CABINET FOR HEALTH AND FAMILY SERVICES

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Governor

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Janie Miller
Secretary

August 30, 2011

James G. Luehman, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Luehman:

Enclosed is a copy of the final revisions to the Kentucky Radiological Health Kentucky Administrative Regulations, Title 902, Chapter 100 Radiology published in final form on June 3, 2011. The final regulations are attached and correspond to the following equivalent amendments to NRC's regulations.

Rats ID	Title	State Section
• 1998-5, 1999-3, 2001-1, 2000-2 2004-1, 2005-2, 2006-1	Definitions for 902 KAR Chapter 100.	902 KAR 100:010
• 1995-3, 1998-6	Disposal of radioactive material.	902 KAR 100:021
• 2006-1	Specific licenses to manufacture, assemble, repair, or distribute products.	902 KAR 100:058
• 2004-1	Transportation of radioactive material.	902 KAR 100:070
• 2005-2, 2006-1	Use of radionuclides in the health arts.	902 KAR 100:072
• 2004-1	Notices, reports, and instructions to employees.	902 KAR 100:165

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at502-564-3700 ext. 3701 or Curt Pendergrass of my staff at 502-564-3700 ext. 4140 or curt.pendergrass@ky.gov .

Sincerely,

Matthew W. McKinley
Program Manager,
Kentucky Radiation Health Branch

Enclosures:
As stated

902 KAR 100:010. Definitions for 902 KAR Chapter 100.
http://www.lrc.ky.gov/kar/902/100/010.htm

RELATES TO: KRS 211.840, 211.842-211.852, 211.990(4), 10 C.F.R. 20.1003-20.1005, NCRP Report 141, 42 U.S.C. 2011 et seq. STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.844, 10 C.F.R. 20.1003-20.1005

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 authorizes the Cabinet for Health and Family Services to provide by administrative regulation 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. The Nuclear Regulatory Commission (NRC) approves or denies Kentucky's program for regulating radioactive materials after the effective date of administrative regulations within 902 KAR Chapter 100. The federal guidance manual, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements - SA - 200, issued June 5, 2009, provides parameters states shall follow in order for approval. The parameters include the provision that definitions shall be identical to NRC definitions. This administrative regulation establishes definitions for 902 KAR Chapter 100.

Section 1. Definitions.

(1) "A_1" and "A_2":
    (a) "A_1" means the maximum activity of special form radioactive material permitted in a Type A package;
    (b) "A_2" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package;
    (c) These values are listed in 10 C.F.R. 71, Appendix A, or may be derived under the procedure prescribed in 10 C.F.R. 71 Appendix A.

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

(3) "Accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one (1) MeV, such as the cyclotron, synchrotron, synchrocyclotron, betatron, linear accelerator, and Van de Graaff electrostatic generator.

(4) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(5) "Act" means the "Kentucky Radiation Control Act of 1978", as established in KRS 211.840.

(6) "Activity" means the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

(7) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used or stored.

(8) "Adult" means an individual eighteen (18) or more years of age.

(9) "Agreement state" means a state with which the United States Nuclear Regulatory Commission or the United States Atomic Energy Commission has entered into an

effective agreement under subsection 274 b. of the Atomic Energy Act of 1954, 42 U.S.C. 200 et seq., as amended (73 Stat. 689).

(10) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(11) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of radioactive material, exists in concentrations:

(a) In excess of the derived air concentrations specified in 10 C.F.R. 20 Appendix B; or

(b) That an individual present in the area without respiratory protective equipment may exceed an intake of six-tenths (0.6) percent of the annual limit on intake or twelve (12) DAC hours.

(12) “Air kerma (K)” means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

(13) “Air-purifying respirator” means a respirator with an air-purifying filer, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(14) "Alert" means the notice given when an event may occur, is in progress, or has occurred that may lead to a release of radioactive material, but the release is not expected to require a response by an off-site response organization in order to protect persons offsite.

(15) "Aluminum equivalent" means the thickness of type 1100 aluminum, which is composed of at least ninety-nine (99.0) percent aluminum, 0.12 percent copper, affording the same attenuation, under specified conditions, as the material for which it is substituted.

(16) "Analytical x-ray system" means a system which utilizes x-rays for the examination of the structure of materials, such as x-ray diffraction and spectrographic equipment.

(17) "Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of annual intake of a given radionuclide by the reference man that would result in:

(a) A committed effective dose equivalent of five (5) rems, or 0.05 Sv; or

(b) A committed dose equivalent of fifty (50) rems, or five-tenths (0.5) Sv, to an individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are established in 10 C.F.R. 20 Appendix B.

(18) "Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using or storing radioactive material.

(19) "As low as reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposures to radiation as far below the dose limits established in 902 KAR 100:019 as practical, consistent with the purpose for which the licensed activity is undertaken. ALARA shall take into account the state of technology, the economics of improvement in relation to benefits to the public health and safety,

and other societal and socioeconomic considerations, in relation to the utilization of nuclear energy and radioactive materials in the public interest.

(20) “Assigned protection factor” or “APF” means the expected workplace level of respirator protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration may be estimated by dividing the ambient airborne concentration by the APF.

(21) “Atmosphere-supplying respirator” means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(22) "Attenuation" means the reduction of exposure rate upon passage of radiation through matter.

(23) "Attenuation block" means a block or stack, having dimensions twenty (20) centimeters by twenty (20) centimeters by three and eight-tenths (3.8) centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(24) “Authorized medical physicist” means an individual who:

(a) Meets the requirements in 902 KAR 100:072, Sections (63) and 65(1); or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use licensee issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state;
2. A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee;
3. A permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state broad scope medical use licensee; or
4. A permit issued by the U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(25) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in 902 KAR 100:072, Sections 63 and 66(1);

(b) Is identified as an authorized nuclear pharmacist on a:

1. Specific license issued by the cabinet, state, or U.S. Nuclear Regulatory Commission that authorizes the medical use or the practice of nuclear pharmacy;
2. Permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
3. Permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
4. Permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

(c) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(d) Is designated as an authorized nuclear pharmacist under 902 KAR 100:058, Section 9(2)(c).

(26) “Authorized user” means a physician, dentist, or podiatrist who:

(a) Meets the requirements in 902 KAR 100:072, Sections 63 and 68(1), 69(1), 71(1), 72(1), 74(1), 76(1), and 77(1); or

(b) Is identified as an authorized user on:

1. The cabinet’s, U.S. Nuclear Regulatory Commission’s, or an agreement state’s license that authorizes the medical use of radioactive material;
2. A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;
3. A permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or agreement state licensee of broad scope that is authorized to permit the medical use of radioactive material; or
4. A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(27) "Automatic exposure control" means a device that automatically controls one (1) or more technique factors in order to obtain, at a preselected location, a required quantity of radiation.

(28) "Background radiation" means radiation not under the control of the licensee, including:

(a) From cosmic sources;

(b) Naturally occurring radioactive materials;

(c) Radon that is not a decay product of source or special nuclear material; and

(d) Global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents. Background radiation shall not include radiation from radioactive materials regulated by the Cabinet for Health and Family Services.

(29) "Beam axis" means the axis of rotation of the beam limiting device.

(30) "Beam limiting device" or "collimator" means a device that provides a means to restrict the dimensions of the x-ray field.

(31) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

(32) “Beam scattering foil” means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(33) "Becquerel" means a unit, in the International System of Units (SI), of measurement of radioactivity equal to one (1) transformation per second.

(34) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

(35) "Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver radiation at a distance to a few centimeters, by surface, intracavitary, or interstitial application.

(36) "Broker" or "waste broker" means a person who takes possession of low-level waste solely for the purposes of consolidation and shipment.
(37) "By-product material" means:
  (a) Radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; or
  (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations shall not constitute by-product material within this definition.
(38) "Cabinet" means Cabinet for Health Services, or its duly authorized representatives.
(39) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 902 KAR 100:019, Section 11.
(40) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed or used in a permanent enclosure in which the enclosure is intended to contain at least that portion of the material being irradiated, not to include x-ray systems used by licensed practitioners of the healing arts. The enclosure:
  (a) May be the architectural structure or may be independent of the architectural structure;
  (b) Shall provide attenuation of the radiation to meet the requirements of 902 KAR 100:105; and
  (c) Shall exclude personnel from its interior during the generation of x-radiation.
(41) "Calendar quarter" means between twelve (12) and fourteen (14) consecutive weeks.
  (a) The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be arranged so that no day is included in more than one (1) calendar quarter and no day in a one (1) year period is omitted from inclusion within a calendar quarter.
  (b) A licensee or registrant shall not change the method observed of determiningcalendar quarters, except at the beginning of a calendar year.
(42) "Calibration" means the determination of:
  (a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
  (b) The strength of a source of radiation relative to a standard.
(43) "Carrier" is defined by KRS 174.405(1).
(44) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
(45) “Certificate holder” means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.
(46) “Certificate of Compliance" or "CoC” means the certificate issued by the U.S. Nuclear Regulatory Commission under 10 C.F.R. Part 71, which approves the design of a package for the transportation of radioactive material.

(47) "Certified cabinet x-ray system" means an x-ray system that has been certified under 21 C.F.R. 1010.2 as being manufactured and assembled according to the provisions of 21 C.F.R. 1020.40.
(48) "Certified component" means a component of an x-ray system subject to 21 C.F.R. Subchapter J.
(49) "Certified system" means an x-ray system that has one (1) or more certified component.
(50) "C.F.R." means Code of Federal Regulations.
(51) "Changeable filters" means a filter, exclusive of inherent filtration, which can be removed from the useful beam through an electronic, mechanical, or physical process.
(52) “Chemical description” means a description of the principal chemical characteristics of a low-level radioactive waste.
(53) "Class" or "lung class" or "inhalation class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials shall be classified as D, W, or Y, which applies to a range of clearance half-times:
  (a) For Class D (Days) of less than ten (10) days;
  (b) For Class W (Weeks) from ten (10) to 100 days; and
  (c) For Class Y (Years) of greater than 100 days.
(54) “Close reflection by water” means immediate contact by water of sufficient thickness for maximum reflection of neutrons.
(55) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
(56) "Collimator" means a device used to limit the size, shape, and direction of the primary radiation beam.
(57) "Commission" means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
(58) "Committed dose equivalent ($H_{T,50}$)" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the fifty (50) year period following the intake.
(59) "Committed effective dose equivalent ($H_{E,50}$)" means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = W\sum_T H_{T,50}$).
(60) “Computer-readable medium” means the cabinet’s computer can transfer the information from the medium into its memory.
(61) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.
(62) “Consignee” means the designated receiver of the shipment of low-level radioactive waste.
(63) “Consignment” means each shipment of a package or groups of packages or load of radioactive material officered by a shipper for transport.
(64) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(65) "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) centimeters of the surface being treated.

(66) “Containment system” means the assembly of components of the package intended to retain the radioactive material during transport.

(67) "Controlled area" means an area, outside of a restricted area but inside the site boundary, to which access can be limited by the licensee or registrant for a stated reason.

(68) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(69) “Conveyance” means:

(a) For transport by public highway or rail, a transport vehicle or large freight container;

(b) For transport by water, a vessel or a hold, compartment, or defined deck area of a vessel including a transport vehicle on board the vessel; or

(c) Transportation by an aircraft.

(70) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(71) “Criticality Safety Index" or “CSI”, means the dimensionless number, rounded up to the next tenth, assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in 10 C.F.R. 71.22, 71.23, and 71.59.

(72) "Curie" means a quantity of radioactivity.

(a) One (1) curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps).

(b) Commonly used submultiples of the curie are the millicurie and the microcurie.

1. One (1) millicurie (mCi) = 0.001 curie = 3.7×10^{7} dps.
2. One (1) microcurie (uCi) = 0.000001 curie = 3.7×10^{4} dps.

(73) "Dead man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(74) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is not longer pregnant.

(75) "Decommission" means the:

(a) Safe removal from service of a facility or site;

(b) Termination of license; and

(c) Reduction of residual radioactivity to a level permitting release of the property:

1. For unrestricted use; or
2. Under restricted conditions.

(76) “Decontamination facility” means a facility operating under the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle,

reuse, or other waste management objectives, and is not considered to be a consignee for LLW shipments.

(77) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. The source may also be used for other purposes.

(78) "Deep-dose equivalent (H_d)" which applies to external whole-body exposure, means the dose equivalent at a tissue depth of one (1) centimeter (cm) (1000 mg/cm^2).

(79) “Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(80) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one (1) ALI.

(a) "Light work" produces an inhalation rate of one and two-tenths (1.2) cubic meters ($1.2m^3$) of air per hour.

(b) DAC values are given in 10 C.F.R., 20 Appendix B.

(81) "Derived air concentration-hour" or "DAC-hour" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one (1) ALI, equivalent to a committed effective dose equivalent of five (5) rems (0.05 Sv).

(82) "Diagnostic clinical procedure manual" means the collection of written procedures, methods, instructions, and precautions by which the licensee performs diagnostic clinical procedures, where each diagnostic clinical procedure:

(a) Has been approved by the authorized user; and

(b) Includes the radiopharmaceutical name, dosage, and route of administration.

(83) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(84) "Diagnostic-type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at a distance of one (1) meter from the source cannot exceed 100 milliroentgens in one (1) hour if the tube is operated at its maximum continuous rated current for the maximum tube potential.

(85) "Diagnostic x-ray system" means an x-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

(86) "Direct scatter radiation" means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam. (See also "scattered radiation").

(87) “Disposable container” means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility. (See also “high integrity container”.) For some shipments, the disposal container may be transport package.

(88) “Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use.

Disposal respirator may include, but not limit to a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(89) "Disposal" means the disposition of waste as authorized by 902 KAR 100:021.

(90) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentrations of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurements technology, survey, and statistical techniques.

(91) "Dose" or "radiation dose" means:

(a) Absorbed dose;

(b) Dose equivalent;

(c) Effective dose equivalent;

(d) Committed dose equivalent;

(e) Committed effective dose equivalent; or

(f) Total effective dose equivalent.

(92) "Dose commitment" means the total radiation dose to a part of the body that results from retention in the body of radioactive material. Estimation assumes the period of exposure to retained material to be less than fifty (50) years.

(93) "Dose equivalent (H_T)" means the product of the absorbed dose in tissue, the quality factor, and other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

(94) Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(95) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

(96) "DOT " means the U.S. Department of Transportation.

(97) "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = W_T H_T$).

(98) "Embryo or fetus" means the developing human organism from conception until the time of birth.

(99) "Energy compensation source or "ECS" means a small sealed source, with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool, or other

tool components, to provide a reference standard to maintain the tool's calibration when in use.

(100) "Entrance or access point" means a location through which an individual may gain access to a radiation area or radioactive material, including an entry or exit portal of sufficient size to permit human entry, irrespective of its intended use.

(101) "Entrance exposure rate" means the roentgens per unit time at the point the center of the useful beam enters the patient.

(102) "Environmental Protection Agency "EPA" Identification number" means the number received by a transporter following application to the EPA as required by 40 C.F.R. Part 263.

