicant has filed RPS-7 Application for Radioactive Material License in accordance with the instructions in Section 4 of this administrative regulation;

(b) The applicant has paid any applicable fee as provided in 902 KAR 100:012 of this chapter;

(c) The cabinet finds the applicant equipped and committed to observe the safety standards established by the cabinet in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of 902 KAR 100:040, 100:041, 100:042, and 100:045 of this chapter.

(2) The cabinet shall issue a license for mobile medical service if the applicant:

(a) Meets the requirements in subsection (1) of this section; and

(b) Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with Section 27 of this administrative regulation.

Section 9. Specific Exemptions. The cabinet may, as established in 10 C.F.R. 35.19, upon application of any interested person or upon its own initiative, grant exemptions from the administrative regulations in this chapter 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.

Section 10. Authority and Responsibilities for the Radiation Protection Program. (1) In addition to the radiation protection program requirements of 902 KAR 100:019 of this administrative regulation, a licensee's management shall approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the cabinet;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted in under Section 11 of this administrative regulation.

(2) 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.

(3) 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 Sections 63 and 64, of this administrative regulation to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in subsection (7) of this section, if the licensee takes the actions required in subsections (2), (5), (7), and (8) of this section and notifies the cabinet in accordance with Section 6 of this administrative regulation.

(4) A licensee may simultaneously appoint more than one (1) temporary radiation safety officer in accordance with subsection (3) of this section, 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 uses of radioactive material permitted by the license.

(5) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

(6) A licensee authorized for two (2) or more different types of uses of radioactive material under Sections 33, 37, and 46 of this administrative regulation or two (2) or more types of units under Section 46 of this administrative regulation 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. The committee may include other members the licensee considers appropriate.

(7) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide corrective actions;

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(8) A licensee shall retain a record of actions taken under subsections (1), (2), and (5) of this section as follows:

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection (1) of this section, for five (5) years. The record shall include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer, as required in subsection (5) of this section, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required in subsection (5) of this section, for the duration of the license. The records shall include the signature of the radiation safety officer and licensee management.

Section 11. Radiation Protection Program Changes. (1) A licensee may revise its radiation protection program without cabinet approval if:

(a) The revision does not require a license amendment under Section 5 of this administrative regulation;

(b) The revision is in compliance with 902 KAR Chapter 100 and the license;

(c) The revision has been reviewed and approved by the radiation safety officer and licensee management; and

(d) The affected individuals are instructed on the revised program before the changes are implemented.

(2) A licensee shall retain a record of each radiation protection program change made in accordance with subsection (1) of this section for five (5) years. The record shall 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.

Section 12. Supervision. (1) 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 Section 2(2)(a) of this administrative regulation shall:

(a) In addition to the requirements in 902 KAR 100:165, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, administrative regulations of this chapter, and license conditions with respect to the use of radioactive material; and

(b) 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, administrative regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

(2) 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 Section 2(2)(b) of this administrative regulation shall:

(a) In addition to the requirements in 902 KAR 100:165, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(b) 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, the administrative regulations of this chapter, and license conditions.

(3) A licensee that permits supervised activities under subsections (1) and (2) of this section is responsible for the acts and omissions of the supervised individual.

Section 13. Written Directives. (1) A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (Thirty (30) microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

(a) 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 shall be acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record.

(b) A written directive shall be prepared within forty-eight (48) hours of the oral directive.

(2) The written directive shall contain the patient or human research subject's name and the following information:

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

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

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

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

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

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

1. Before implantation: treatment site, the radionuclide, and dose; and

2. 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).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(a) 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 shall be acceptable. The oral revision shall be documented as soon as possible in the patient's record.

(b) A revised written directive shall be signed by the authorized user within forty-eight (48) hours of the oral revision.

(4) The licensee shall retain a copy of the written directive as required by this section for three (3) years.

Section 14. Procedures for Administrations Requiring a Written Directive. (1) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by subsection (1) of this section shall address the following items that are applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) Checking both manual and computer-generated dose calculations; and

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 46 or 62 of this administrative regulation.

(3) A licensee shall retain a copy of the procedures required under subsection (1) for the duration of the license.

Section 15. Report and Notification of Medical Events. (1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(a) 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, five-tenths (0.5) Sv (50 rem) to an organ or tissue, or five-tenths (0.5) Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

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

1. An administration of a wrong radioactive drug containing radioactive material;

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

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

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

5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by five-tenths (0.5) Sv (fifty (50) rem) to an organ or tissue and fifty (50) percent 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).

(2) 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.

(3) The licensee shall notify the cabinet by telephone no later than the next calendar day after discovery of the medical event. The commercial telephone number of the Cabinet for Health and Family Services, Radiation Health Branch is (502) 564-3700. The twenty-four (24) hour emergency number is (800) 255-2587.

(4) The licensee shall submit a written report to the Cabinet for Health and Family Services, Radiation Health Branch, Manager,
275 East Main Street, Mailstop HS1C-A, Frankfort, Kentucky 40621, within fifteen (15) days after discovery of the medical event.

(a) The written report shall include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual who received the administration;

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

7. Certification that the licensee notified the individual (or the individual’s responsible relative or guardian), and if not, why not.

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

(5)(a)1. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee shall not be required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four (24) hours, the licensee shall notify the individual as soon as possible thereafter.

2. The notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian;

(b) 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 this written description if requested; and

(c) The licensee shall not delay any appropriate medical care for the individual including any necessary remedial care as a result of the medical event, because of any delay in notification.

(6) Aside from the notification requirement, this section shall not affect any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(7) A licensee shall:

(a) Annotate a copy of the report provided to the cabinet with the:

1. Name of the individual who is the subject of the event; and

2. Social Security number or other identification number, if one (1) has been assigned, of the individual who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen (15) days after the discovery of the event.