(103) "Exclusive use" means the sole use of a conveyance by a single consignor in which initial, intermediate, and final loading and unloading are carried out under the direction of the consignor or consignee.
(a) Consignor and carrier shall each ensure that loading and unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment.
(b) Consignor shall include with the shipping paper information provided to the carrier, specific written instructions for maintenance of exclusive use shipment controls.
(104) "Exposure" means being exposed to ionizing radiation or to radioactive material.
(105) "Exposure rate" means the exposure per unit of time.
(106) “External beam radiation therapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.
(107) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.
(108) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.
(109) "Eye dose equivalent". See "lens dose equivalent".
(110) "Facility" means a location at which one (1) or more devices or sources are installed or located within one (1) building, vehicle, or under one (1) roof, under the same administrative control.
(111) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
(112) “Field-flattening filter” means a filter used to homogenize the absorbed dose rate over the radiation field.
(113) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.
(114) "Filter" means the material in the useful beam which usually absorbs preferentially the less penetrating radiations.
(a) "Inherent filtration" means the filter permanently in the useful beam. It includes the window of the x-ray tube and the permanent tube enclosure.
(b) "Added filter" means the filter added to the inherent filtration.
(c) "Total filter" means the sum of the inherent and added filters.
(115) “Filtering facepiece (dust mask)” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.
(116)(a) "Fissile material" means the:
1. Radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides; and
2. Fissile nuclides themselves, not material containing fissile nuclides.
(b) Fissile material does not include unirradiated natural and depleted uranium; and natural or depleted uranium that has been irradiated in thermal reactors only;

(c) Fissile material also excludes certain controls as provided in 10 C.F.R. 70.15.

(117) "Fissile material package" means a fissile material packaging together with its fissile material contents.

(118) “Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator while worn.

(119) “Fit test” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(120) "Fluoroscopic imaging assembly" means a component that comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if present, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

(121) "Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

(122) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(123) “Gantry” means that part of a radiation producing machine supporting and allowing movements of the radiation head about a center of rotation.

(124) "General purpose radiographic x-ray system" means a radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(125) "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of 42 U.S.C. sec. 2011 et seq., that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(126) "Generator" or means a licensee operating under the cabinet, U.S. Nuclear Regulatory Commission or an agreement state who:

(a) Is a waste generator as defined in this administrative regulation; or

(b) Is the licensee to whom waste can be attributed within the context of the Low Level Radioactive Waste Policy Amendments Act of 1985, such as, waste generated as a result of decontamination or recycle activities.

(127) "Gonad shield" means a protective barrier for the testes or ovaries.

(128) "Gray" or "Gy" means the SI unit of absorbed dose. One (1) gray equals an absorbed dose of one (1) Joule/kilogram (100 rads).

(129) "Half-value layer" or "HVL" means the thickness of specified material which attenuates the beam of radiation to one-half (1/2) of its original air kerma rate, exposure rate or absorbed dose rate. This excludes the contribution of scattered radiation, other than that which might be present initially in the beam concerned.

(130) "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications if these tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe these x-ray tests for the purpose of diagnosis or treatment.
(131) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds.
(132) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.
(133) “High integrity container or “HIC” means a container commonly designated to meet the structural stability requirements of 10 C.F.R. 61.56, and to meet the U.S. Department of Transportation requirements for a Type A package.
(134) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body may result in an individual receiving a dose equivalent in excess of one-tenth (0.1) rem (1m Sv) in one (1) hour at thirty (30) centimeters from the radiation source or thirty (30) centimeters from a surface that the radiation penetrates.
(135) “Hood” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.
(136) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.
(137) "Image intensifier" means a device that converts instantaneously, by means of photoemissive surfaces and electronic circuitry, an x-ray pattern into a light pattern of greater intensity than would have been produced by the original x-ray pattern.
(138) "Image receptor" means a device that transforms incident radiation into a visual image or into another form which can be made into a visual image by further transformations.
(139) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.
(140) "Individual" means a human being.
(141) "Individual monitoring" means the assessment of:
(a) Dose equivalent by the use of an individual monitoring device;
(b) Committed effective dose equivalent by:
1. Bioassay; or
2. Determination of the time-weighted air concentrations to which an individual has been exposed; or
(c) Dose equivalent by the use of survey data.
(142) "Individual monitoring device" or "individual monitoring equipment" means a device designed to be worn by a single individual for the assessment of dose equivalent, such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, or personal (“lapel”) air sampling devices.
(143) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.

(144) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
(145) “Interlock” means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.
(146) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
(147) "Irradiation" means the exposure of matter to ionizing radiation.
(148) “Kilovolt (kV) {kilo electron volt” means the energy equal to that acquired by a particle with one (1) electron charge in passing through a potential difference of 1,000 volts in a vacuum. {Note: current convention is to use kV for photons and keV for electrons.}
(149) "Kilovolt peak" or "kVp" means the crest value in kilovolts of the potential difference of a pulsating potential generator. If only one-half (1/2) of the wave is used, the value refers to the useful half of the wave.
(150) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
(151) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly, except for the useful beam.
(152) "Leakage technique factor" means, with respect to different tube housing assemblies:
(a) For capacitor energy storage equipment: the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential, with a charge per exposure of ten (10) milliampere seconds (mAs) or the minimum obtainable from the unit, whichever is larger.
(b) For field emission equipment rated for pulsed operation: the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
(c) For all other equipment: the maximum rated continuous tube current for the maximum rated peak tube potential.
(153) "Lens dose equivalent" or "LDE" means the external exposure of the lens of the eye, and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).
(154) "License" means a license issued by the cabinet under 902 KAR Chapter 100.
(155) "Licensed material" means radioactive material, source material, or special nuclear material received, possessed, used, or transferred, under a general or specific license issued by the cabinet, U.S. Nuclear Regulatory Commission or an agreement state.
(156) “Light field” means the area illuminated by light, simulating the radiation field.
(157) "Limits" or "dose limits"" means the permissible upper bounds of radiation doses.
(158) "Lixiscope" means a portable light-intensified imaging device using a sealed source.
(159) "Logging assistant" means an individual who, under the personal supervision of a logging supervisor:
(a) Handles sealed sources or tracers that are not in logging tools or shipping containers; or
(b) Uses survey instruments in well-logging activities.

(160) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

(161) "Logging tool" means a device used subsurface to perform well-logging.

(162) “Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

(163) "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(164) "Low-level radioactive waste" means radioactive waste not classified as:

(a) High-level radioactive waste;

(b) Transuranic waste;

(c) Spent nuclear fuel; or

(d) By-product material as defined in Section 11e(2) of the Atomic Energy Act of 1954, 42 U.S.C. 2014.

(165) "Low specific activity" or "LSA" means radioactive material with limited specific activity, which is nonfissile or is excepted under 10 C.F.R. 70.15 and that satisfies the descriptions and limits established in paragraphs (a), (b), and (c) of this subsection. Shielding materials surrounding the LSA material shall not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one (1) of three (3) groups:

(a) LSA-I:

1. Uranium and thorium ores, uranium or thorium concentrates of these ores, and other ores containing naturally occurring radioactive nuclides that are

not intended to be processed for the use of these radionuclides;

2. Solid unirradiated natural or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

3. Radioactive material for which the A_2 value is unlimited; or

4. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed thirty (30) times the value for exempt material activity concentration determined in 10 C.F.R. 71 Appendix A.

(b) LSA-II:

1. Water with tritium concentration up to 20.0 curies/liter (0.8 TBq/liter); or

2. Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/gram for solids and gases, and 10^{-5} A_2/gram for liquids.

(c) LSA-III: Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 C.F.R. 71.77 in which:

1. The radioactive material is distributed throughout a solid or a collection of solid objects;

2. Is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

3. The radioactive material is relatively insoluble, or it is intrinsically contained in

a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven (7) days, would not exceed 0.1 A_2; and the average specific activity of the solid does not exceed 2 x 10^{-3} A_2/gram; and

4. The average specific activity of the solid does not exceed 2 x 10^{-3} A_2/gram.

(166) "Low toxicity alpha emitter" means natural uranium, depleted uranium, natural thorium, uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten (10) days.

(167) "mA" means milliampere.

(168) "Management" means the chief executive officer or that individual's designee.

(169) "mAs" means milliampere second.

(170) "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of one (1) year under the heat condition specified in 10 C.F.R. Part 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(171) "Medical institution" means an organization in which several medical disciplines are practiced.

(172) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

(173) "Member of the public" means an individual except when the individual is receiving an occupational dose.

(174) "Microscopic analytical x-ray equipment" means a device which utilizes x-rays for examining the microscopic structure of materials. This includes x-ray diffraction and spectrographic equipment.

(175) "Mineral logging" means logging performed for the purpose of mineral exploration other than oil or gas.

(176) "Minor" means an individual less than eighteen (18) years of age.

(177) "Misadministration" means the administration of:

(a) A radiopharmaceutical dosage greater than thirty (30) microcuries of sodium iodide I-125 or I-131:

1. Involving the wrong patient or human research subject or the wrong radiopharmaceutical; or
2. If both the administered dosage differs from the prescribed dosage by more than twenty (20) percent of the prescribed dosage and the difference between the administered dosage and prescribe dosage exceeds thirty (30) microcuries.

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

1. Involving the wrong patient, human research subject, radiopharmaceutical, or route of administration; or
2. If the administered dosage differs from the prescribed dosage by more than twenty (20) percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:
1. Involving the wrong patient, human research subject, or treatment site; or
2. If the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent.

(d) A teletherapy radiation dose:
1. Involving the wrong patient, human research subject, mode of treatment, or treatment site;
2. If the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten (10) percent;
3. If the calculated weekly administered dose is thirty (30) percent greater than the weekly prescribed dose; or
4. If the calculated total administered dose differs from the total prescribed dose by more than twenty (20) percent.

(e) A brachytherapy radiation dose:
1. Involving the wrong patient, human research subject, radioisotope, or treatment site except for permanent implant seeds that were implanted in the correct site but migrated outside the treatment site;
2. Involving a sealed source that is leaking;
3. If, for a temporary implant, one (1) or more sealed sources are not removed upon completion of the procedure; or
4. If the calculated administered dose differs from the prescribed dose by more than twenty (20) percent.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than thirty (30) microcuries of sodium iodide I-125 or I-131:
1. Involving the wrong patient, human research subject, radiopharmaceutical, or route of administration, or if the administered dosage differs from the prescribed dosage; and
2. If the dose to the patient or human research subject exceeds five (5) rems effective dose equivalent or fifty (50) rems dose equivalent to an individual organ.

(178) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(179) “Monitor unit (MU)” (See “Dose monitor unit”).

(180) "Monitoring" or "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

(181) “Moving beam radiation therapy” means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

(182) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes; that is, 100 weight percent thorium-232.

(183) “Negative pressure respirator (tight fitting)” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(184) “Nominal treatment distance” means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along

the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(185) "Nonstochastic effect" or "deterministic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist.

(186) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

(187) "NRC" means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(188)(a) “NRC Forms 540, 540A, 541, 541A, 542, and 542A” means official NRC forms as referenced in 902 KAR 100:021.

(b)Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information.

(c) Upon agreement between the shipper and consignee, NRC Forms 541, 541A, 542, and 542A may be completed, transmitted, and stored in electronic media.

(d) The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(189) "Occupational dose" means dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose shall not include dose received:

(a) From background radiation;

(b) As a medical patient;

(c) From voluntary participation in a medical research program;

(d) As a member of the public; or

(e) From exposure to individuals administered radioactive material and released in accordance with 902 KAR 100:072, Section 27.

(190) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(191) "Operating procedures" means detailed written instructions, such as:

(a) Normal operation of equipment and movable shielding;

(b) Closing of interlock circuits;

(c) Manipulation of controls;

(d) Radiation monitoring procedures for personnel and areas;

(e) Testing of interlocks; and
(f) Recordkeeping requirements.

(192) "Package" means the packaging together with its radioactive contents as presented for transport:
(a) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package are all fissile material packaging types together with its fissile material complete.
(b) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and shall comply with the DOT regulations in 49 C.F.R. Part 173.
(c) Type B package means a Type B packaging together with its radioactive contents.
(i) On approval, a Type B package design is designated by the U.S. Nuclear Regulatory Commission as B(U) unless the package has a maximum normal operating pressure of more than 100 pounds/in^2 (700 kPa) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 C.F.R. Part 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M).
(ii) B(U) refers to the need for unilateral approval of international shipments.
(iii) B(M) refers to the need for multilaterial approval of international shipments.
(iv) There is no distinction made in how packages with these designations may be used in domestic transportation.
(v) To determine their distinction for international transportation, refer to U.S. Department of Transportation Regulations in 49 C.F.R. Part 173.
(vi) A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 902 KAR 100:070, Section 7.

(193) "Packaging" means the assembly of components necessary to ensure compliance with the requirements of 902 KAR 100:070.
(a) It may consist of one (1) or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks.
(b) The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(194) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

(195) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(196) “Periodic quality assurance check” means a procedure which is performed to ensure that a previous calibration continues to be valid.

(197) "Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed.

(198) "Person" is defined at KRS 216B.015(16).

(199) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the job site and watching the performance of the operation in proximity so that contact can be maintained and immediate assistance given as required.
(200) "Personnel monitoring equipment" means a device designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.
(201) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
(202) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated. See "automatic exposure control".
(203) “Physical description” means the items called for on NRC Form 541 to describe low-level radioactive waste.
(204) "Physician" is defined by KRS 311.720(9).
(205) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.
(206) "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
(207) “Positive pressure respirator” means a respirator in which the pressure inside the respirator inlet covering exceeds the ambient air pressure outside the respirator.
(208) “Powered air-purifying respirator" or “PAPR” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.
(209) “Preceptor” means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.
(210) “Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.
(211) "Preregistrant" means a person who is preregistered with the cabinet for the intent of obtaining a radiation producing machine registerable under 902 KAR 100:110.
(212) "Preregistration" means preregistration with the cabinet as specified in 902 KAR 100:110.
(213) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:
    (a) In a written directive;
    (b) In the diagnostic clinical procedures manual; or
    (c) In an appropriate record in accordance with the directions of the authorized user for diagnostic procedures.
(214) "Prescribed dose" means:
    (a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
(c) For brachytherapy, the total source strength and exposure time or the total dose, as documented in the written directive.

(215) "Primary dose monitoring system" means a system that:
(a) Monitors the useful beam during irradiation; and
(b) Terminates irradiation if a preselected number of dose monitor units have been acquired.

(216) "Principal activities" means activities authorized by the license that are essential to achieving the purpose for which the license was issued or amended. "Principal activities" do not include:
(a) Storage during which licensed material is not accessed for use or disposal; and
(b) Activities incidental to decontamination or decommissioning.

(217) "Protective apron" means an apron made of radiation absorbing materials of at least 0.25 mm lead equivalency; that is, if the HVL of the apron is not less than 0.25 mm lead at normal operating voltages.

(218) "Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.
(a) "Primary protective barrier" means a barrier sufficient to attenuate the useful beam to the required degree.
(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(219) "Protective glove" means a glove made of radiation absorbing materials of at least 0.25 mm lead equivalency; that is, if the HVL of the glove is not less than 0.25 mm lead at normal operating voltages.

(220) "Public dose" means the dose received by a member of the public from sources of radiation from licensed or registered operations. It shall not include radiation received:
(a) As an occupational dose;
(b) From background radiation;
(c) As a medical patient;
(d) From voluntary participation in a medical research program; or
(e) From exposure to an individual administered radioactive material and released in accordance with 902 KAR 100:072, Section 27.

(221) "Qualified expert" means an individual who has been recognized by the cabinet to possess the knowledge and training to:
(a) Measure ionizing radiation;
(b) Evaluate safety techniques; and
(c) Advise regarding radiation protection needs.

(222) “Qualitative fit test or “QFT” means a pass or fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

(223) "Quality factor" or "Q" means the modifying factor used to derive dose equivalent from absorbed dose.
(a) Quality factors and absorbed dose equivalencies:

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a]Absorbed dose in rad equal to one (1) rem or the absorbed dose in gray equal to one (1) sievert.

(b) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (a) of this subsection, one (1) rem (0.01 sievert) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of twenty-five (25) million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from paragraph (c) of this subsection to convert a measured tissue dose in rads to dose equivalent in rems.

(c) Mean quality factors, Q, and fluency per unit dose equivalent for monoenergetic neutrons:

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluency per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}

	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{6}

[a] Value of quality factor (Q) at the point at which the dose equivalent is maximum in a thirty (30)-cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a thirty (30)-cm diameter cylinder tissue-equivalent phantom.

(224) “Quantitative fit test “QNFT” means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(225) "Quarter" is defined by KRS 341.080(1)(b).

(226) "Rad" means the special unit of absorbed dose. One (1) rad equals an absorbed dose of 0.01 joule per kilogram (0.01 gray) or 100 ergs per gram.

(227) "Radiation" means ionizing radiation.

(a) It includes the following:

1. Gamma rays;
2. X-rays;
3. Alpha particles;
4. Beta particles;
5. High speed electrons;
6. Neutrons;
7. High-speed protons; and
8. Other atomic particles capable of producing ions.

(b) It excludes nonionizing radiations, such as:

1. Sound;
2. Microwaves;
3. Radiowaves; or
4. Visible, infrared, or ultraviolet light.

(c) The following are specific forms of radiation:

1. "Leakage radiation" means radiation coming from within the tube or source housing except the useful beam.

2. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction, and may have been modified by a decrease in energy.
3. "Useful radiation" or "primary beam" means radiation that passes through the window, aperture, cone, or other beam limiting device of the tube or source housing.
4. "Stray radiation" means the sum of leakage and scattered radiation.

(228) "Radiation area" means an area, accessible to individuals, in which there exists radiation at levels that an individual may receive in excess of five (5) millirems (0.05 mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from a surface that the radiation penetrates.

(229) “Radiation detector” means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one (1) or more quantities of incident radiation.

(230) “Radiation head” means the structure from which the useful beam emerges.

(231) "Radiation machine" means a device capable of producing radiation, except a device that produces radiation only from radioactive material.

(232) "Radiation safety officer" means an individual who:

(a) Has the knowledge and responsibility to apply appropriate radiation protection administrative regulations; and

(b) For licenses issued under 902 KAR 100:072, meets the requirements in 902 KAR 100:072, Sections 63 and 64(1) and (3)(a).

1. A specific medical use licensee issued by the cabinet, U.S. Nuclear Regulatory Commission, or an agreement state; or
2. A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(233) "Radiation therapy simulation system" means a fluoroscopic or radiographic x-ray system intended for:

(a) Localizing the volume to be exposed during radiation therapy; and

(b) Confirming the position and size of the therapeutic irradiation field.

(234) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

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

(236) "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

(237) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

(238) "Radiographer" means an individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of administrative regulations and license conditions.

(239) "Radiographer's assistant" means an individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in industrial radiography.

(240) "Radiographer instructor" means a radiographer who has been authorized by the cabinet to provide on-the-job training to radiographer trainees under 902 KAR 100:100, Section 14.

(241) "Radiographer trainee" means an individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of instruction.

(242) "Radiographic exposure device" means an instrument containing a sealed source fastened or contained within, in which the sealed source or its shielding may be moved, or otherwise changed, from a shielded to an unshielded position for purposes of making a radiographic exposure.

(243) "Radiographic imaging system" means a system designed to record a permanent or semipermanent image on an image receptor by the action of ionizing radiation.

(244) "Radiographic personnel" means a:

(a) Radiographer;

(b) Radiographer instructor; or

(c) Radiographer trainee.

(245) "Rating" means the operating limits specified by the component manufacturer.

(246) "Recordable event" means the administration of:

(a) A radiopharmaceutical or radiation without a written directive, if a written directive is required;

(b) A radiopharmaceutical or radiation if a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) A radiopharmaceutical dosage greater than thirty (30) microcuries of sodium iodide I-125 or I-131 if:

1. The administered dosage differs from the prescribed dosage by more than twenty (20) percent; and
2. The difference between the administered dosage and prescribed dosage exceeds fifteen (15) microcuries;

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, if the administered dosage differs from the prescribed dosage by more than twenty (20) percent;

(e) A teletherapy radiation dose, if the calculated weekly administered dose is fifteen (15) percent greater than the weekly prescribed dose; or

(f) A brachytherapy radiation dose, if the calculated administered dose differs from the prescribed dose by more than twenty (20) percent.

(247) "Recording" means producing a permanent form of an image resulting from x-ray photons.

(248) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(249) "Registrant" means a person who is registered with the cabinet and is legally obligated to register with the cabinet under 902 KAR 100:110.
(250) "Registration" means registration with the cabinet under 902 KAR 100:110.
(251) "Regulations of the U.S. Department of Transportation" means the regulations in 49 C.F.R. Parts 100-189.
(252) "Rem" means a special unit of quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (one (1) rem = 0.01 sievert).
(253) "Research and development" means:
(a) Theoretical analysis, exploration, or experimentation; or
(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.
(254) "Residential location" means an area where structures for human habitation are located.
(255) "Residual radioactivity" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.
(256) "Respiratory protective device" means an apparatus used to reduce an individual's intake of airborne radioactive materials.
(257) "Restricted area" means an area access to which is limited by the licensee or registrant for purposes of protection of individuals against undue risks from exposure to radiation and radioactive materials. A restricted area shall not include areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.
(258) "Roentgen" or "R" means the special unit of exposure. One (1) roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air. See "Exposure".
(259) "Sanitary sewerage" means a system of public sewers for carrying off waste, water, and refuse, but excludes sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.
(260) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent leakage or escape of the radioactive material.
(261) "Secondary dose monitoring system" means a system which terminates irradiation upon failure of the primary system.
(262) “Self-contained breathing apparatus" or “SCBA” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.
(263) "Shallow-dose equivalent (H_S)", with respect to external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (seven (7) mg/cm^2).

(264) "Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.
(265) "Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 902 KAR 100:019, Section 10.
(266) “Shipper” means the licensed entity, the generator that offers low-level radioactive waste for transportation, and may consign the waste to a licensed waste collector, waste processor, or land disposal facility operator.
(267) “Shipping paper” means NRC Form 540, and if required, 540A, or their equivalent, and includes the information required by the U.S. Department of Transportation in 49 C.F.R. Part 172.
(268) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
(269) "Sievert" means:
(a) The International System (SI) unit of quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).
(b) See the table in the definition of "quality factors" for the quality factors to convert absorbed dose to dose equivalent.
(270) "Site area emergency" means the existence of situation where an event may occur, is in progress, or has occurred that may:
(a) Lead to a significant release of radioactive material; and
(b) Require a response by an off-site response organization to protect persons off site.
(271) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.
(272) "Source" means the focal spot of the x-ray tube.
(273) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.
(274) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source.
(275) "Source image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.
(276) "Source material" means:
(a) Uranium or thorium, or a combination thereof, in a physical or chemical form; or
(b) Ores that contain by weight 0.05 percent or more of:
1. Uranium;
2. Thorium; or
3. A combination of uranium and thorium.
(c) Source material does not include special nuclear material.
(277) "Source of radiation" means a radioactive material or device, or equipment emitting or capable of producing radiation.

(278) "Special form radioactive material" means radioactive material that satisfies the following conditions:
(a) It is a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(b) The piece or capsule has at least one (1) dimension not less than five (5) millimeters (0.197 inch); and
(c)1. It satisfies the test requirements specified by the NRC in 10 C.F.R. Part 71.75.
2. A special form encapsulation designed under the NRC requirements in 10 C.F.R. 71.4 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used.
3. A special form encapsulation designed in accordance with the NRC requirements in 10 C.F.R. 71.4 in effect on March 31, 1996, and constructed before April 1, 1998 may continue to be used.
4. Any other special form encapsulation shall meet the specifications of this definition.

(279) "Special nuclear material" means:
(a) Plutonium, uranium 233, uranium enriched in the isotope U-233 or in the isotope U-235, and other material which the Governor declares by order to be special nuclear material after the United States Nuclear Regulatory Commission, or successor thereto, has determined the material to be special nuclear material, but does not include source material; or
(b) Material artificially enriched by one (1) of the foregoing, but does not include source material.

(280) "Special nuclear material in quantities not sufficient to form a critical mass" means:
(a) Uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235;
(b) U-233 in quantities not exceeding 200 grams;
(c) Plutonium in quantities not exceeding 200 grams; or
(d) A combination of them as specified by the following formula:
1. For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material.
2. The sum of these ratios for the different kinds of special nuclear material in combination shall not exceed one (1).
3. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175\,(\text{grams contained U-235})}{350} +$$

$$\frac{50\,(\text{grams U-233})}{200} + \frac{50\,(\text{grams Pu})}{200} = 1$$

(281) "Special purpose x-ray system" means a radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

(282) "Specific activity" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.
(283) "Spot check" means a procedure performed to assure that a previous calibration continues to be valid.
(284) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
(285) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
(286) "SSD" means the distance between the source and the skin of the patient.
(287) “Stationary beam radiation therapy” means radiation therapy without displacement of one (1) or more mechanical axes relative to the patient during irradiation.
(288) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose plus threshold factors.
(289) "Storage" or "waste storage" means the holding of waste for treatment or disposal for a period of twenty-four (24) hours or more.
(290) "Storage area" means:
(a) A location, facility, or vehicle used to store, transport, or secure a radiographic exposure device, storage container, or sealed source if the source is not in use; and
(b) Which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.
(291) "Storage container" means a device in which a sealed source is transported or stored.
(292) "Stray radiation" means the sum of leakage and scattered radiation.
(293) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.
(294) “Supplied-air respirator “SAR” “airline respirator” means an atmosphere-supplying respirator for which the source of breathing air is not designated to be carried by the user.
(295) "Surface contaminated object" or "SCO" means a solid object that is not classed as radioactive material, but which has radioactive material distributed on a surface. SCO must be in one (1) of two (2) groups with surface activity not exceeding the following limits:
(a) SCO-I: A solid object on which:
1. The nonfixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-4} microcurie/cm^2 (4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/cm^2) for all other alpha emitters;
2. The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed

1.0 microcurie/cm^2 ($4x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 ($4x10^3$ Bq/cm^2) for all other alpha emitters; and

3. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1 microcurie/cm^2 ($4x10^4$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, for 0.1 microcurie/cm^2 ($4x10^3$ Bq/cm^2) for all other alpha emitters.

(b) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

1. The nonfixed contamination on the accessible surface averaged over 300cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-2} microcurie/cm^2 (400 Bq/cm^2) for beta and gamma and low toxicity alpha emitters or 10^{-3} microcurie/cm^2 (40 Bq/cm^2) for all other alpha emitters;
2. The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcuries/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters; and
3. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 20 microcuries/cm^2 ($8x10^5$ Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcuries/cm^2 ($8x10^4$ Bq/cm^2) for all other alpha emitters.

(296) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. If appropriate, the evaluation shall include at least:

(a) A physical survey of the location of sources of radiation; and

(b) Measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

(297) “Target” means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(298) "Technique factors" means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(c) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(d) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product

of tube current and exposure time in mAs and the scan time if the scan time and exposure time are equivalent; and

(e) For other equipment, peak tube potential in kV and tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(299) “Technically Enhanced Naturally Occurring Radioactive Material “TENORM” means N.O.R.M., which has been separated to various degrees from the original ore or other material, refining or implementing it.

(300) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(301) "Teletherapy physicist" means the individual identified as the teletherapy physicist on a cabinet license.

(302) "Temporary job site" means a location to which radioactive material has been dispatched to perform a job, operation, or study other than the location listed in a specific license or certificate of registration.

(303) “Tenth-value layer (TVL)” means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(304) "Termination of irradiation" means the stopping of irradiation in a fashion that does not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(305) "Tests" means the process of verifying compliance with an applicable regulation.

(306) “Therapeutic radiation machines” means x-ray or electron-producing equipment designed and used for external beam radiation therapy.

(307) "Therapeutic-type protective tube housing" means:

(a) For x-ray therapy equipment not capable of operating at 500 kVp or above: an x-ray tube housing so constructed that the leakage radiation at a distance of one (1) meter from the target does not exceed one (1) roentgen in one (1) hour if the tube is operated at its maximum rated tube potential. Small areas of reduced protection are acceptable providing the average reading over a 100-square centimeter area at one (1) meter distance from the target does not exceed the value established in this paragraph; or

(b) For x-ray therapy equipment capable of operating at 500 kVp or above: an x-ray tube housing so constructed that the leakage radiation at a distance of one (1) meter from the target does not exceed one-tenth (0.1) percent of the useful beam exposure rate at one (1) meter from the target, for its operating conditions. Small areas of reduced protection are acceptable providing the average reading over a 100-square centimeter area at one (1) meter distance from the target does not exceed the value established in this paragraph.

(308) “Tight-fitting facepiece” means a respiratory inlet covering that forms a complete seal with the face.

(309) "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

(310) "Total effective dose equivalent" or "TEDE" means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).
(311) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one (1) or more intermediate steps and that comparisons have been documented.
(312) "Transport container" means a package that is designed to provide radiation safety and security if sealed sources are transported and which meets the requirements of the 49 C.F.R. 173, Subpart I.
(313) "Transport index" means:
(a) The dimensionless number that designates the degree of control to be exercised by the carrier during transportation, rounded up to the next tenth required to be placed on the label of a package.
(b) The transport index is determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one (1) meter (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one (1) meter (3.3 feet).
(314) "Treatment" or "waste treatment" means a method, technique, or process, including storage for radioactive decay, designed to change the physical, chemical, or biological characteristics or composition of a waste in order to render the waste for transport, storage or disposal, amendable to recovery, convertible to another usable material, or reduced in volume.
(315) “Tritium neutron generator target source” means a tritium source used within a neutron generator tube to produce neutrons.
(316) "Tube" means an x-ray tube, unless otherwise specified.
(317) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements if they are contained within the tube housing.
(318) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
(319) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 10 C.F.R. 71 Appendix A, or may be determined by procedures described in 10 C.F.R. 71 Appendix A.
(320) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding required by U.S. Nuclear Regulatory Commission regulations if subjected to the normal conditions of transport and hypothetical accident test conditions established in 10 C.F.R. Part 71.
(321) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.
(322) “Uniform low-level radioactive waste manifest” or “uniform manifest” means the combination of NRC Forms 540, 541, and if necessary, 542, or their equivalents, and their respective continuation sheets as needed, or equivalent.
(323) “Unirradiated uranium” means uranium containing not more than $2x10^3$ Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products

per gram of uranium-235, and not more than 5 x 10^{-3} gram of uranium-236 per gram of uranium-235.

(324) "U.S. Department of Energy" means the Department of Energy established by 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof and retransferred to the Secretary of Energy in 42 U.S.C. 7151, effective October 1, 1977.

(325) "Unrefined and unprocessed ore" means ore in its natural form prior to processing, such as grinding, roasting, beneficiating, or refining.

(326) "Unrestricted area" means an area access to which is not controlled or limited by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material.

(327) "Uranium - natural, depleted, enriched" means:

(a) "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238);

(b) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes;

(c) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(328) "Uranium fuel cycle" means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle shall not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered nonuranium special nuclear and byproduct materials from the cycle.

(329) "Useful beam" means the radiation that passes through the tube housing port and the aperture of the beam limiting device if the exposure switch or timer is activated.

(330) "User" means an individual who personally utilizes or manipulates a source of radiation.

(331) “User seal check" or "fit check” means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamylacetate check.

(332) "Variable-aperture beam limiting device" means a beam limiting device that has capacity for stepless adjustment of the x-ray field size at a given SID.

(333) "Vendor" means a person who sells radiation producing machines or accelerators registerable with the cabinet as specified by 902 KAR 100:110.

(334) "Vendor registrant" means a vendor who is registered with the cabinet.

(335) "Vendor registration" means registration of a vendor with the cabinet described by 902 KAR 100:110.