Section 16. Report and Notification of a Dose to an Embryo/fetus or a Nursing Child. (1) A licensee shall report any dose to an embryo/fetus that is greater than fifty (50) mSv (five (5) rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) Is greater than fifty (50) mSv (five (5) rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify the cabinet by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsections (1) or (2) of this section. The commercial telephone number of the Cabinet for Health and Family Services, Radiation Health Branch is (502) 564-3700. The twenty-four (24) hour emergency number is (800) 255-2587.

(4) The licensee shall submit a written report to the Cabinet for Health and Family Services, Radiation Health Branch, Manager, 275 East Main Street, Mailstop HS1C-A, Frankfort, Kentucky 40621, within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsections (1) or (2) in this section.

(a) The written report shall include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the embryo or fetus or the nursing child;

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

7. 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.

(b) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5)(a)1. The licensee shall 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 twenty-four (24) hours after discovery of an event that would require reporting under subsection (1) or (2) 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. The licensee shall not be required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty-four (24) hours, the licensee shall make the appropriate notifications as soon as possible thereafter.

2. The notification may be made to the mother's or child's responsible relative or guardian instead of the mother. 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 this written description if requested; and

(b) The licensee shall not delay any appropriate medical care for the embryo or fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.

(6) A licensee shall:

(a) Annotate a copy of the report provided to the cabinet with the:

1. Name of the pregnant individual or the nursing child who is the subject of the event; and

2. Social Security number or other identification number, if one (1) has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen (15) days after the discovery of the event.

Section 17. Provisions for the Protection of Human Research Subjects. (1) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(2) If the research is conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, the licensee shall, before conducting research:

(a) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46; and

(b) Obtain informed consent, as defined and described in the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, from the human research subject.

(3) If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee, shall before conducting research, apply for and receive a specific amendment to its cabinet medical use license. The amendment request shall include a written commitment that the licensee shall, before conducting research:

(a) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46; and

(b) Obtain "informed consent", as defined and described in the Federal Policy, form the human research subject.

(4) This section shall not relieve the licensees from complying with the other requirements in this administrative regulation.

Section 18. Report of a Leaking Source. A licensee shall file a report within five (5) days if a leak test required by Section 24, of this administrative regulation reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report shall be filed with the Cabinet for Health and Family Services, Radiation Health Branch, Manager, 275 East Main Street, Frankfort, Kentucky 40621. The written report shall include the model number 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.

Section 19. Quality Control of Diagnostic Equipment. A licensee shall establish written quality control procedures for diagnostic equipment used for radionuclide studies. (1) As a minimum, the procedures shall include:

(a) Quality control procedures recommended by equipment manufacturers; or

(b) Procedures submitted by the licensee and approved by the cabinet.

(2) The licensee shall conduct quality control procedures in accordance with written procedures.

Section 20. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material. (1) For direct measurements performed in accordance with Section 22, of this administrative regulation a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) A licensee shall calibrate the instrumentation required in subsection (1) of this section in accordance with nationally-recognized standards or the manufacturer's instructions.

(3) A licensee shall maintain a record of instrument calibrations, required by this section, for three (3) years. The records shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Section 21. Calibration of Survey Instruments. (1) A licensee shall calibrate the survey instruments used to show compliance with this administrative regulation and 902 KAR 100:019 before first use, annually, and following a repair that affects the calibration. A licensee shall:

(a) Calibrate all scales with readings up to ten (10) mSv (1,000 mrem) per hour with a radiation source;

(b) Calibrate two (2) separated readings on each scale or decade that will be used to show compliance; and

(c) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(2) A licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than twenty (20) percent.

(3) A licensee shall maintain a record of each radiation survey instrument calibrations for three (3) years. The record shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Section 22. Determination of Dosages of Unsealed Radioactive Material for Medical Use. (1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination shall be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

1. A manufacturer or preparer licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements; or

2. A cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state license for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(3) For other than unit dosages, this determination shall be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty (20) percent.

(5) A licensee shall retain a record of the dosage determination, required by this section, for three (3) years. The record shall contain:

(a) The radiopharmaceutical;

(b) The patient's or human research subject's name, or identification number if one (1) has been assigned;

(c) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 μCi);

(d) The date and time of the dosage determination; and

(e) The name of the individual who determined the dosage.

Section 23. Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by Section 2 of this administrative regulation for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use. (1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements.

(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(4) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in 902 KAR 100:030.

(5) Technetium-99m in amounts as needed.

Section 24. Requirements for Possession of Sealed Sources and Brachytherapy Sources. (1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(2) A licensee in possession of a sealed source shall:

(a) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six (6) months before transfer to the licensee; and

(b) Test the source for leakage at intervals not to exceed six (6) months or at other intervals approved by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state in the Sealed Source and Device Registry.

(3) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(4) A licensee shall retain leak test records in accordance with subsection (8)(a) of this section.

(5) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 902 KAR 100:019, 100:021, 100:040, and 100:058; and

(b) File a report within five (5) days of the leak test in accordance with 902 KAR 100:072, Section 18.

(6) A licensee need not perform a leak test on the following sources:

(a) Sources containing only radioactive material with a half-life of less than thirty (30) days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(d) Seeds of iridium-192 encased in nylon ribbon; and

(e) Sources stored and not being used. However, the licensee shall test each source for leakage before any use or transfer unless it has been leak tested within six (6) months before the date of use or transfer.

(7) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semiannual physical inventory of all these sources in its possession. The licensee shall retain each inventory record in accordance with subsection (8)(b) of this section.

(8) A licensee shall keep records of leaks tests and inventory of sealed sources and brachytherapy sources as follows:

(a) A licensee shall retain records of leak tests for three (3) years. The records shall include the model number and serial number, if one (1) 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.

(b) A licensee shall retain records of the semiannual physical inventory of sealed sources and brachytherapy sources for three (3) years. The inventory records shall contain the model number of each source, and serial number if one (1) 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.

Section 25. Labeling of Vials and Syringes. Each syringe and vial that contains unsealed radioactive material shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

Section 26. Surveys of Ambient Radiation Exposure Rate. (1) In addition to the surveys required by 902 KAR 100:019, a licensee shall survey with a radiation detection survey instru-

ment at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee shall not be required to perform the surveys required by subsection (1) of this section in an area where patients or human research subjects are confined when they cannot be released under Section 27 of this administrative regulation.

(3) 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 conduct the survey, and the name of the individual who performed the survey.

Section 27. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material. (1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material 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 five (5) mSv (five-tenths (0.5) rem). 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 five (5) mSv (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written 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 one (1) mSv (one-tenth (0.1) rem). If the total effective dose equivalent to a nursing infant or child could exceed one (1) mSv (one-tenth (0.1) rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(a) Guidance on the interruption or discontinuation of breast-feeding; and

(b) Information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with this section, if the total effective dose equivalent is calculated by:

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

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

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

(d) Considering the shielding by tissue.

(4) A licensee shall retain a record that the instructions, required by this section, 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 five (5) mSv (five-tenths (0.5) rem).

(5) The records required by subsections (3), and (4) of this section shall be retained for three (3) years after the date of release of the individual.

(6) A report shall be filed in accordance with Section 15 of this chapter and submitted to the cabinet if a dose greater than 50 mSv (5 rem) is received by an individual from a patient released under this section.

Section 28. Provision of Mobile Medical Service. (1) A licensee providing mobile medical service shall:

(a) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(b) 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 required by this paragraph shall include a constancy check;

(c) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(d) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 902 KAR 100:019.

(2) A mobile 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 byproduct material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(3) A licensee providing mobile medical services shall retain the letter required in subsection (1)(a) and the record of each survey required in subsection (1)(d) of this section respectively:

(a) A licensee shall retain a copy of each letter required in subsection (1)(a) that permits the use of radioactive material at a client's address. 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.

(b) A licensee shall retain the record of each survey required by subsection (1)(d) 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.

(4) The cabinet shall license mobile medicine services in accordance with this administrative regulation and applicable requirements of 902 KAR 100:012, 100:015, 100:019, 100:021, 100:040, 100:050, 100:060, 100:070, and 100:165.

Section 29. Decay-in-storage. (1) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(a) Holds radioactive material for decay a minimum of ten (10) half-lives;

(b) Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(c) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(2) A licensee shall retain a record of each disposal for three (3) years. The record shall include the:

(a) Date of the disposal;

(b) Date on which the radioactive material was placed in storage;

(c) Radionuclides disposed;

(d) Model and serial number of the survey instrument used;

(e) Background dose rate;

(f) Radiation dose rate measured at the surface of each waste container; and

(g) Name of the individual who performed the disposal.

Section 30. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required. Except for quantities that require a written directive under Section 13(2), of this administrative regulation a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

(1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040 and 902 KAR 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;

(2) Prepared by:

(a) An authorized nuclear pharmacist;

(b) A physician who is an authorized user and who meets the requirements specified in Section 69 or 70 and Section 69(3)(a)2.g of this administrative regulation; or

(c) An individual under the supervision of either as specified in Section 12 of this administrative regulation; or

(3) Obtained from and prepared by a licensee of the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Section 31. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required. Except for quantities that require a written directive under Section 13(2) of this administrative regulation a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040 or 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;

(2) Prepared by:

(a) An authorized nuclear pharmacist;

(b) A physician who is an authorized user and who meets the requirements specified in Sections 69 or 70 and Section 69(3)(a)2.g. of this administrative regulation; or

(c) An individual under the supervision, as specified in Section 12 of this administrative regulation;

(3) Obtained from and prepared by a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational
New Drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Section 32. Permissible Radionuclide Contaminant Concentration. (1) A licensee shall not administer to humans a radiopharmaceutical containing more than:

(a) 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(b) 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or

(c) 0.02 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride);

(2) A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant of the first eluate after receipt of a generator to demonstrate compliance with limits specified in subsection (1) of this section.

(3) A licensee required to measure radionuclide contaminant concentration, in this section, shall retain a record of each measurement for three (3) years;

(a) The record shall include, for each elution or extraction tested, the:

1. Measured activity of the radiopharmaceutical expressed in millicuries;

2. Measured activity of contaminant expressed in microcuries;

3. Ratio of the measurements in subsection (1)(a), (b), and (c) of this section expressed as microcuries of contaminant per millicurie of radiopharmaceutical;

4. Date of the test; and

5. Initials of the individual who performed the test.

(b) A licensee shall report immediately to the cabinet each occurrence of contaminant concentration exceeding the limits specified in this section.

Section 33. Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040 or 902 KAR 100:058 of this chapter, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;

(2) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in Section 69 or 70 of this administrative regulation, or an individual under the supervision, as specified in Section 12 of this administrative regulation;

(3) Obtained from and prepared by a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Section 34. Safety Instruction. (1) In addition to 902 KAR 100:165, a licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for the patient or the human research subjects receiving radiopharmaceutical therapy and hospitalized for compliance with Section 27 of this administrative regulation. To satisfy this requirement, the instruction shall describe the licensee's procedures for:

(a) Patient or human research subject control;

(b) Visitor control:

1. Routine visitation to hospitalized individuals in accordance with 902 KAR 100:019, Section 10(1)(a) of this chapter; and

2. Visitation authorized in accordance with 902 KAR 100:019, Section 10(6) of this chapter;

(c) Contamination control;

(d) Waste control; and

(e) Notification of the radiation safety officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(2) A licensee shall retain a record of individuals receiving safety instructions for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Section 35. Safety Precautions. (1) For each patient or human research subject who cannot be released under Section 27 of this administrative regulation a licensee shall:

(a) Quarter the patient or the human research subject either in:

1. A private room with a private sanitary facility; or

2. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under Section 27 of this administrative regulation;

(b) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign:

(c) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(d) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(2) A licensee shall notify the radiation safety officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Section 36. Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee shall only use:

(1) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state;

(2) Sealed sources or devices noncommercially transferred from a 902 KAR 100:072 license, U.S. Nuclear Regulatory Commission, or equivalent State Medical License; or

(3) Teletherapy sources manufactured and distributed in accordance with a license issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state.