(336) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body may result in an individual receiving an absorbed dose in excess of 500 rads (five (5) grays) in one (1)
hour at one (1) meter from a radiation source or one (1) meter from a surface that the radiation penetrates.
(337) “Virtual source” means a point from which radiation appears to originate.
(338) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
(339) "Visiting authorized nuclear pharmacist" means a nuclear pharmacist who is not identified on the license of the licensee being visited.
(340) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.
(341) "Waste". See "low-level radioactive waste".
(342) “Waste collector” means an entity, operating under the cabinet, U.S. Nuclear Regulatory Commission or agreement state license whose principal purpose is to collect and consolidate low level waste generated by others and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.
(343) “Waste description” means the physical, chemical, and radiological description of a low-level radioactive waste as called for on NRC Form 541.
(344) “Waste generator” means an entity, operating under the cabinet, U.S. Nuclear Regulatory Commission, or agreement state license, who:
(a) Possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and
(b) Transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be waste generator if the transfer of low-level radioactive waste from its facility is defined as “residual waste”.
(345) “Waste processor” means an entity, operating under a cabinet, U.S. Regulatory Commission or agreement state license, whose principal purpose is to process, repackage, or treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.
(346) “Waste type” means a waste within a disposal container having a unique physical description, such as a specific waste descriptor code or description, or a waste sorbed on or solidified in a specifically defined media.
(347) "Wedge filter" means an added filter effecting continuous progressive attenuation on the useful beam or a part thereof.
(348) "Week" means seven (7) consecutive days starting on Sunday.
(349) "Weighting factor (W_T)", for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total

risk of stochastic effects if the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of (W_T) are:

Organ Dose Weighting Factors	
Organ or tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[1]0.30
Whole Body	[2]1.00

[1]0.30 results from 0.06 for each of five (5) "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2]For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, W_T=1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis, pursuant to 10 C.F.R. Part 20, until a time as specific guidance is issued.

(350) "Well-bore" means a drilled hole in which wire line service operations and subsurface tracer studies are performed.

(351) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation in well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

(352) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(353) "Wire line" means a cable containing one (1) or more electrical conductors which is used to lower and raise logging tools in the well-bore.

(354) "Wire line service operation" means an evaluation or mechanical service which is performed in the well-bore using devices on a wire line.

(355) "Worker" means an individual engaged in activities licensed or registered by the cabinet and controlled by a licensee or registrant, but does not include the licensee or registrant.

(356) "Working level" or "WL" means a combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one (1) liter of air that results in the ultimate emission of 1.3×10^5MeV of potential alpha particle energy.

(357) "Working level month" or "WLM" means an exposure to one (1) working level for 170 hours (2,000 working hours per year/twelve (12) months per year = approximately 170 hours per month).

(358) "Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the

administration of a radiopharmaceutical or radiation, except as specified in paragraph (f) of this subsection, and containing the following information:

(a) For an administration of quantities greater than thirty (30) microcuries of sodium iodide I-125 or I-131: the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) For all other brachytherapy:

1. Prior to implementation: the radioisotope, number of sources, and source strengths; and
2. After implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(359) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure.

(360) "X-ray equipment" means an x-ray system, subsystem, or component thereof. X-ray equipment is further classified as:

(a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(b) "Portable" means x-ray equipment designed to be hand-carried.

(c) "Stationary" means x-ray equipment which is installed in a fixed location.

(d) "Transportable" means x-ray equipment installed in a vehicle or trailer.

(361) "X-ray field" means that area of the intersection of the useful beam and one (1) of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth (1/4) of the maximum in the intersection.

(362) "X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube, high-voltage switches, electrical protective devices, and other appropriate elements.

(363) "X-ray subsystem" means a combination of two (2) or more components of an x-ray system.

(364) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

(365) "X-ray tube" means an electron tube designed to be used primarily for the production of x-rays.

(366) "Year" means the period of time, beginning in January, used to determine compliance with the provisions of 902 KAR Chapter 100. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant if:

(a) The change is made at the beginning of the year; and

(b) A day is not omitted or duplicated in consecutive years.

(1 Ky.R. 381; eff. 2-5-75; Am. 12 Ky.R. 979; eff. 1-3-86; 16 Ky.R. 2515; 17 Ky.R. 39; eff. 6-27-90; 18 Ky.R. 1474; eff. 1-10-92; 21 Ky.R. 610; 1057; eff. 9-21-94; 24 Ky.R. 2770; 25 Ky.R. 336; eff. 8-17-98; 26 Ky.R. 2371; 27 Ky.R. 782; eff. 9-11-2000; 37 Ky.R. 1799; 2594; eff. 6-3-11.)

902 KAR 100:021. Disposal of radioactive material.
http://www.lrc.ky.gov/kar/902/100/058.htm

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 20.2001-.2007, Appendix G-20.2001-.2401, 61
STATUTORY AUTHORITY: KRS 13B.170, 194A.050(1), 211.090(3), 211.844
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to provide by administrative regulation for the registration and licensing of the possession or use of a source of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation provides waste disposal limitations for radioactive material and shall apply to a person disposing of radioactive material or waste.

Section 1. General Requirements.
(1) A person or licensee shall dispose of radioactive material or waste only:
[(a) missing]By transfer to an authorized recipient as provided in 902 KAR 100:040, Section 12, or 902 KAR 100:022;
(b) By decay in storage;
(c) By release in an effluent within the limits in 902 KAR 100:019, Section 10; or
(d) As authorized by Sections 2, 3, 4, or 5 of this administrative regulation.
(2) A person shall be specifically licensed to receive waste containing radioactive material or waste from other persons for:
(a) Treatment prior to disposal;
(b) Treatment or disposal by incineration;
(c) Decay in storage; or
(d) Disposal at a land disposal facility licensed under 902 KAR 100:022.

Section 2. Method for Obtaining Approval of Proposed Disposal Procedures. A person, licensee, or applicant for a license may apply to the cabinet for approval of a proposed procedure, not authorized in 902 KAR 100:019, 100:021, 100:022, 100:050, or 100:072, to dispose of radioactive material or waste generated by their activity. An application shall include:
(1) A description of the waste containing radioactive material to be disposed of, including the:
(a) Physical and chemical properties important to risk evaluation; and
(b) Proposed manner and conditions of waste disposal;
(2) An analysis and evaluation of pertinent information on the nature of the environment;
(3) The nature and location of other potentially affected licensed and unlicensed facilities; and
(4) An analysis and a procedure to ensure doses shall be maintained ALARA and within the dose limits in 902 KAR 100:019, Sections 3, 8, 9, and 10.

Section 3. Disposal by Release into Sanitary Sewerage.
(1) A person or licensee may discharge licensed material into sanitary sewerage under the following conditions:

(a) The material shall be readily soluble or shall be readily dispersible biological material, in water;
(b) The quantity of licensed or other radioactive material that the licensee released into the sewer in one (1) month, divided by the average monthly volume of water released into the sewer by the licensee, shall not exceed the concentration in 10 C.F.R. 20, Appendix B;
(c) For the release of more than one (1) radionuclide, the following conditions shall be satisfied:
1. The licensee shall determine the fraction of the limit in 10 C.F.R. 20, Appendix B, represented by discharges into the sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide in 10 C.F.R. 20, Appendix B; and
2. The sum of the fractions for each radionuclide required by subsection (1)(c)1 of this section shall not exceed unity; and
(d) The total quantity of licensed and other radioactive material that the licensee releases into the sewerage system in a year shall not exceed five (5) curies (185 GBq) of hydrogen-3, one (1) curie (37 GBq) of carbon-14, and one (1) curie of other radioactive materials combined.

(2) Excreta from an individual undergoing medical diagnosis or therapy with radioactive material shall not be subject to the limitations contained in subsection (1) of this section.

Section 4. Treatment or Disposal by Incineration. A licensee may treat or dispose of licensed material by incineration only:
(1) In the amounts and forms specified in Section 5 of this administrative regulation; or
(2) As specifically approved by the cabinet in accordance with Section 2 of this administrative regulation.

Section 5. Disposal of Specific Wastes.
(1) A person or licensee may dispose of the following radioactive material without regard to its radioactivity:
(a) 0.05 microcurie or less of hydrogen-3, or tritium, carbon-14, or iodine-125 per gram of medium used for liquid scintillation counting or in vitro clinical or in vivo laboratory testing; and
(b) 0.05 microcurie (1.85 kBq) or less of hydrogen-3, carbon-14, or iodine-125 per gram of animal tissue averaged over the weight of the entire animal.
(2) A licensee shall not dispose of tissue pursuant to subsection (1)(b) of this section in a manner that may permit its use as food for a human or as animal feed.
(3) A licensee shall maintain records required by Section 11 of this administrative regulation.
(4) A licensee shall comply with other applicable federal, state, and local regulations governing other toxic or hazardous properties of these materials.

Section 6. Classification of Radioactive Waste for Near-Surface Disposal.
(1) Considerations. Determination of the classification of waste shall be given the following

considerations:

(a)1. The concentration of long-lived radionuclides, and their shorter-lived precursors, whose potential hazard shall persist long after a precaution such as an institutional control, improved waste form, and deeper disposal have ceased to be effective.

2. The precaution delays the time long-lived radionuclides may cause an exposure.

3. The magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure; and

(b) The concentration of a shorter-lived radionuclide for which a requirement on an institutional control, waste form, and disposal methods are effective.

(2) Classes of waste.

(a)1. Class A waste shall be segregated from other waste classes at the disposal site, except for waste described at subparagraph 2 of this paragraph.

2. The physical form and characteristics of Class A waste shall meet the minimum requirements in Section 7 of this administrative regulation.

3. If Class A waste also meets the stability requirements in Section 7(2) of this administrative regulation, it shall not be necessary to segregate Class A waste for disposal.

(b)1. Class B waste shall meet more rigorous requirements on waste form to ensure stability after disposal.

2. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements in Section 7 of this administrative regulation.

(c)1. Class C waste shall meet more rigorous requirements on waste form to ensure stability and shall require additional measures at the disposal facility to protect against inadvertent intrusion.

2. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements in Section 7 of this administrative regulation.

(3) Classification determined by long-lived radionuclides. If the waste contains only a radionuclide in Table 1 of this subsection, classification shall be determined as follows:

(a) If the concentration does not exceed one-tenth (0.1) times the value in Table 1, the waste shall be Class A.

(b) If the concentration exceeds one-tenth (0.1) times the value, but does not exceed the value in Table 1, the waste shall be Class C.

(c) If the concentration exceeds the value in Table 1, as established in 10 C.F.R. 61.55, the waste shall not generally be acceptable for near-surface disposal.

(d) For waste containing a mixture of radionuclides in Table 1, the total concentration shall be determined by the sum of fractions rule described in subsection (7) of this section.

TABLE 1	
Radionuclide	Concentration curies/cubic meter
C-14	8

C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic radio-nuclides with half-life greater than five (5) years	100*
Pu-241	3500*
Cm-242	20000*
Ra-226	100*

*Units are nanocuries per gram.

(4) Classification determined by short-lived radionuclides.

1. If the waste contains none of the radionuclides in Table 1 of subsection (3) of this section, classification shall be determined based on the concentrations shown in Table 2 of this subsection.
2. If a radionuclide is not in Table 2, it shall not be considered in determining the waste class.

(a) If the concentration does not exceed the value in Column 1, the waste shall be Class A.

(b) If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste shall be Class B.

(c) If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste shall be Class C.

(d) If the concentration exceeds the value in Column 3, as established in 10 C.F.R. 61.55, the waste shall not generally be acceptable for near-surface disposal.

(e) For waste containing a mixture of the radionuclides in Table 2, the total concentration shall be determined by the sum of fractions rule described in subsection (7) of this section.

TABLE 2			
Radionuclide	Concentration, curies/cubic meter		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than five (5) year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

* Limits have not been established for a radionuclide in Class B or C waste. Practical considerations, such as the effects of external radiation and internal heat generation on transportation, handling, and disposal, limit the concentrations for these wastes. This waste shall be Class B unless the concentrations of other radionuclides in Table 2 determine the waste to be Class C independent of these radionuclides.

(5) Classification determined by both long-lived and short-lived radionuclides.

(a) If the waste contains a mixture of radionuclides, some in Table 1 of this section, and some in Table 2 of this section, classification shall be determined as follows:

(b) If the concentration of a radionuclide in Table 1 does not exceed one-tenth (0.1) times the value in Table 1, the class shall be determined by the concentration of a radionuclide in Table 2.

(c) If the concentration of a radionuclide in Table 1 exceeds one-tenth (0.1) times the value, but does not exceed the value in Table 1, the waste shall be Class C, if the concentration of a radionuclide in Table 2 does not exceed the value shown in Column 3 of Table 2.

(6) Classification of waste with a radionuclide other than those in Tables 1 and 2. If the waste contains none of the radionuclides in Table 1 or 2 of this section, the waste shall be Class A.

(7) The sum of fractions rule for mixtures of radionuclides. The following shall be considered in determining classification for waste that contains a mixture of radionuclides:

(a) The sum of fractions shall be determined by dividing each radionuclide concentration by the appropriate limit and adding the resulting values.

(b) The appropriate limit shall be taken from the same column of the same table.

(c) The sum of the fractions for the column shall be less than one (1.0) if the waste class is determined by that column.

(d) Example: A waste contains Sr-90 in a concentration of fifty (50) curies/cubic meter and Cs-137 in a concentration of twenty-two (22) curies/cubic meter. Because the concentrations both exceed the values in Column 1, Table 2, they shall be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Because the sum is less than one (1.0), the waste shall be Class B.

(8) Determination of concentrations in waste.

(a) If there is reasonable assurance that an indirect method may be correlated with an actual measurement, the concentration of a radionuclide may be determined by an indirect method, such as use of a scaling factor, which relates the inferred concentration of one (1) radionuclide to another that is measured or radionuclide material accountability.

(b) If the units are expressed as nanocuries per gram, the concentration of a radionuclide may be averaged over the volume or weight of the waste.

Section 7. Radioactive Waste Characteristics.

(1) The following minimum requirements for each class of waste facilitate handling and provide protection of health and safety of personnel at the disposal site:

(a) Waste shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste shall be shipped. If the conditions of the site license are more restrictive than the provisions of this administrative regulation, the site license conditions shall govern.

(b) Waste shall not be packaged for disposal in a cardboard or fiberboard box.

(c) Liquid waste shall be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(d) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable. The liquid shall not exceed one (1) percent of the volume.

(e) Waste shall not be readily capable of:

1. Detonation;
2. Explosive decomposition or reaction at normal pressures and temperatures; or
3. Explosive reaction with water.

(f) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to a person transporting, handling, or disposing of the waste. This shall not apply to radioactive gaseous waste packaged in accordance with paragraph (h) of this subsection.

(g) Waste shall not be pyrophoric. Pyrophoric material contained in waste shall be treated, prepared, and packaged to be nonflammable.

(h) Waste in a gaseous form shall be packaged at a pressure that shall not exceed one and five-tenths (1.5) atmospheres at twenty (20) degrees Centigrade. Total activity shall not exceed 100 curies per container.

(i) Waste containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological material.

(2) Stability shall ensure that the waste shall not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and lead to water infiltration. Stability shall also be a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste. The following requirements shall provide stability of the waste:

(a) Waste shall have structural stability.

1. A structurally-stable waste form shall maintain its physical dimension and its form under expected disposal conditions, such as:
   a. Weight of overburden and compaction equipment;
   b. Presence of moisture and microbial activity; and
   c. Internal factors such as radiation effects and chemical changes.
2. Structural stability may be provided by:
   a. The waste form itself;
   b. Processing the waste to a stable form; or
   c. Placing the waste in a disposal container or structure that provides stability after disposal.

(b) Unless otherwise exempted in subsection (1)(c) and (d) of this section, liquid waste or waste containing liquid shall be converted into a form that contains as little free standing and noncorrosive liquid as is reasonably achievable. The

liquid shall not exceed one (1) percent of the volume of the waste if the waste is in a disposal container designed to ensure stability, or five-tenths (0.5) percent of the volume of the waste for waste processed to a stable form.

(c) Void spaces within and between the waste and its package shall be eliminated.

Section 8. Labeling. Each package of waste shall be clearly labeled to identify if it is Class A, Class B, or Class C waste, in accordance with Section 6 of this administrative regulation.

Section 9. Transfer for Disposal and Manifests.

(1) The requirements of this section and Section 10 of this administrative regulation shall:

(a) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in 902 KAR 100:010, who ships low-level waste either directly or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as established in 902 KAR 100:022;

(b) Establish a manifest tracking system; and

(c) Supplement existing requirements concerning transfers and recordkeeping for the wastes being transferred.

(2) Any licensee shipping radioactive material intended for ultimate disposal at a licensed land disposal facility shall document the information required on U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest, or its equivalent, and transfer this recorded manifest information to the intended consignee in accordance with Section 10 of this administrative regulation.

(3) The shipment manifest shall include a certification by the waste generator as specified in Section 10(12) of this administrative regulation.

(4) A person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section 10(13) of this administrative regulation.

Section 10. Requirements for Low-level Waste Transfers Intended for Disposal at Land Disposal Facilities and Manifests.

(1) A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility shall prepare a manifest reflecting information requested on the following applicable forms, or their equivalent:

(a) NRC Form 540, Uniform Low-Level Radioactive Waste Manifest, Shipping Paper;

(b) NRC Form 541, Uniform Low-Level Radioactive Waste Manifest, Container and Waste Description; and

(c) If necessary, NRC Form 542, Uniform Low-Level Radioactive Waste Manifest, Manifest Index and Regional Compact Tabulation.

(2) NRC Forms 540 and 540A shall be completed and shall physically accompany the pertinent low-level waste shipment.
(3) Upon agreement between shipper and consignee, NRC Forms 541, 541A, 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms.
(4) A licensee shall not be required by the cabinet to comply with the manifesting requirements of this section, if they ship:
    (a) LLW for processing and expect its return for storage as prescribed by their license, prior to disposal at a licensed land disposal facility;
    (b) LLW that is being returned to the licensee who is the waste generator or generator, as defined in 902 KAR 100:010; or
    (c) Radioactive contaminated material to a waste processor that becomes the processor's residual waste.
(5) For guidance in completing a form, refer to instructions that accompany the form.
(6) A copy of a manifest required by this section may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.
(7) Information on hazardous, medical, or other waste, required to meet U.S. Environmental Protection Agency regulations, for example, 40 C.F.R. Parts 259 and 261, is not addressed in this section, and shall be provided on the required EPA form. The required EPA form shall accompany the Uniform Low-Level Radioactive Waste Manifest required by this section.
(8) The shipper of the radioactive waste, shall provide the following information on the uniform manifest:
    (a) The name, facility address, and telephone number of the licensee shipping the waste;
    (b) An explicit declaration indicating whether the shipper shall be acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
    (c) The name, address, and telephone number, or the name and U.S. Environmental Protection Agency hazardous identification number, for the carrier transporting the waste.
    (d) The shipper of the radioactive waste shall provide, on the uniform manifest, the following information:
        1. The date of the waste shipment;
        2. The total number of packages or disposal containers;
        3. The total disposal volume and disposal weight in the shipment;
        4. The total radionuclide activity in the shipment;
        5. The activity of each of the radionuclides, hydrogen-3, carbon-14, technetium-99, and iodine-129 contained in the shipment;
        6. The total masses of uranium-233, uranium-235, and plutonium in special nuclear material; and
        7. The total mass of uranium and thorium in source material.

(9) The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and disposal container of waste in the shipment:

(a) An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(b) A physical description of the disposal container, including the manufacturer and model of a high integrity container;

(c) The volume displaced by the disposal container;

(d) The gross weight of the disposal container, including the waste;

(e) For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(f) A physical and chemical description of the waste;

(g) The total weight percentage of a chelating agent for waste containing more than one-tenth (0.1) percent of a chelating agent by weight, and the identity of the principal chelating agent;

(h) The approximate volume of waste within a container;

(i) The sorbing or solidification media, if present, and the identity of the solidification media vendor and brand name;

(j)1. The identity and activity of a radionuclide contained in each container;

2. The masses of uranium-233, uranium-235, and plutonium in special nuclear material;

3. The masses of uranium and thorium in source material; and

4. The identity and activity of each radionuclide associated with, or contained in, discrete waste types within a disposal container, such as:

a. Activated materials;

b. Contaminated equipment;

c. Mechanical filters;

d. Sealed sources or devices; and

e. Wastes in solidification or stabilization media;

(k) The total radioactivity within each container;

(l) The classification of the waste in accordance with Section 6 of this administrative regulation, for wastes cosigned to a disposal facility; and

(m) Identification of waste not meeting the structural stability requirements of Section 7(2) of this administrative regulation.

(10) The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(a) The approximate volume and weight of the waste;

(b) A physical and chemical description of the waste;

(c) The total weight percentage of a chelating agent if the chelating agent exceeds one-tenth (0.1) percent by weight, and the identity of the principal chelating agent;

(d) The classification of the waste in accordance with Section 6 of this administrative regulation for waste cosigned to a disposal facility;

(e) Identification of waste not meeting the structural stability requirements of Section 7(2) of this administrative regulation;

(f)1. The identity and activity of a radionuclide contained in the waste;

2. The masses of uranium-233, uranium-235, and plutonium in special nuclear material;
3. The masses of uranium and thorium in source material; and

(g) For a waste cosigned to a disposal facility, the maximum radiation level at the surface of the waste.

(11)(a) The origin of the LLW resulting from activities of a processor may be attributable to one (1) or more generators, including a waste generator. The requirements in this subsection apply to:

1. A disposal container enclosing a mixture of waste originating from different generators; and
2. A mixture of waste shipped in a form without a disposal container, for which portions of the mixture within the shipment originate from different generators.

(b) For a homogeneous mixture of a waste, such as incinerator ash, provide the:

1. Waste description applicable to the mixture; and
2. Volume of the waste attributed to each generator;

(c) For a heterogeneous mixture of a waste such as:

1. The combined products from a large compactor, identify each generator contributing waste to the disposal container; and
2. A discrete waste type, for example, activated materials, contaminated equipment, mechanical filters, sealed sources or devices, and wastes in solidification or stabilization media, the identity and activity of individual radionuclides contained on the waste type within the disposal container;

(d) For a generator, the following information shall be provided:

1. The volume of waste within the disposal container;
2. A physical and chemical description of the waste, including, if present, the solidification agent;
3. The total weight percentage of a chelating agent for a disposal container containing more than one-tenth (0.1) percent of a chelating agent by weight, plus the identity of the principal chelating agent;
4. The sorbing or solidification media, if present, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Section 7(2) of this administrative regulation; and

5.a. Radionuclide identity and activity contained in the waste;

b. The mass of uranium-233, uranium-235, and plutonium in special nuclear material; and

c. The mass of uranium and thorium in source material if contained in the waste.

(12)(a) An authorized representative of the waste generator, processor, or collector shall certify, by signing and dating the shipment manifest, that the transported materials are:

1. Properly classified;
2. Described;
3. Packaged;
4. Marked;
5. Labeled; and

6. In proper condition for transportation according to 10 C.F.R. 20, Appendix G to Part 20, and the NRC; and

(b) A collector in signing the certification shall certify that nothing has been done to the collected waste which would invalidate the waste generator's certification.

(13) A licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs (d) through (l) of this subsection. A licensee who transfers waste to a land disposal facility or a licensed waste collector shall:

(a) Prepare waste to meet a classification in Section 6 of this administrative regulation and the waste characteristics requirements in Section 7 of this administrative regulation;

(b) Label each disposal container, or transport container if potential radiation hazards preclude labeling of the individual disposal container, of waste to identify if the waste is Class A, Class B, Class C, or greater than Class C waste, in accordance with Section 6 of this administrative regulation;

(c) Conduct a quality assurance program including, management evaluation of audits to assure compliance with Sections 6 and 7 of this administrative regulation.

(d) Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this subsection;

(e) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that:

1. Receipt of the manifest precedes the LLW shipment;
2. The manifest and the waste are delivered to the consignee at the same time; or
3. Both methods of manifest delivery described in subparagraphs 1 and 2 of this paragraph are used.

(f) Include NRC Form 540 and Form 540A, if required, with the shipment, regardless of the option chosen in paragraph (e) of this subsection;

(g) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(h) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 902 KAR 100:040; and

(i) For a shipment, or parts of a shipment, for which acknowledgment of receipt has not been received within the times established in this section, conduct an investigation in accordance with subsection (17) of this section.

(14) A waste collector licensee who handles only prepackaged waste shall:

(a) Acknowledge receipt of the waste from the generator within one (1) week of receipt by returning a signed copy of NRC Form 540;

(b) Prepare a new manifest to reflect consolidated shipments that meet the requirements of this section, including identification of the generator of each container of waste in the shipment;

(c) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

1. Receipt of the manifest precedes the LLW shipment; or

2. The manifest and the waste are delivered to the consignee at the same time; or
3. Both methods of manifest delivery described in subparagraphs 1 and 2 of this paragraph are used;

(d) Include NRC Form 540 and Form 540A, if required, with the shipment regardless of the option chosen in paragraph (c) of this subsection;

(e) Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(f) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 902 KAR 100:040;

(g) For a shipment, or parts of a shipment, for which acknowledgment of receipt is not received within the time established in this section, conduct an investigation in accordance with subsection (17) of this section;

(h) Notify the shipper and the cabinet if a shipment, or part of a shipment, has not arrived within sixty (60) days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

(15) A licensed waste processor who treats or repackages waste shall:

(a) Acknowledge receipt of the waste from the shipper within one (1) week of receipt by returning a signed copy of the manifest or equivalent documentation;

(b) Prepare a new manifest that meets the requirements of this subsection:
1. Preparation of the new manifest shall reflect that the processor shall be responsible for meeting these requirements; and
2. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and other information required by subsection (11) of this section;

(c) Prepare waste to meet a classification in Section 6 of this administrative regulation and the waste characteristics requirement in Section 7 of this administrative regulation;

(d) Label each package of waste to identify the waste as Class A, Class B, or Class C, in accordance with Sections 6 and 8 of this administrative regulation;

(e) Conduct a quality control program to assure compliance with Sections 6 and 7 of this administrative regulation, including management evaluation of audits;

(f) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that:
1. Receipt of the manifest precedes the LLW shipment;
2. The manifest and the waste are delivered to the consignee at the same time; or
3. Both methods of manifest delivery described in subparagraphs 1 and 2 of this paragraph are used;

(g) Include NRC Form 540 and 540A, if required with the shipment regardless of the option chosen in subsection (15)(f) of this section;

(h) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material required by 902 KAR 100:040;

(i) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;
(j) For a shipment or part of a shipment for which acknowledgment of receipt is not received within the time established in this section, conduct an investigation in accordance with subsection (17) of this section; and
(k) Notify the shipper and the cabinet when a shipment, or part of a shipment, has not arrived within sixty (60) days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

(16) The land disposal facility operator shall:
(a) Acknowledge receipt of the waste within one (1) week of receipt by returning a signed copy of the manifest or equivalent documentation to the licensee that last possessed the waste and transferred the waste to the operator. If the returned copy of the manifest or equivalent documentation indicates discrepancies between materials on the manifest and materials received, copies or electronic transfer of the affected forms shall be returned indicating the discrepancy;
(b) Maintain copies of completed manifests, or equivalent documentation, and electronically store the information required by 10 C.F.R. 61.80(l) until the cabinet terminates the license; and
(c) Notify the shipper, generator, collector, or processor and the cabinet if a shipment, or part of a shipment, has not arrived within sixty (60) days after the advance manifest was received, unless notified by the shipper that the shipment has been cancelled.

(17)(a) The shipper shall investigate a shipment or part of a shipment for which acknowledgment is not received within the time established in this section, if the shipper has not received notification of receipt within twenty (20) days after transfer.
(b) The investigation shall include tracing the shipment and filing a report with the cabinet.
(c) A licensee who conducts a trace investigation shall file a written report with the cabinet within two (2) weeks of completion of the investigation.

Section 11. Records. (1) A licensee shall maintain a record in the same units used in this administrative regulation.

(2) A record of disposal of licensed material required by this administrative regulation shall be maintained until the cabinet authorizes disposition, or in accordance with 902 KAR 100:072, Section 29.

(3) A licensee shall maintain a record of the disposal of licensed materials required by 902 KAR 100:022 and Sections 2, 3, 4, and 5 of this administrative regulation, and disposal by burial in soil, including burials authorized before January 28, 1981.

(4) A licensee shall retain the records required in subsection (3) of this section until the cabinet terminates each pertinent license requiring the record.

Section 12. Annual Report of Waste Generated.

(1) A licensee issued a specific license, pursuant to 902 KAR 100:040, shall file an annual report with the cabinet containing information regarding low-level radioactive

waste associated with activities authorized by the license. The report shall be filed if the licensee was, or was not, a waste generator during the reporting period.

(2) The report shall contain information regarding the waste for a period of one (1) calendar year and shall be filed no later than January 15 of the following year.

(3) The report shall be filed on a Low-Level Radioactive Waste (LLW) Report Form provided by the cabinet and shall contain types and amounts of generated waste and estimates of future wastes to be generated.

Section 13. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) NRC Form 540, "Uniform Low-Level Radioactive Waste Manifest, Shipping Paper", 7/2007;

(b) NRC Form 540A, "Uniform Low-Level Radioactive Waste Manifest", 7/2007;

(c) NRC Form 541, "Uniform Low-Level Radioactive Waste Manifest, Container and Waste Description", 7/2007;

(d) NRC Form 541A, "Uniform Low-Level Radioactive Waste Manifest", 7/2007;

(e) NRC Form 542, "Uniform Low-Level Radioactive Waste Manifest, Manifest Index and Regional Compact Tabulation", 8/2010;

(f) NRC Form 542A, "Uniform Low-Level Radioactive Waste Manifest, Manifest Index and Regional Compact Tabulation", 8/2010; and

(g) "Low-Level Radioactive Waste (LLW) Report", 3/2011.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, Office of the Commissioner, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(12 Ky.R. 1123; eff. 1-3-86; Am. 16 Ky.R. 2538; eff. 6-27-90; 20 Ky.R. 2380; 2867; eff. 5-18-94; 28 Ky.R. 1940; 2210; eff. 3-28-2002; 37 Ky.R. 1814; 2607; eff. 6-3-11.)

902 KAR 100:058. Specific licenses to manufacture, assemble, repair, or distribute products. http://www.lrc.ky.gov/kar/902/100/058.htm

RELATES TO: KRS 211.842 - 211.852, 211.990(4), 10 C.F.R. 32.11, 32.18, 32.19, 32.51 - 32.74, 32.101 - 32.103, 32.110, 40.34, 40.35
STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to regulate 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 for issuing specific licenses to persons who manufacture, assemble, repair, or distribute commodities, products, or devices, that contain radioactive material.

Section 1. Registration of Product Information.
1) A manufacturer or initial distributor of a sealed source, or device containing a sealed source, whose product is intended for use under a specific license, shall submit a request to the cabinet for evaluation of radiation safety information about its product and for its registration.
(2) The request for review of a sealed source or device shall include sufficient information to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.
(3) The request shall include information on:
- (a) Design;
- (b) Manufacture;
- (c) Prototype testing;
- (d) Quality control program;
- (e) Labeling;
- (f) Proposed uses; and
- (g) Leak testing.

(4) For a device, the request shall also include sufficient information about:
- (a) Installation;
- (b) Service and maintenance;
- (c) Operating and safety instructions; and
- (d) Potential hazards.

(5) The cabinet shall evaluate a sealed source or device using radiation safety criteria in accepted industry standards. If the standards and criteria do not readily apply to a particular case, the cabinet shall formulate reasonable standards and criteria, with the help of the manufacturer or distributor. The cabinet shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.
(6) After completion of the evaluation, the cabinet shall issue a certificate of registration to the person making the request. The certificate shall acknowledge the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(7) A person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

Section 2. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.