Section 37. Use of Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA if the requirements of Section 36(1) of this administrative regulation are met.

Section 38. Surveys After Source Implant and Removal. (1) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(2) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(3) A licensee shall retain a record of the surveys required by subsections (1) and (2) of this section for three (3) years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Section 39. Brachytherapy Sources Accountability. (1) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(2) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(3) A licensee shall maintain a record of the brachytherapy source accountability for three (3) years for:

(a) Temporary implants, the record shall include:

1. 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; and

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

(b) Permanent implants, the record shall include:

1. 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;

2. 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

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

Section 40. Safety Instruction. In addition to the requirements of 902 KAR 100:165 of this chapter. (1) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under Section 27 of this administrative regulation. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and shall include the:

(a) Size and appearance of the brachytherapy sources;

(b) Safe handling and shielding instructions;

(c) Patient or human research subject control;

(d) Visitor control, including both:

1. Routine visitation of hospitalized individuals in accordance with 902 KAR 100:019, Section 10(1)(a) of this chapter; and

2. Visitation authorized in accordance with 902 KAR 100:019, Section 10(6) of this chapter; and

(e) Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(2) A licensee shall retain a record of individuals receiving instruction for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name of the attendee, and the name of the individual who provided the instruction.

Section 41. Safety Precautions. (1) For each patient or human research subject who is receiving brachytherapy and cannot be released under Section 27 of this administrative regulation a licensee shall:

(a) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(b) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(c) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(2) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(a) Dislodged from the patient; and

(b) Lodged within the patient following removal of the source applicators.

(3) A licensee shall notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Section 42. Calibration Measurements of Brachytherapy Sources. (1) Before the first medical use of a brachytherapy source on or after October 24, 2005, a licensee shall have:

(a) Determined the source output or activity using a dosimetry system that meets the requirements of Section 51(1) of this administrative regulation;

(b) Determined source positioning accuracy within applicators; and

(c) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subsection (1)(a) and (b) of this section.

(2) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection (1) of this section.

(3) A licensee shall mathematically correct the outputs or activities determined in subsection (1) of this section for physical decay at intervals consistent with one (1) percent physical decay.

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

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(c) The source output or activity;

(d) The source positioning accuracy within the applicators; and

(e) The name of the individual, source manufacturer, or the calibration laboratory that performed the calibration.

Section 43. Decay of strontium-90 sources for ophthalmic treatments. (1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under Section 42 of this administrative regulation.

(2) A licensee shall retain a record of the activity of each strontium-90 source for the life of the source. The record shall include:

(a) The date and initial activity of the source as determined under Section 42 of this administrative regulation; and

(b) For each decay calculation, the date and the source activity as determined under subsection (1) of this section.

Section 44. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally-recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays; and

(4) The accuracy of the software used to determine sealed source positions from radiographic images.

Section 45. Use of Sealed Sources for Diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Section 46. Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Section 36(1) of this administrative regulation are met.

Section 47. Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit. (1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of the surveys for three (3) years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Section 48. Installation, Maintenance, Adjustment, and Repair. (1) Only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

(4) 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 of the individual who performed the work.

Section 49. Safety Procedures and instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall:

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(c) Prevent dual operation of more than one (1) radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation if the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by subsection (1)(d) of this section shall be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of:

(a) The location of the procedures required by subsection (1)(d) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(a) The procedures identified in paragraph (1)(d) of this section; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instructions for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name of the attendee, and the name of the individual who provided the instruction.

(7) A licensee shall retain a copy of the procedures until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Section 50. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source to be shielded when an entrance door is opened; and

(c) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(a) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the unit. This backup power supply may be a battery system.

(b) If the radiation monitor is inoperable, the licensee shall require any individual entering the treatment room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check

source for proper operation at the beginning of each day of use. The licensee shall keep a record as established in this section.

(c) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities in which a source is placed within the patient's or human research subject's body, a licensee shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in subsections (1) through (5) of this section, a licensee shall:

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator if there is an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(a) Remaining in the unshielded position; or

(b) Lodged within the patient following completion of the treatment.

Section 51. Dosimetry Equipment. (1) Except for low dose-rate remote afterloader sources in which the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one (1) of the following two (2) conditions shall be met:

(a) The system shall have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two (2) years and after any servicing that may have affected system calibration; or

(b) The system shall have been calibrated within the previous four (4) years. Eighteen (18) to thirty (30) months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past twenty-four (24) months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall

indicate that the calibration factor of the licensee's system had not changed by more than two (2) percent. The licensee shall not use the intercomparison result to change the calibration factor. If intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (1) of this section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection (1) of this section.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with this section for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

(a) The date;

(b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections (1) and (2) of this section;

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

Section 52. Full Calibration Measurements on Teletherapy Units. (1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. If spot-check measurements indicate that the output differs by more than five (5) percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; or

3. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding one (1) year.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements shall include determination of:

(a) The output within +/- three (3) percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in Section 51(1) of this administrative regulation to measure the output for one (1) set of exposure conditions. The remaining ra-

diation measurements required in subsection (2)(a) of this section may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally-recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section for physical decay for intervals not exceeding one (1) month for cobalt-60, six (6) months for cesium-137, or at intervals consistent with one (1) percent decay for all other nuclides.

(6) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (5) of this section shall be performed by the authorized medical physicist.

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

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

(c) The results and an assessment of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

Section 53. Full calibration measurements on remote afterloader units. (1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

2. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

(c) At intervals not exceeding one (1) quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy-five (75) days; and

(d) At intervals not exceeding one (1) year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements shall include, as applicable, determination of:

(a) The output within ± five (5) percent;

(b) Source positioning accuracy to within ± one (1) millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Length of the source transfer tubes;

(e) Timer accuracy and linearity over the typical range of use;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in Section 51(1) of this administrative regulation to measure the output.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally-recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection (2) of this section, a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one (1) quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections (1) through (5) of this section.