(1) In addition to the requirements established in 902 KAR Chapter 100 a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another, to be transferred to a person exempt under 902 KAR 100:045, Section 2(1)(a) shall be issued if:

(a) The applicant submits a description of the:

1. Product or material into which the radioactive material will be introduced;
2. Intended use of the radioactive material and the product or material into which it is introduced;
3. Method of introduction;
4. Initial concentration of the radioactive material in the product or material;
5. Control methods to assure that no more than the specified concentration shall be introduced into the product or material;
6. Estimated time interval between introduction and transfer of the product or material; and
7. Estimated concentrations of the radioactive material in the product or material at the time of transfer; and

(b) The applicant provides reasonable assurance that the:

1. Concentrations of the radioactive material at the time of transfer shall not exceed the concentrations established in 902 KAR 100:085;
2. Reconcentration of the radioactive material in concentrations exceeding those in 902 KAR 100:085 is not likely;
3. Use of lower concentrations is not feasible; and
4. Product or material is not likely to be incorporated in a food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) A person licensed pursuant to this administrative regulation shall:

(a) Maintain records of transfer of radioactive material;

(b) File an annual report with the cabinet that shall include the:

1. Type and quantity of a product or material into which radioactive material has been introduced during the reporting period;
2. Name and address of the person who owned or possessed the product or material into which radioactive material has been introduced at the time of introduction;
3. Type and quantity of radionuclide introduced into a product or material; and

4. Initial concentrations of the radionuclide in the product or material at the time of transfer of the radioactive material by the licensee;

(c) Indicate in the report if no transfers of radioactive material have been made during the reporting period;

(d) File a report by July 30 covering the year ending the previous June 30; and

(e) Maintain the record of a transfer for a period of one (1) year after the event is included in a report to the cabinet.

Section 3. Resins Containing Scandium-46 and Designed for Sand-Consolidation in Oil Wells: Requirements for License to Manufacture or Initially Transfer for Sale or Distribution. An application for a specific license to manufacture or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use as indicated in 902 KAR 100:045, Section 3(3), shall be approved if:

(1) The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4;

(2) The product is designed to be used only for sand-consolidation in oil wells;

(3) The applicant submits the following information:

(a) A general description of the product to be manufactured or initially transferred; and

(b) A description of control procedures used to assure that the concentration of scandium-46 in the final product at the time of distribution shall not exceed $1.4x10^{-3}$ micro-curie/milliliter; and

(4) A container of the product bears a durable, legible label approved by the cabinet based on the following information:

(a) The product name;

(b) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(c) Instructions necessary for proper use; and

(d) The manufacturer's name.

Section 4. Licensing the Manufacture and Distribution of a Device to a Person Generally Licensed under 902 KAR 100:050.

(1) In addition to the requirements established in 902 KAR Chapter 100 an application for a specific license to distribute certain devices containing radioactive material, excluding special nuclear material, to a person generally licensed shall be issued only if the applicant submits sufficient information relating to the:

(a) Design;

(b) Manufacture;

(c) Prototype testing;

(d) Quality control;

(e) Labels;

(f) Proposed uses;

(g) Installation;

(h) Servicing;

(i) Leak testing;

(j) Operating and safety instructions; and

(k) Potential hazards of the device to provide reasonable assurance that:

1. Under accident conditions, such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:
   a. Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye - 15 rems (150 mSv);
   b. Hands and forearms, feet and ankles, or localized areas of skin averaged over areas no larger than one (1) square centimeter - 200 rems (2 Sv); or
   c. Other organs - 50 rems (500 mSv).
2. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device shall not be released or inadvertently removed from the device, and it is unlikely that a person will receive in a period of one (1) calendar year a dose in excess of ten (10) percent of the limits specified in 902 KAR 100:019, Section 3; and
3. The device can be safely operated by individuals not having training in radiological protection.

(2) A device identified in subsection (1) of this section shall bear a durable, legible, clearly visible label or labels, in accordance with 902 KAR 100:050, which contain in a clearly identified and separate statement:

(a) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(b) The requirement, or lack of requirement, for leak testing or for testing an "on-off" mechanism and indicator, including the maximum time interval for the testing and the identification of radioactive material by:
   1. Isotope;
   2. Quantity of radioactivity; and
   3. Date of determination of the quantity; and

(c) The information called for in the following statement, in the same or substantially similar form:

"The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.
CAUTION - RADIOACTIVE MATERIAL
Name of manufacturer or distributor

The model, serial number, and name of the manufacturer or distributor may be omitted from this label if the information is elsewhere specified in labeling affixed to the device.

(3)(a) If the applicant desires that the device identified in subsection (1) of this section be required to be tested for proper operation of the "on-off" mechanism and indicator or for leakage of radioactive material, subsequent to the initial tests required by this administrative regulation at intervals longer than six (6) months but not exceeding three (3) years, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by:
   1. Performance characteristics of the device or similar devices; and

2. Design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator.

(b) In determining the acceptable interval for the test for leakage of radioactive material, the cabinet may consider information that shall include:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction materials;
5. Form of contained radioactive material;
6. Maximum temperature withstood during prototype tests;
7. Maximum pressure withstood during prototype tests;
8. Maximum quantity of contained radioactive material;
9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices.

(4)(a) If the applicant desires authorization of the general licensee established in 902 KAR 100:050, Section 3, or pursuant to equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application:

1. Written instructions to be followed by the general licensee;
2. Estimated calendar quarter doses associated with the activity or activities; and
3. Basis for the estimates.

(b) The information shall demonstrate that performance of the activity by an individual untrained in radiological protection, handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten (10) percent of the annual limits specified in 902 KAR 100:019, Section 3.

(5) A person licensed pursuant to this administrative regulation to distribute devices to generally licensed persons shall:

(a) Furnish a copy of the general license identified in 902 KAR 100:050, Section 3, to each person to whom the licensee, directly or through an intermediate person, transfers radioactive material in a device for use as authorized by a general license;

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, Section 3, or alternatively, furnish a copy of the general license to each person to whom the licensee directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or the Agreement State. If a copy of the general license identified in 902 KAR 100:050, Section 3, is furnished to the person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear

Regulatory Commission or Agreement State under requirements substantially the same as those in 902 KAR 100:050, Section 3;

(c) Report to the cabinet transfers of the devices to persons for use under the general license.

1. The report shall identify:
    a. A general licensee by name and address;
    b. An individual by name or position who may constitute a point of contact between the cabinet and the general licensee;
    c. The type and model number of device transferred; and
    d. The quantity and type of radioactive material contained in the device.
2. If one (1) or more intermediate persons possess the device temporarily at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.
3. If no transfers have been made to persons generally licensed during the reporting period, the report shall so indicate.
4. The report shall cover a calendar quarter and shall be filed within thirty (30) days of the close of the quarter.

(d) Furnish reports to other agencies as follows:

1. Report to the U.S. Nuclear Regulatory Commission transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 C.F.R. Part 31; or
2. Report to the responsible state agency transfers of devices manufactured and distributed for use under a general license in that state's regulations equivalent to 902 KAR 100:050, Section 3; and
3. The reports shall identify:
    a. A general licensee by name and address;
    b. An individual by name or position who may constitute a point of contact between the agency and the general licensee;
    c. The type and model of the device transferred; and
    d. The quantity and type of radioactive material contained in the device.
4. If one (1) or more intermediate persons possess the device temporarily at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user;
5. The report shall be submitted within thirty (30) days after the end of the calendar quarter in which the device is transferred to the generally licensed person;
6. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission; and
7. If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency;

(e) Keep records showing the name, address, and the point of contact for a general licensee to which the licensee, directly or through an intermediate person, transfers radioactive material in devices for use as authorized by a general license or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall show:

1. The date of transfer;
2. The radionuclide and the quantity of radioactivity in each device transferred;
3. The identity of the intermediate person; and
4. Compliance with the report requirements; and

(f) Maintain the records required by paragraphs (c) and (d) of this subsection for a period of five (5) years from the date of the recorded transfer.

Section 5. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed pursuant to 902 KAR 100:050 shall be approved if:
(1) The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4; and
(2) The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.2(b), 32.53, 32.54, 32.55, 32.56, 32.101, and 32.110 or their equivalent.

Section 6. Special Requirements for License to Manufacture and Distribute Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed pursuant to 902 KAR 100:050. An application for a specific license to manufacture or distribute calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed pursuant to 902 KAR 100:050 shall be approved if:
(1) The applicant satisfies the requirements established in 902 KAR 100:040, Section 4; and
(2) The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.57, 32.58, 32.59, and 32.102, and 10 C.F.R. Part 70, Section 70.39, or their equivalent.

Section 7. Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed shall be approved if:
(1) The applicant satisfies the requirements established in 902 KAR 100:040, Section 4; and
(2) The criteria of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.2(b), 32.61, 32.62, 32.103, and 32.110 are met.

Section 8. Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing under a General License. An application for a specific

license to manufacture or distribute radioactive material for use pursuant to the general license established in 902 KAR 100:050, Section 4, shall be approved if:

(1) The applicant satisfies the general requirements specified in 902 KAR 100:040, Section 4;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Iodine-125 in units not exceeding ten (10) microcuries (370 kBq) each;

(b) Iodine-131 in units not exceeding ten (10) microcuries (370 kBq) each;

(c) Carbon-14 in units not exceeding ten (10) microcuries (370 kBq) each;

(d) Hydrogen-3 (tritium) in units not exceeding fifty (50) microcuries (1.85 MBq) each;

(e) Iron-59 in units not exceeding twenty (20) microcuries (704 kBq) each;

(f) Selenium-75 in units not exceeding ten (10) microcuries (370 kBq) each;

(g) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 MBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or

(h) Cobalt-57 in units not exceeding fifty (50) microcuries (370 kBq) each;

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed:

1. Ten (10) microcuries (370 kBq) of iodine-131, iodine-125, selenium-75, cobalt-57, or carbon-14;
2. Fifty (50) microcuries (1.85 MBq) of hydrogen-3 (tritium);
3. Twenty (20) microcuries (740 kBq) of iron-59; or
4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(b) Displaying the radiation caution symbol described in 902 KAR 100:019, Section 23, and the words, "Caution, Radioactive Material" and "Not for Internal or External Use in Humans or Animals";

(4) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to a prepackaged unit, or appears in a leaflet or brochure which accompanies the package: "This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the administrative regulations and a general license or the equivalent of the United States Nuclear Commission or of an Agreement State. (Name of Manufacturer)"; and

(5) The label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information regarding precautions to be observed in handling and storing the radioactive material. For a mock iodine-125 reference or calibration source, the information accompanying the source shall contain directions to the licensee regarding the waste disposal requirements established in 902 KAR 100:021, Section 1.

Section 9. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses.

(1) An application for a specific license to manufacture, prepare or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 902 KAR 100:072, shall be approved if the applicant:

(a) Satisfies the requirements specified in 902 KAR 100:040, Section 4;

(b) Submits evidence that the applicant is at least one (1) of the following:

1. Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
2. Registered or licensed with a state agency as a drug manufacturer;
3. Licensed as a pharmacy by the State Board of Pharmacy; or
4. Operating as a nuclear pharmacy within the federal medical institution.

(c) Submits information on:

1. The radionuclide;
2. Chemical and physical form;
3. Maximum activity per vial, syringe, generator, or other container of the radioactive drug; and
4. Shielding provided by the packaging of the radioactive material to show it is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

(d) Satisfies the following labeling requirements:

1. The label shall be affixed to the transport radiation shield, if it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label shall include:
   a. The radiation symbol;
   b. The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";
   c. The name of the radioactive drug or its abbreviation; and
   d. The quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.
2. A label shall be affixed to a syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include:
   a. The radiation symbol;
   b. The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and
   c. An identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by subsection (1)(b)3 of this section may:

(a) Prepare radioactive drugs for medical use, as defined in 902 KAR 100:010, if the radioactive drug is prepared by an authorized nuclear pharmacist, as specified in paragraphs (b) and (c) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist, as specified in 902 KAR 100:072, Section 12;

(b) Allow a pharmacist to work as an authorized nuclear pharmacist if the individual:

1. Qualifies as an authorized nuclear pharmacist as defined in 902 KAR 100:010;

2. Meets the requirements specified in 902 KAR 100:072, Sections 63 and 66, and the licensee has received an approved license amendment identifying the individual as an authorized nuclear pharmacist; or
3. Is designated as an authorized nuclear pharmacist in accordance with paragraph (c) of this subsection.

(c) Designate a pharmacist as an authorized nuclear pharmacist if the individual is identified as an authorized user on a nuclear pharmacy license issued by the cabinet.

(3) The actions authorized in subsections (2)(a) and (b) of this section are permitted in spite of more restrictive language in license conditions.

(4) A licensee shall provide to the cabinet a copy of an individual's certification by the Board of Pharmaceutical Specialties, the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state license, and a copy of the state pharmacy licensure or registration, no later than thirty (30) days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist, pursuant to subsection (2)(b)1 and 3 of this section.

(5) A licensee shall:

(a) Possess and use instrumentation to measure the radioactivity of radioactive drugs;

(b) Have procedures for use of the instrumentation;

(c) Measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting radioactive drugs prior to transfer for commercial distribution;

(d) Perform accuracy, linearity, and geometry dependence tests on an instrument before initial use, periodically, and following repair, as appropriate for the instrument, and make necessary adjustments; and

(e) Check an instrument for constancy and proper operation at the beginning of each day of use.

(6) Nothing in this section relieves a licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

Section 10. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as authorized by 902 KAR 100:072 for use as a calibration, transmission, or reference source or for medical uses listed in 902 KAR 100:072, Sections 37, 45 and 46 shall be approved if:

(1) The applicant satisfies the requirements established in 902 KAR 100:040, Section 4;

(2) The applicant submits sufficient information regarding a type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form, and amount;

(b) Details of design and construction of the source or device;

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(d) For devices containing radioactive material, the radiation profile of a prototype device;
(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
(f) Procedures and standards for calibrating sources and devices;
(g) Legend and methods for labeling sources and devices as to their radioactive content; and
(h) Instructions for handling and storing the source or device from the radiation safety standpoint. The instructions shall be included on a durable label attached to the source or device, or attached to a permanent storage container for the source or device. Instructions too lengthy for a label may be summarized on the label and printed in detail on a brochure referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains:
(a) Information on the radionuclide;
(b) Quantity; and
Date of assay; and
(d) A statement that the name of source or device is licensed by the cabinet for distribution to persons licensed as authorized by 902 KAR 100:072, or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;

(4) If an applicant desires the source or device to be tested for leakage of radioactive material at intervals longer than six (6) months, he shall include in the application sufficient information to demonstrate that the longer interval is justified by:
(a) Performance characteristics of the source or device, or similar sources or devices; and
(b) Design features having a significant bearing on the probability or consequence of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for tests of leakage of radioactive material, the cabinet shall consider information that includes:
(a) Primary containment or source capsule;
(b) Protection of primary containment;
(c) Method of sealing containment;
(d) Containment construction materials;
(e) Form of contained radioactive material;
(f) Maximum temperature withstood during prototype tests;
(g) Maximum pressure withstood during prototype tests;
(h) Maximum quantity of contained radioactive material;
(i) Radiotoxicity of contained radioactive material; and
(j) Operating experience with identical sources or devices, or similarly designed and constructed sources or devices.

Section 11. Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.

(1) An application for a specific license to manufacture or distribute an industrial product or device containing depleted uranium for use authorized by 902 KAR 100:050, Section 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be approved if:

(a) The applicant satisfies the general requirements specified in 902 KAR 100:040, Section 4;

(b) The applicant submits sufficient information relating to the:

1. Design;
2. Manufacture;
3. Prototype testing;
4. Quality control procedures;
5. Labeling or marking;
6. Proposed uses; and
7. Potential hazards of the industrial product or device;

(c) The applicant provides reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause an individual to receive in a period of one (1) year a radiation dose in excess of ten (10) percent of the limits specified in 902 KAR 100:019, Section 3; and

(d) The applicant submits sufficient information regarding the industrial product or device, and the presence of depleted uranium for a mass-volume application in the product or device, to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) For an industrial product or device that is unique benefits are questionable, the cabinet may approve an application for a specific license pursuant to this section only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The cabinet shall deny an application for a specific license pursuant to this section if the end use of the industrial product or device cannot reasonably be foreseen.

(4) A person licensed as authorized by this section shall:

(a) Maintain the level of quality control required by the license in:

1. Manufacture of the industrial product or device; and
2. Installation of the depleted uranium into the product or device;

(b) Label or mark each unit to identify:

1. The manufacturer of the product or device;
2. The number of the license under which the product or device was manufactured or distributed;
3. The fact that the product or device contains depleted uranium;
4. The quantity of depleted uranium in the product or device; and
5. That the receipt, possession, use, or transfer of the product or device is subject to a general license, or the equivalent, and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(c) Assure that the depleted uranium, before being installed in a product or device, has been impressed with the legend "DEPLETED URANIUM" clearly legible through plating or other covering;

(d) Furnish a copy of the general license contained in:
1. 902 KAR 100:050 to a person to whom depleted uranium is transferred in a product or device for use authorized by the general license; or
2. The U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, and a copy of an applicable U.S. Nuclear Regulatory Commission's or Agreement State's certificate, to a person to whom depleted uranium is transferred in a product or device for use as authorized by the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 902 KAR 100:050;

(e) Furnish the following to either the cabinet, U.S. Nuclear Regulatory Commission, or agreement state:
1. A report of each transfer of an industrial product or device to a person for use pursuant to the general license in 902 KAR 100:050. The report shall identify:
a. A general licensee by name and address;
b. An individual, by name or position, who constitutes a point of contact between the cabinet and the general licensee;
c. The type and model number of device transferred; and
d. The quantity of depleted uranium contained in the product or device.
2. The report identified in subparagraph 1 of this paragraph shall be submitted within thirty (30) days after the end of a calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed pursuant to 902 KAR 100:050 during the reporting period, the report shall so indicate; and

(f) Keep records showing the name, address, and point of contact for a general licensee to whom he transfers depleted uranium in an industrial product or device for use authorized by the general license provided in 902 KAR 100:050 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of three (3) years from the date of transfer and shall show the date of each transfer, the quantity of depleted uranium in a product or device transferred, and compliance with the report requirements of this section.

Section 12. Licensing the Distribution of Naturally Occurring and Accelerator Produced Radioactive Material (NARM) in Exempt Quantities. (1) An application for a specific license to distribute NARM to persons exempted from these regulations authorized by 902 KAR 100:045 shall be approved if:

(a) The radioactive material is not contained in a food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(b) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting

standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device intended for commercial distribution; and

(c) The applicant submits copies of prototype labels and brochures in accordance with 10 C.F.R. 32.18 and 32.19 and the cabinet approves the labels and brochures.

(2) The license issued pursuant to this section is subject to the following conditions:

(a) No more than ten (10) exempt quantities shall be sold or transferred in a single transaction. However, an exempt quantity may be composed of fractional parts of one (1) or more of the exempt quantity, if the sum of the fractions does not exceed unity.

(b) An exempt quantity shall be packaged separately and individually. No more than ten (10) packaged exempt quantities shall be contained in an outer package for transfer to persons exempt as authorized by 902 KAR 100:045. The dose rate at the external surface of the outer package shall not exceed five-tenths (0.5) millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

1. Identifies the radionuclide and the quantity of radioactivity; and
2. Bears the words "Radioactive Material."

(d) In addition to the labeling information required by this subsection, the label affixed to the immediate container, or an accompanying brochure, shall:

1. State that the contents are exempt from licensing agency requirements;
2. Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined"; and
3. Establish appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3)(a) A person licensed pursuant to this section shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use in accordance with 902 KAR 100:045 or the equivalent regulations of a licensing agency, and stating the kinds and quantities of radioactive material transferred.

(b) An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the cabinet.

(c) A report shall cover the year ending June 30 and shall be filed within thirty (30) days after June 30. If no transfers of radioactive material have been made, as authorized by this section, during the reporting period, the report shall so indicate.

Section 13. Licensing the Incorporation of Naturally Occurring and Accelerator Produced Radioactive Material (NARM) into Gas and Aerosol Detectors. (1) An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt pursuant to 902 KAR 100:045

shall be approved if the application satisfies requirements equivalent to those contained in U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32.26.
(2) The maximum quantity of radium-226 in a device shall not exceed one-tenth (0.1) microcurie (3.7 kBq). (1 Ky.R. 396; eff. 2-5-75; Am. 12 Ky.R. 1020; eff. 1-3-86; 13 Ky.R. 1766; eff. 5-14-87; 18 Ky.R. 1510; eff. 1-10-92; 26 Ky.R. 2395; 27 Ky.R. 970; eff. 10-16-2000; 37 Ky.R. 1820; 2612; eff. 6-3-11.)

902 KAR 100:070. Transportation of radioactive material.
http://www.lrc.ky.gov/kar/902/100/070.htm

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 71, 39 C.F.R. 111.1, 49 C.F.R. 170-189
STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to provide by administrative regulation 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 for transportation of radioactive material.

Section 1. Applicability.
(1) Applies to a licensee authorized by a specific or general license issued by the cabinet to receive, possess, use, or transfer radioactive material, when:
(a) The licensee delivers that material to a carrier for transport;
(b) Transports the material outside the site of usage as specified in the cabinet license; or
(c) Transports the material on public highways.
(2) No provision of this administrative regulation authorizes the possession of radioactive material.

Section 2. Requirement for a License. A person shall not deliver radioactive material to a carrier for transport, or transport radioactive material, unless:
(1) Authorized in a general or specific license issued by the cabinet; or
(2) Exempted pursuant to Section 3 of this administrative regulation.

Section 3. Exemptions.
(1) A licensee is exempt from all the requirements of this administrative regulation with respect to shipment or carriage of the following low-level materials:
(a) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten (10) times the values specified in 10 C.F.R. 71, Appendix A; and
(b) Materials for which the activity concentration is not greater than the activity concentration values, or for which the consignment activity is not greater than the limit for an exempt consignment found in 10 C.F.R. 71, Appendix A.
(2) A licensee shall be exempt from requirements in this administrative regulation, except for Sections 4 and 12 of this administrative regulation, with respect to shipment or carriage of the following packages, provided the packages do not contain fissile material, or the material is exempt from classification as fissile material under Section 14;
(a) A package that contains no more than a Type A quantity of radioactive material;
(b) A package transported within the United States that contains no more than twenty (20) Curies (0.74 TBq) of special form plutonium-244; or
(c) The package contains only LSA or SCO radioactive material, provided:

1. The LSA or SCO material has an external radiation dose of less than or equal to one (1) rem/hour (10 mSv/hour), at a distance of three (3) meters from the unshielded material; or
2. The package contains only LSA-1 or SCO-1 material.

(3) A physician licensed by the Commonwealth to dispense drugs in the practice of medicine shall be exempt from Section 4 of this administrative regulation with respect to transport by the physician of radioactive material for use in the practice of medicine. However, a physician operating under this exemption shall be licensed pursuant to 902 KAR 100:072 or equivalent regulations of the NRC or an agreement state.

Section 4. Transportation of Licensed Material. (1) A licensee who transports licensed material outside of the confines of his plant or other place of use specified in the cabinet license, or who transports on a public highway, or who delivers licensed material to a carrier for transport, shall:

(a) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation in 49 C.F.R. 107, 171 through 189, and 390 through 397; and

(b) Assure that special instructions needed to open the package safely are sent to, or have been made available to, the consignee for the consignee's use in accordance with 902 KAR 100:019, Section 28(5).

(2) If the regulations of the U.S. Department of Transportation (DOT) are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the Department of Transportation regulations, specified in subsection (1)(a) of this section, to the same extent as if the shipment was subject to the DOT regulations.

Section 5. General Licenses for Carriers.

(1) A general license shall be issued to a common or contract carrier, not exempt under Section 3 of this administrative regulation, to receive, possess, transport, and store radioactive material in the regular course of carriage for another, or storage incident to the transportation and storage, if the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation relating to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(2) A general license shall be issued to a private carrier to transport radioactive material, if the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation relating to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(3) The notification of incidents referred to in the U.S. Department of Transportation requirements identified in subsection (1) of this section shall be filed with, or made to, the cabinet.

(4) A person authorized by a general license described in this section, who transports radioactive material, is exempt from the requirements of 902 KAR 100:019 and 902 KAR 100:165.

Section 6. General License: NRC Approved Packages.

(1) A general license shall be issued to a licensee of the cabinet to transport or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.
(2) The general license shall apply only to a licensee who:
(a) Has a quality assurance program approved by the NRC as satisfying the provisions of 10 C.F.R. 71.101 through 137;
(b) Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
(c) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137; and
(d) Submits in writing to Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, using an appropriate method listed in 10 C.F.R. 71.1(a), before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.
(3) The general license identified in subsection (1) of this section shall apply only if the package approval authorizes use of the package under the general license.
(4) For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license shall be subject to additional restrictions contained in Section 7 of this administrative regulation.

Section 7. Previously Approved Type B Packages.
(1) A Type B package previously approved by the NRC, but not designated as B(U) or B(M) in the NRC Certificate of Compliance, may be used under the general license of Section 6 of this administrative regulation, with the following limitations:
(a) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by its model number, in accordance with NRC regulations;
(b) The package shall not be used for a shipment to a location outside the United States after August 31, 1986, except under multilateral approval by the U.S. Department of Transportation, as defined in 49 C.F.R. 173.403; and
(2) A serial number that uniquely identifies each package that conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each package.
(3) A Type B(U) package, a Type B(M) package, an LSA material package, or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC Certificate of Compliance, may be used under the general license of Section 6 of this administrative regulation, with the following conditions:
(a) Fabrication of the package shall have been satisfactorily completed by April 1, 1999, as demonstrated by its model number, in accordance with NRC regulations, 10 C.F.R.;

(b) A package used for shipment to a location outside the United States shall be subject to multilateral approval by the U.S. Department of Transportation, as defined in 49 C.F.R. 173.403; and
(c) A serial number that uniquely identifies each package that conforms to the approved design shall be assigned to, and legibly and durably marked on the outside of, each package.

Section 8. General License: DOT Specification Container.
(1) A general license shall be issued to a licensee of the cabinet to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material, or for a Type B quantity of radioactive material, as specified in 49 C.F.R. Parts 173 and 178.
(2) The general license shall apply only to a licensee who:
(a) Has a quality assurance program approved by the cabinet as satisfying the requirements of 10 C.F.R. 71.101 through 71.137;
(b) Has a copy of the specification; and
(c) Complies with the terms and conditions of the specification, and the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137.
(3) The general license shall be subject to the limitation that the specification container shall not be used for a shipment to a location outside the United States except by multilateral approval, as defined in 49 C.F.R. 173.403.
(4) This section expires October 1, 2008.

Section 9. General License: Use of Foreign Approved Package.
(1)(a) A general license shall be issued to a licensee of the cabinet to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate and revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 C.F.R. 171.12.
(b) Except as provided in this section, the general license shall apply only to a licensee who has a quality assurance program approved by the NRC as satisfying the applicable provisions of 10 C.F.R. 71.101 through 71.137.
(2) The general license shall apply only to shipments made to or from locations outside the United States.
(3) The general license shall apply to a licensee who:
(a) Has copies of the applicable certificate, the revalidation, the drawings, and other documents referenced in the certificate relating to the:
1. Use and maintenance of the packaging; and
2. Actions to be taken prior to shipment; and
(b) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this administrative regulation and 10 C.F.R. 71.0 through 71.11, 71.81 through 71.100, and 71.101 through 71.137.
(4) With respect to the quality assurance provisions of 10 C.F.R. 71.101 through 71.137, the licensee shall be exempt from design, construction, and fabrication considerations.

Section 10. Preliminary Determinations. Before the first use of a packaging for the shipment of radioactive material:
(1) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that may significantly reduce the effectiveness of the packaging;
(2) If the maximum normal operating pressure will exceed thirty-five (35) kilopascal (five (5) lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least fifty (50) percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure; and
(3) The licensee shall mark the packaging, conspicuously and durably, with its model number, serial number, gross weight, and a package identification number assigned by the NRC, in accordance with 10 C.F.R. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

Section 11. Routine Determinations. Before making a shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this administrative regulation and of the license. The licensee shall determine that:
(1) The package is proper for the contents to be shipped;
(2) The package is in unimpaired physical condition except for superficial defects, such as marks or dents;
(3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
(4) A system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
(5) A pressure relief device is operable and set in accordance with written procedures;
(6) The package has been loaded and closed in accordance with written procedures;
(7) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;
(8) A structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by 10 C.F.R. 71.45.
(9) The level of nonfixed, or removable, radioactive contamination on the external surfaces of each package offered for shipment is ALARA, and within the limits specified by the U.S. Department of Transportation in 49 C.F.R. 173.443;
(10) External radiation levels around the package and around the vehicle, if applicable, shall not exceed the limits specified in 49 C.F.R. 71.47 during transportation.
(11) Accessible package surface temperatures shall not exceed the limits specified in 10 C.F.R. 71.43(g) at any time during transportation.

Section 12. Air Transport of Plutonium. In addition to the requirements of a general license and exemptions stated in this administrative regulation or included by citation of U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(1) The plutonium is contained in a medical device designed for individual human application;
(2) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in 10 C.F.R. 71, Appendix A and in which the radioactivity is essentially uniformly distributed;
(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in an isotope or form and is shipped in accordance with Section 4 of this administrative regulation;
(4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC; or
(5) For a shipment of plutonium by air which is subject to subsection (4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 C.F.R. 175.704, applicable to the air transport of plutonium;
(6) Nothing in this section shall be interpreted as removing or diminishing the requirements of 10 C.F.R. 73.24.

Section 13. Advance Notification of Transport of Irradiated Reactor Fuel and Nuclear Waste.
(1)(a) Before the transport of nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or before the delivery of nuclear waste to a carrier for transport, a licensee shall provide advance notification of the transport to the governor, or governor's designee, of each state through which the waste will be transported.
(b) Advance notification shall be required for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements in 10 C.F.R. 73.37(f).
(2) Advance notification shall also be required for licensed material, other than irradiated fuel, if:
(a) The nuclear waste is required to be in Type B packaging for transportation;
(b) The nuclear waste is being transported to, through, or across a state boundary to a disposal site, or to a collection point for transport to a disposal site; and
(c) The quantity of licensed material in a single package exceeds the least of the following:
1. 3,000 times the A_1 value of the radionuclides as specified in 10 C.F.R. 71, Appendix A for special form radioactive material;
2. 3,000 times the A_2 value of the radionuclides as specified in 10 C.F.R. 71 Appendix A for normal form radioactive material; or
3. 27,000 curies (1000 TBq).
(3) Each advance notification shall be in writing and contain the following information:
(a) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
(b) A description of the nuclear waste contained in the shipment as required by 49 C.F.R. 172.202 and 172.203(d);
(c) The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;

(d) The seven (7) day period during which arrival of the shipment at state boundaries is estimated to occur;
(e) The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and
(f) A point of contact with a telephone number for current shipment information.

(4) The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the cabinet.
(a) A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.
(b) A notification delivered by messenger shall reach the office of the governor, or governor's designee, at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three (3) years.

(5) The licensee who finds that schedule information previously furnished will not be met, shall telephone a responsible individual in the office of the governor, or governor's designee and the cabinet and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain for three (3) years a record of the name of the individual contacted.