(7) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section for physical decay at intervals consistent with one (1) percent physical decay.

(8) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (7) of this section shall be performed by the authorized medical physicist.

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

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

(c) The results and an assessment of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

Section 54. Full calibration measurements on gamma stereotactic radiosurgery units (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. Whenever spot-check measurements indicate that the output differs by more than five (5) percent from the output obtained at the last full calibration corrected.

2. Following replacement of the sources or following reinstallation of the gamma mathematically for radioactive decay, stereotactic radiosurgery unit in a new location, and

3. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding one (1) year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements shall include determination of:

(a) The output within ± three (3) percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in Section 51(1) of this administrative regulation to measure the output for one (1) set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this section may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section at intervals not exceeding one (1) month for cobalt-60 and at intervals consistent with one (1) percent physical decay for all other radionuclides.

(6) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (5) of this section shall be performed by the authorized medical physicist.

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

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

(c) The results and an assessment of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

Section 55. Periodic Spot-checks for Teletherapy Units. (1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that shall include determination of:

(a) Timer accuracy, and timer linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one (1) typical set of operating conditions measured with the dosimetry system described in Section 51(2) of this administrative regulation; and

(f) The difference between the measurement made in subsection (1)(e) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual shall not be required to actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) Viewing and intercom systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and shall not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each spot-check for teletherapy units for three (3) years. The record shall include:

(a) The date of the spot-check;

(b) 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;

(c) An assessment of timer linearity and constancy;

(d) The calculated on-off error;

(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) The determined accuracy of each distance measuring and localization device;

(g) The difference between the anticipated output and the measured output;

(h) 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

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(7) A licensee shall retain a copy of the procedures required by subsection (2) of this section until the licensee no longer possesses the teletherapy unit.

Section 56. Periodic Spot-checks for Remote Afterloader Units. (1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) A licensee shall perform the measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual shall not be required to actually perform the spot check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of subsection (1) of this section, spot-checks shall, at a minimum, assure proper operation of:

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed source activity in the unit's computer.

(5) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and shall not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each spot-check for remote afterloader units for three (3) years. The record shall include, as applicable:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(c) An assessment of timer accuracy;

(d) 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

(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(7) A licensee shall retain a copy of the procedures required by subsection (2) of this section until the licensee no longer possesses the remote afterloader unit.

Section 57. Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units. (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(a) Monthly;

(b) Before the first use of the unit on a given day; and

(c) After each source installation.

(2) A licensee shall:

(a) Perform the measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual shall not be required to actually perform the spot check measurements.

(b) Have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of subsection (1)(a) of this section, spot-checks shall, at a minimum:

(a) Assure proper operation of:

1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine:

1. The output for one (1) typical set of operating conditions measured with the dosimetry system described in Section 51(2) of this administrative regulation;

2. The difference between the measurement made in subsection (3)(b)1. of this section and the anticipated output, expressed as a percentage of the anticipated output (the value obtained at last full calibration corrected mathematically for physical decay);

3. Source output against computer calculation;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. Trunnion centricity.

(4) To satisfy the requirements of subsection (1)(b) and (c) of this section, spot-checks shall assure proper operation of:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in subsection (3) of this section that is not operating properly as soon as possible.

(6) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and shall not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by this section for three (3) years. The record shall include:

(a) The date of the spot-check;

(b) 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;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

(f) The difference between the anticipated output and the measured output;

(g) An assessment of source output against computer calculations;

(h) 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

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(8) A licensee shall retain a copy of the procedures required by subsection (2) of this section until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Section 58. Additional Technical Requirements for Mobile Remote Afterloader Units. (1) A licensee providing mobile remote afterloader service shall:

(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) Account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by Section 56 of this administrative regulation a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

(a) Electrical interlocks on treatment area access points;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(e) Radiation monitors used to indicate room exposures;

(f) Source positioning (accuracy); and

(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in subsection (2) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in subsection (2) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and shall not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) A licensee shall retain a record of each check for mobile remote afterloader units for three (3) years. The record shall include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) 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

(e) The signature of the individual who performed the check.

Section 59. Radiation Surveys. (1) In addition to the survey requirement in 902 KAR 100:019, Section 12, a person licensed under this administrative regulation shall conduct surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee shall conduct the survey required by subsection (1) of this section at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

(3) A licensee shall maintain a record of radiation surveys of treatment units for the duration of use of the unit. The record shall include:

(a) The date of the measurements;

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

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the individual who performed the test.

Section 60. Five (5) year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state.

(3) A licensee shall maintain a record of the five (5) year inspections for teletherapy and gamma stereotactic radiosurgery units for the duration of use of the unit. The record shall contain:

(a) The inspector's radioactive materials license number;
(b) The date of inspection;
(c) The manufacturer's name and model number and serial number of both the treatment unit and source;
(d) A list of components inspected and serviced, and the type of service; and
(e) The signature of the inspector.

Section 61. Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:
(1) The source-specific input parameters required by the dose calculation algorithm;
(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;
(3) The accuracy of isodose plots and graphic displays;
(4) The accuracy of the software used to determine sealed source positions from radiographic images; and
(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Section 62. Other Medical Uses of Radioactive Material or Radiation from Radioactive Material. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in Sections 30, 31, 33, 37, 45, and 46 of this administrative regulation if:
(1) The applicant or licensee has submitted the information required by Section 4(2) through (4) of this administrative regulation; and
(2) The applicant or licensee has received written approval from the cabinet in a license or license amendment and uses the material in accordance with the administrative regulations and specific conditions the cabinet considers necessary for the medical use of the material.

Section 63. Recentness of Training. The training and experience specified in Sections 64 through 77 of this administrative regulation shall have been obtained within the seven (7) years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

Section 64. Training for Radiation Safety Officer. Except as provided in Section 67 of this administrative regulation, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 902 KAR 100:072, Section 10 to be an individual who:
(1)(a) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in subsections (2) and (3) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:
1.a. Hold a bachelor’s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of twenty (20) college credits in physical science;
b. Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience) including at least three (3) years in applied health physics; and

c. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurements of radioactivity, radiation biology, and radiation dosimetry; or

2.a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

b. Have two (2) years of full-time practical training, two (2) years of supervised experience, or two (2) years of a combination of full-time practical training and supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state; or

(ii) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 902 KAR 100:072, Sections 67, 69, or 70 of this administrative regulation; and

c. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety;

(b) Has completed a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiation dosimetry; and

2. One (1) year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a cabinet, U.S. Nuclear Regulatory Commission, or agreement state license or permit issued by a Commission master material licensee that authorizes similar type of use of radioactive material involving the following:

a. Shipping, receiving, and performing related radiation surveys;

b. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

c. Securing and controlling radioactive material;

d. Using administrative controls to avoid mistakes in the administration of radioactive material;

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

f. Using emergency procedures to control radioactive material; and

g. Disposing of radioactive material; or

(c)1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state pursuant to 902 KAR 100:072, Section 65(1), and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer, and who meets the requirements in subsections (2) and (3) of this section; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities;

(2) Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

(3) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

Section 65. Training for an Authorized Medical Physicist. Except as provided in Section 67 of this administrative regulation the licensee shall require the authorized medical physicist to be an individual who:

(1)(a) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in paragraph (b)2. of this subsection and subsection (2) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two (2) years of full-time practical training, two (2) years of supervised experience, or two (2) years of a combination of full-time practical training and supervised experience in medical physics:

a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state; or

b. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in Section 67, 74, or 77 of this administrative regulation; and

3. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provides high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services and shall include:

1. Performing sealed source leak test and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in Sections 65 or 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type of use for which authorization is sought that includes hands-on device operation, safety operations, clinical use, and the operation of a treatment planning system. This training requirement shall be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type of use for which the individual is seeking authorization.

Section 66. Training for an Authorized Nuclear Pharmacist. Except as provided in Section 67 of this administrative regulation the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in subsection (2)(b) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4,000 hours of training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Has completed 700 hours in a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Supervised practical experience in a nuclear pharmacy involving:

a. Shipping, receiving, and performing related radiation surveys;

b. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

c. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

d. Using administrative controls to avoid medical events in the administration of radioactive material; and

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (1)(a), (1)(b) and (1)(c) or (2)(a) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Section 67. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist and Authorized Nuclear Pharmacist. (1)(a) An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a cabinet, U.S. Nuclear Regulatory Commission, or agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2005 shall not be required to comply with the training requirements of Section 64, 65, or 66, of this administrative regulation respectively:

(b) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on a cabinet, U.S. Nuclear Regulatory Commission, or agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state broad scope licensee or master material license permit or master material licensee permittee of broad scope between October 24, 2002 and April 29, 2005 is not required to comply with the training requirements of Section 64, 65, or 66 of this administration regulation respectively.

(2)(a) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state, a permit issued by a Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date shall not be required to comply with the training requirements of 902 KAR 100:072, Sections 68 through 77.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state, a permit issued by a Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission or an agreement state broad scope licensee or a permit issued by a Commission master material license broad scope permittee who performs only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005 shall not be required to comply with the training requirements of Sections 68 through 77 of this administrative regulation.

Section 68. Training for Uptake, Dilution, and Excretion Studies. Except as provided in Section 67 of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized pursuant to Section 30 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or an agreement state and who meets the requirements in subsection (3)(b) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete sixty (60) hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in subsection (3)(a)1 through 3(a)2 of this section; and

(b) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;

(2) Is an authorized user under Section 69 or 70 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(3)(a) Has completed sixty (60) hours of training and experience, including a minimum of eight (8) hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include:

1. Classroom and laboratory training, in the following areas;

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Section 67, 68, 69, or 70, of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages of radioactive drugs to patients or human research subjects; and

(b) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Section 67, 68, 69, or 70 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or (3)(a) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized pursuant to Section 30 of this administrative regulation.

Section 69. Training for Imaging and Localization Studies. Except as provided in Section 67 of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized pursuant to Section 31 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in subsection (3)(b) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 700 hours of training and experience in basis radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for

imaging and localization studies that includes the topics listed in subsection (3)(a)1 through (3)(a)2 of this section; and

(b) Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;

(2) Is an authorized user pursuant to Section 70 of this administrative regulation and meets the requirements in subsection (3)(a)2.g of this section, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(3)(a) Has completed 700 hours of training and experience, including a minimum of eighty (80) hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user, who meets the requirements in Section 67, 69 or 70 and Section 69(3)(a)2.g of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Sections 67, 69, or 70 and Section 69(3)(a)2.g of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or (3)(a) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized pursuant to Sections 30 and 31 of this administrative regulation.

Section 70. Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in Section 67 of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized pursuant to Section 33 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or an agreement state, and who meets the requirements in subsection (2)(a)2.f and (b) of this section. To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in subsection (2)(a)1 through 2.e of this section. Eligible training programs shall be approved by:

1. Residency Review Committee of the Accreditation Council for Graduate Medical Education;

2. Royal College of Physicians and Surgeons of Canada; or

3. Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by the diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2)(a) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. A supervising authorized user, who meets the requirements in this subsection, shall have experience in administering dosages in the same dosage category or categories (clause f. of this subparagraph) of this administrative regulation as the individual requesting authorized user status. The work experience shall involve:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three (3) cases in each of the following categories for which the individual is requesting authorized user status:

(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; or

(iv) Parenteral administration of any other radionuclide, for which a written directive is required; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (1)(a) and (2)(a)2.f or (2)(a) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized pursuant to Section 33 of this administrative regulation. The written attestation shall be signed by a preceptor authorized user who meets the requirements of this section, and section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. The preceptor authorized user, who meets the requirements in subsection (2) of this section, shall have experience in administering dosages in the same dosage category or categories (Section 70(2)(a)2.f) of this administrative regulation as the individual requesting authorized user status.

Section 71. 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). Except as provided in Section 67 of this administrative regulation, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (b) of this section and whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in subsection (3)(c) of this section;

(2) Is an authorized user pursuant to Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f.(i) or (ii), or Section 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(3)(a) Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to the medical use of sodium iodide I–131 for procedures requiring a written directive. The training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in Section 67, 70, 71,, or 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. A supervising authorized user who meets the requirements in Section 70 (2)(a) of this administrative regulation shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(i) or (ii) of this administrative regulation. The work experience shall involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3)(a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized pursuant to Section 33 of this administrative regulation. The written attestation shall be signed by a preceptor authorized user who meets the requirements in Section 67, 70, 71, or 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. A preceptor authorized user, who meets the requirement in Section 70(2) of this administrative regulation shall also have experience in administering dosages as specified in Section 70(2)(a)2.f.(i) or (ii) of this administrative regulation.

Section 72. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). Except as provided in Section 67 of this administrative regulation the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (b) of this section, and whose certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in subsection of (3)(c) of this section; or

(2) Is an authorized user pursuant to Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f.(ii) of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(3)(a) Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection; and
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology;

(b) Has work experience, under the supervision of an authorized user who meets the requirements in Section 67, 70, or 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. A supervising authorized user, who meets the requirements in Section 70(2) of this administrative regulation, shall also have experience in administering dosages as specified in Section 70(2)(a)2.f.(ii) of this administrative regulation. The work experience shall involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3)(a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized pursuant to Section 33 of this administrative regulation. The written attestation shall be signed by a preceptor authorized user who meets the requirements in Section 67, 70 or 72 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements. A preceptor authorized user, who meets the requirements in Section 70(2) of this administrative regulation, shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(ii).

Section 73. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive. Except as provided in Section 67 of this administrative regulation, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user pursuant to Section 70 for uses listed in Section 70(2)(a)2.f.(iii) or Section 70(2)(a)2.f.(iv) of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(2)(a)1. Is an authorized user pursuant to Sections 74 or 77 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state and who meets the requirements in paragraph (b) of this subsection; or

2. Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state pursuant to Sections 74 or 77 of this administrative regulation; and who meets the requirements in paragraph (b) of this subsection; and

(b)1. Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of a beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of other radionuclides for which a written directive is required. The training shall include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology;

2. Has work experience, under the supervision of an authorized user who meets the requirements in Sections 67, 70, or 73 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, in the parenteral administration, for which a written directive is required, of a beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of other radionuclides for which a written directive is required. A supervising authorized user who meets the requirements in Section 70 of this administrative regulation shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) or (iv) of this administrative regulation or both. The work experience shall involve:

a. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subjects dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, that include at least three (3) cases involving the parenteral administration, for which a written directive is required, of a beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV, or a minimum of three (3) cases involving the parenteral administration of other radionuclides, for which a written directive is required, or both; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)1. or 2. of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation shall be signed by a preceptor authorized user who meets the requirements in Sections 67, 70, or 73 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in Section 70 of this administrative regulation, shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) or (iv) of this administrative regulation or both.

Section 74. Training for Use of Manual Brachytherapy Sources. Except as provided in Section 67 of this administrative regulation, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized pursuant to Section 37 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in (2)(c) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum or three (3) years of residency training in a radiation oncology program approved by the:

1. Residency Review Committee of the Accreditation Council for Graduate Medical Education; or

2. Royal College of Physicians and Surgeons of Canada; or

3. Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2)(a) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements at a medical institution, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving the use of radioactive material;

f. Using emergency procedures to control radioactive material; and

(b) Has completed three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (2)(a)2. of this section; and

(c) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or (2)(a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized pursuant to Section 37 of this administrative regulation.

Section 75. Training for Ophthalmic Use of Strontium-90. Except as provided in Section 67 of this administrative regulation the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user pursuant to Section 74 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

(2)(a) Has completed twenty-four (24) hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five (5) individuals. This supervised clinical training shall involve:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow up and review of each individual's case history; and

(c) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Sections 67, 74, or 75 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Section 76. Training for use of sealed sources for diagnosis. Except as provided in Section 67 of this administrative regulation, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized pursuant to Section 45 of this administrative regulation to be a physician, dentist, or podiatrist who:

(1)(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this subsection and subsection (2) of this section and whose certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state; or

(b) Has completed eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Has completed training in the use of the device for the uses requested.

Section 77. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in Section 67 of this administrative regulation, the licensee shall require an authorized user of a sealed source for a use authorized pursuant to Section 46 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state and who meets the requirements in (2)(c) and (3) of this section. To have its certification recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three (3) years of residency training in a radiation therapy program approved by the:

1. Residency Review Committee of the Accreditation Council for Graduate Medical Education;
2. Royal College of Physicians and Surgeons of Canada; or
3. Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2)(a) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity; and
d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements at a medical institution, involving:

a. Reviewing full calibration measurements and periodic spot-checks;
b. Preparing treatment plans and calculating treatment doses and times;
c. Using administrative controls to prevent a medical event involving the use of radioactive material;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

e. Checking and using survey meters; and

f. Selecting the proper dose and how it is to be administered; and

(b) Has completed three (3) years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (2)(a)2 of this section; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (1)(a) or (2)(a) and (b), and (3) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in this section, or Section 67 of this administrative regulation, or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought, This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

Section 78. Alternative Training. During a two (2) year period after the effective date of October 24, 2005, alternative training and experience requirements shall be available. Licensees shall have the option of complying with either the training requirements of Section 78 of this administrative regulation or the new requirements in Sections 65 through 77 of this administrative regulation. After October 24, 2007, licensee shall not have the option of using Section 78 of this administrative regulation. Except as provided in Section 67 of this administrative regulation, the licensee shall require for:

(1) A radiation safety officer, an individual fulfilling the responsibilities of the radiation safety officer as provided in Section 10 of this administrative regulation to be an individual who:

(a) Is certified by the:

1. American Board of Health Physics in Comprehensive Health Physics;
2. American Board of Radiology;
3. American Board of Nuclear Medicine;
4. American Board of Science in Nuclear Medicine;
5. Board of Pharmaceutical Specialties in Nuclear Pharmacy;
6. American Board of Medical Physics in radiation oncology physics;
7 Royal College of Physicians and Surgeons of Canada in nuclear medicine;
8. American Osteopathic Board of Radiology; or
9. American Osteopathic Board of Nuclear Medicine;

(b) Has had classroom and laboratory training and experience as follows:

1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry; and

2. One (1) year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the radiation safety officer on a cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state license that authorizes the medical use of radioactive material; or

(c) Is an authorized user identified on the licensee's license.

(2) Authorized user of a radiopharmaceutical for uptake, dilution, and excretion in Section 30(1) of this administrative regulation to be a physician who:

(a) Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine;

2. Diagnostic radiology by the American Board of Radiology;

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

5. American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

1. Forty (40) hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry; and

2. Twenty (20) hours of supervised clinical experience under the supervision of an authorized user and that includes:

a. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients or human research subjects and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radioisotope test results; and

e. Patient or human research subject follow up; or

(c) Has successfully completed a six (6) month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

(3) Authorized user for imaging and localization studies using a radiopharmaceutical, generator, or reagent kit in Section 31(1) of this administrative regulation to be a physician who:

(a) Is certified in:

1. Nuclear medicine by the American Board of Nuclear Medicine;

2. Diagnostic radiology by the American Board of Radiology;

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

5. American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(c)1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiopharmaceutical chemistry; and

e. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an authorized user that includes:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

c. Calculating and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent the medical event of radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

3. 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

a. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

b. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

c. Administering dosages to patients or human research subjects and using syringe radiation shields;

d. Collaborating with the authorized user in the interpretation of radioisotope test results; and

e. Patient or human research subject follow up; or

(c) Has successfully completed a six (6) month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

(4) The authorized user of radiopharmaceuticals for therapeutic use in Section 33 of this administrative regulation to be a physician who:

(a) Is certified by:

1. The American Board of Nuclear Medicine;

2. The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

3. The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

4. The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

1. Eighty (80) hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

a. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten (10) individuals; and

b. Use of iodine-131 for treatment of thyroid carcinoma in three (3) individuals.

(5) The authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) Eighty (80) hours of classroom and laboratory training that includes:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten (10) individuals.

(6) The authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) Eighty (80) hours of classroom and laboratory training that includes:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three (3) individuals.

(7) The authorized user of a brachytherapy source in Section 36 of this administrative regulation for therapy to be a physician who:

(a) Is certified in:

1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

2. Radiation oncology by the American Osteopathic Board of Radiology;

3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing sealed sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving radioactive material; and

f. Using emergency procedures to control radioactive material; and

3. Three (3) years of supervised clinical experience that includes one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

a. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

b. Selecting the proper brachytherapy sources and dose and method of administration;

c. Calculating the dose; and

d. Post-administration follow-up and review of case histories in collaboration with the authorized user.

(8) The authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(a) Twenty-four (24) hours of classroom and laboratory training that includes:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five (5) individuals that includes:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow up and review of each individual's case history.

(9) The authorized user of a sealed source for diagnosis in a device listed in Section 45 of this administrative regulation to be a physician, dentist, or podiatrist who:

(a) Is certified in:

1. Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

2. Nuclear medicine by the American Board of Nuclear Medicine;

3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Has had eight (8) hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

1. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

2. Radiation biology;

3. Radiation protection; and

4. Training in the use of the device for the uses requested.

(10) The authorized user of a sealed source for therapeutic medical devices listed in Section 46 of this administrative regulation to be a physician who:

(a) Is certified in:

1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

2. Radiation oncology by the American Osteopathic Board of Radiology;

3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology";

4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows:

1. 200 hours of classroom and laboratory training that includes:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology;

2. 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

a. Review of the full calibration measurements and periodic spot-checks;

b. Preparing treatment plans and calculating treatment times;

c. Using administrative controls to prevent medical events;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

e. Checking and using survey meters; and

3. Three (3) years of supervised clinical experience that includes one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

a. Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

b. Selecting the proper dose and how it is to be administered;

c. Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

d. Postadministration follow up and review of case histories.

(11) The authorized medical physicist shall be an individual who:

(a) Is certified by the American Board of Radiology in:

1. Therapeutic radiological physics;
2. Roentgen ray and gamma ray physics;
3. X-ray and radium physics; or
4. Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one (1) year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in Sections 24, 52, 53, 54, 55, 56, 57 and 58 of this administrative regulation as applicable.

(12) The authorized nuclear pharmacist to be a pharmacist who:

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)1. Has completed 700 hours in a structured educational program consisting of both:

a. Didactic training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

b. Supervised experience in a nuclear pharmacy involving the following:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

(v) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

2. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

(13) An authorized experienced nuclear pharmacist must be a pharmacist who has completed a structured educational program as specified in subsection (12)(b)(1) of this section before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist shall not be required to comply with the requirements for a preceptor statement (subsection (12)(b)(2) of this section) and recentness of training (Section 63 of this administrative regulation) to qualify as an authorized nuclear pharmacist.

Section 79. Food and Drug Administration (FDA), Other Federal and State Requirements. Nothing in this administrative regulation relieves the licensee from complying with applicable FDA, other federal and state requirements governing radioactive drugs or devices. (31 Ky.R. 656; 1163; eff. 1-4-2005; 37 Ky.R. 1837; 2627; eff. 6-3-2011; 41 Ky.R. 921; 1612; eff. 2-5-2015.)