(6) A licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the cabinet. The licensee shall state in the notice that it is a cancellation and shall identify the advance notification that is being cancelled. A copy of the notice shall be retained by the licensee for three (3) years.

Section 14. Exemption from Classification as Fissile Material. Fissile material meeting the requirements of at least one (1) of the subsections (1) through (6) of this section are exempt from classification as fissile material and from the fissile material package standards of 10 C.F.R. 71.55 and 71.59, but are subject to all other requirements of this administrative regulation, except as noted.

(1) Individual package containing two (2) grams or less fissile material;

(2) Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material;

(3)(a) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:
1. There is at least 2000 grams of solid nonfissile material for every gram of fissile material; and
2. There is no more than 180 grams of fissile material distributed within 360 kilograms of contiguous nonfissile material.
(b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and with total plutonium and uranium content of up to one (1) percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five (5) percent of the uranium mass;
(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two (2) percent by mass, with a total plutonium and uranium-233 content not exceeding two one-thousands (0.002) percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two (2). The material shall be contained in at least a DOT Type A package.
(6) Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than twenty (20) percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

Section 15. General License: Fissile Material (1) A general license is issued to any licensee of the cabinet to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section of this administration regulation. The fissile material need not be contained in a package which meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).
(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71.101 through 71.137.
(3) The general license shall apply only when a package's contents:
(a) Contain less than a Type A quantity of radioactive material; and
(b) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.
(4) The general license shall apply only to packages containing fissile material that are labeled with a Criticality Safety Index (CSI) that:
(a) Has been determined in accordance with subsection (5) of this section;
(b) Has a value less than or equal to ten (10); and
(c) For a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance, and less than or equal to 100, for shipment on an exclusive use conveyance.
(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$\left(\frac{\text{grams of U-235}}{X} + \frac{\text{grams of U-233}}{X} + \frac{\text{grams of Pu}}{X} \right)$$

$$\text{CSI} = 10$$

(b) The calculated CSI shall be rounded up to the first decimal place;
(c) The values of X, Y, and Z used in the CSI equation shall be taken from 10 C.F.R. 71 Appendix A, Table A-1 or A.2, as appropriate;
(d) If Table A-2 is used to obtain the value of X, then the values of the terms in the equation for uranium-233 and plutonium shall be assumed to be zero (0); and
(e) Table A-1 values for X, Y, and X shall be used to determine the CSI if:
1. Uranium-233 is present in the package;
2. The mass of plutonium exceeds one (1) percent of the mass of uranium-235;
3. The uranium is of unknown uranium-235 enrichment or greater than twenty-four (24) percent enrichment; or
4. Substances having a moderating effectiveness (an average hydrogen density greater than water), such as, certain hydrocarbons oils or plastics, are present in any form, except as polyethylene used for packaging or wrapping.

Section 16. General License: Plutonium-beryllium Special Form Material.
(1) A general license is issued to any licensee of the cabinet to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section of this administrative regulation. This material need not be contained in a package which meets the standards of 10 C.F.R. 71.41 through 71.65 and 71.71 through 71.77, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of 49 C.F.R. 173.417(a).
(2) The general license shall apply only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the provisions of 10 C.F.R. 71 Subpart H.
(3) The general licensee applies only if a package's contents:
(a) Contain less than a Type A quantity of radioactive material; and
(b) Contain less than 1000 grams of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.
(4) The general license applies only to packages labeled with a CSI that:
(a) Have been determined in accordance with subsection (5) of this section;
(b) Have a value less than or equal to 100; and
(c) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to fifty (50), for shipment on a nonexclusive use conveyance and less than or equal to 100, for shipment on an exclusive use conveyance.
(5)(a) The value for the CSI shall be greater than or equal to the number calculated by the following equation:

$$\left(\frac{\text{Grams of Pu-239 + grams of Pu-241}}{24}\right)$$

CSI = 10 and:

(b) The calculated CSI shall be rounded up to the first decimal place.

Section 17. External Radiation Standards for all Packages.

(1) Except as provided in subsection (2) of this section, a package of radioactive materials offered for transportation shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level shall not exceed 200 millirem/hour (mrem/h) (2 milliservierts/h) (2 mSv/h) at any point on the external surface of the package, and the transport index shall not exceed ten (10).

(2) A package that exceeds the radiation level limits specified in subsection (1) of this section shall be transported by exclusive use shipment only, and the radiation levels for the shipment shall not exceed the following during transportation:

(a) 200 mrem/h (2 mSv/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 1000 mrem/h (10 mSv/h);
1. The shipment is made in a closed transport vehicle;
2. The package is secured within the vehicle so that its position remains fixed during transportation; and
3. There are no loading or unloading operations between the beginning and end of the transportation;

(b) 200 mrem/h (2 mSv/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or in case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(c)1. Ten (10) mrem/h (0.1 mSv/h) at any point eighty (80) inches (2 meters) from the outer lateral surface of the vehicle, excluding the top and underside of the vehicle; or

2. In the case of a flat-bed style vehicle, an any point six and six tenths (6.6) feet (2 meters) from the vertical planes projected by the outer edges of the vehicle, excluding the top and underside of vehicle; and

(d) Two (2) mrem/h (0.02 mSv/h) in any normally occupied space, except that this provision shall not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices as required by 902 KAR 100:019, Section 13.

(3) For shipments made under the provisions of subsection (2) of this section, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions shall be included with the shipping paper information.

(4) The written instructions required for exclusive use shipments shall be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposure to transport workers or members of the general public.

Section 18. Assumption as to Unknown Properties. If the isotopic abundance, mass, concentration, degree of moderation, or other pertinent property of fissile material in any

package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

Section 19. Opening Instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 902 KAR 100:019, Section 28(5).

Section 20. Quality Assurance Requirements.
(1) The requirements in Sections 20 through 28 shall apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging important to safety. As used in this administrative regulation, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.
(2) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.
(3) The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging.
(4) A licensee is responsible for the quality assurance provision that applies to its use of a packaging for the shipment of licensed material subject to this administrative regulation.
(5) A licensee, certificate holder, and applicant for a CoC shall:

1. Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 C.F.R. 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and
2. Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(6) A licensee shall, before the use of a package for the shipment of licensed material subject to this administrative regulation, obtain U.S. Nuclear Regulatory Commission approval of its quality assurance program. Using an appropriate method listed in 10 C.F.R. 71.1(a), a licensee shall file a description of its quality assurance program, including a discussion of which requirements of this administrative regulation are applicable and how they will be satisfied, by submitting the description to: Attention: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.
(7) A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 902 KAR 100:100, Section 9(3) is deemed to satisfy the requirements of Section 6(2)(a) and subsection (5) of this section.

Section 21. Quality Assurance Organization. (1) The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall be responsible for the

establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(2) The quality assurance functions are:

(a) Assuring an appropriate quality assurance program is established and effectively executed; and

(b) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(3) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to:

(a) Identify quality problems;

(b) Initiate, recommend, or provide solutions; and

(c) Verify implementation of solutions.

(4) While the term "licensee" is used, the requirements in this section shall be applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.

Section 22. Quality Assurance Program.

(1) The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 C.F.R. 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following conditions concerning the complexity and proposed use of the package and its components:

(a) The impact of malfunction or failure of the item to safety;
(b) The design and fabrication complexity or uniqueness of the item;
(c) The need for special controls and surveillance over processes and equipment;
(d) The degree to which functional compliance can be demonstrated by inspection or test; and
(e) The quality history and degree of standardization of the item.

(4) The license, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary, to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

Section 23. Handling, Storage, and Shipping Control. The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. If necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels shall be specified and provided.

Section 24. Inspection, Test and Operating Status.

(1) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures shall provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by passing of the inspections and tests.

(2) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Section 25. Nonconforming Materials, Parts, or Components. The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee’s requirements to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Section 26. Corrective Action. The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Section 27. Quality Assurance Records.
(1) The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records shall include the instructions, procedures, and drawings required by 10 C.F.R. 71.111 to prescribe quality assurance activities and shall include closely related specifications such as required qualifications of personnel, procedures, and equipment.
(2) The records shall include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.
(3) The licensee, certificate holder, and applicant for a CoC shall retain these records for three (3) years beyond the date when the licensee, certificate holder, applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for CoC shall retain the superseded material for three (3) years after it is superseded.

Section 28. Audits.
(1) The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.
(2) The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.
(3) Audited records shall be documented and reviewed by management having responsibility in the area audited.
(4) Follow-up action, including reaudit of deficient areas, shall be taken as indicated.

Section 29. Determination of A_1 and A_2. (1) Values of A_1 and A_2 shall be determined as described in 10 C.F.R. 71 Appendix A. (1 Ky.R. 403; eff. 2-5-75; Am. 2 Ky.R. 479; eff. 4-14-76; 12 Ky.R. 1044; eff. 1-3-86; 13 Ky.R. 1769; eff. 5-14-87; 18 Ky.R. 1525; eff. 1-10-92; 26 Ky.R. 2402; 27 Ky.R. 976; eff. 10-16-2000; 37 Ky.R. 1827; 2618; eff. 6-3-11.)

902 KAR 100:072. Use of radionuclides in the health arts.
http://www.lrc.ky.gov/kar/902/100/072.htm

RELATES TO: KRS 211.842 to 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, 902 KAR 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) 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. 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. To meet the requirements of this subsection, 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. 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.

(6) Aside from the notification requirement, nothing in this section shall 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) 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. 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. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. 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.

(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) Nothing in this section relieves 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 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 (1000 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; or

(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 instrument 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 is not 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 (fife-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:

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

2. 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:
An authorized nuclear pharmacist;
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
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 described 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 in the event of 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 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 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) Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state and who meets the requirements in subsections (4) and (5) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a)1. 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;

2. 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

3. 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

(b)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 equivalent agreement state; or

b. 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;

3. 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; or

(2)(a) 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 equivalent 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

(3)(a) 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 equivalent agreement state under 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 (4) and (5) of this section; or

(b) 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, and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (5) and in (1)(a)1 and 2 or (1)(b)1 and 2 or (2)(a) or (3)(a) 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

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

(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 a 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:

1. 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 equivalent agreement state; or
2. 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 of authorized users in Section 67, 74, or 77 of this administrative regulation, and

(c) 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

(2)(a) 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

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3), and (1)(a) and (b), or subsection (2)(a) and (3) 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, U.S. Nuclear Regulatory Commission, or equivalent 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 equivalent 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 equivalent agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent 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 equivalent agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or 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 equivalent agreement state, a permit issued by a Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent 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 equivalent agreement state, a permit issued by a master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission or agreement state broad scope licensee or a permit issued by a U.S. Nuclear Regulatory 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.

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 under Section 30 of this administrative regulation to be a physician who:

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

1. 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
2. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

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

(2) Is an authorized user under Section 70 of this administrative regulation and meets the requirements in subsection (3)(a)2.g of this section, U.S. Nuclear Regulatory Commission, or equivalent 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, U.S. Nuclear Regulatory Commission, or equivalent 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 or Section 69(3)(a)2.g of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under 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 under Section 33 of this administrative regulation to be a physician who:

(1) Is certified by a medical specialty board whose certification process ~~of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or equivalent 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 or 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 of Sections 67 and 70 of this administrative regulation, or U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in Section 70(2) of this administrative regulation, 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. 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 under 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 U.S. Nuclear Regulatory Commission, or equivalent 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 has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state and who meets the requirements in subsection (3)(c) of this section;

(2) Is an authorized user under Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f(i), or Section 72 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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, U.S. Nuclear Regulatory Commission, or equivalent 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 under 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, U.S. Nuclear Regulatory Commission, or equivalent 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 equivalent agreement state and who meets the requirements in subsection of (3)(c) of this section; or

(2) Is an authorized user under Section 70 of this administrative regulation for uses listed in Section 70(2)(a)2.f.(ii) of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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, and 72 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under 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, U.S. Nuclear Regulatory Commission, or equivalent 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 under Section 70 for uses listed in Section 70(2)(a)2.f.(iii) or Section 70(2)(a)2.f.(iv) or of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state regulations;

(2) Is an authorized user under Sections 74 or 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state and who meets the requirements in subsection (4) of this section;

(3) Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state under Sections 74 or 77 of this administrative regulation; and who meets the requirements in subsection (4) of this section; or

(4)(a) Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less that 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. 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 Sections 67, 70, and 73 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Section 70 shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) and/or Section 70(2)(a)2.f.(iv). 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 of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subjects dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed 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 include at least three (3) cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three (3) cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (2) or (3) of this section, 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. A preceptor authorized user, who meets the requirements in Section 70, shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) and/or Section 70(2)(a)2.f.(iv) of this administrative regulation.

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 under 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 equivalent 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 Sections 67 and 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 sections 67 and 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 of this section and Sections 67 and 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under 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 under Section 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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, and 75 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under Section 45 of this administrative regulation to be a physician, dentist, or podiatrist who:

(1) Is certified by a specialty board whose certification process includes all of the requirements in subsection (2) and (3) of this section and whose certification has been

recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state; or
(2) 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:
(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity; and
(d) Radiation biology; and
(3) 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 under 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 equivalent 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 Sections 67 and 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 Sections 67 and 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 Sections 67 and 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 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 license from complying with applicable FDA, other federal and state requirements governing radioactive drugs or devices. (31 Ky.R. 656; Am. 1163; eff. 1-4-2005; 37 Ky.R. 1837; 2627; eff. 6-3-11.)

902 KAR 100:072 (proposed 5/2011) http://www.lrc.ky.gov/kar/902/100/072.htm (As approved for revision)		10 CFR 35 (effective 12/2010) http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0050
Section 64. Training for Radiation Safety Officer. Except as provided in Section 67 [~~68~~] 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)** Is certified by a specialty board whose certification process [~~includes all of the requirements in subsection (1) of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~another~~] agreement state and who meets the requirements in subsections (4) and (5) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to: [~~;or~~] **(a)1.** 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; **(a)2.** 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** **(a)3.** 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** **(b)1.** Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied		**§ 35.50 Training for Radiation Safety Officer.** Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who-- **(a)** Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State **and** who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)(i)** 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 20 college credits in physical science; **(1)(ii)** Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; **AND** **(1)(iii)** Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; **OR** **(2)(i)** 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)2.** Have two (2) years of full-time practical training**, two (2) years of supervised experience in medical physics, or two (2) years of a combination of full-time practical training and[~~and/or~~] 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 equivalent agreement state; **OR** **b.** In clinical nuclear medicine facilities providing diagnostic **or**[~~and/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; **(b)3.** 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; **OR** **(2)(a)** Has completed a structured educational program consisting of **BOTH**: **1.** 200 hours of classroom and laboratory [~~didactic~~] 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	mathematics from an accredited college or university; **(2)(ii)** Have 2 years of full-time practical training and/or 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 Commission or an Agreement State; **OR** **(B)** In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; **(2)(iii)** Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; **OR** **(b)(1)** Has completed a structured educational program consisting of **BOTH** **(i)** 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** **(ii)** One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following--

Commission, or equivalent [~~another~~] agreement state license or permit issued by a Commission master material licensee that authorizes similar **type[**~~type(s)~~**]** of **use[**~~use(s)~~**]** 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** **(3)(a)** 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 equivalent agreement state under 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 (4) and (5) of this section; **OR** **(3)(b)** 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,		**(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 byproduct material; **(D)** Using administrative controls to avoid mistakes in the administration of byproduct material; **(E)** Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; **(F)** Using emergency procedures to control byproduct material; and **(G)** Disposing of byproduct material; **OR** **(b)(2)** [Reserved] **(c)(1)** Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; **OR** **(c)(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 byproduct material for which the individual has Radiation Safety Officer responsibilities; **AND,** **(d)** Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs

AND **(4)** Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (5) and in (1)(a)1 and 2 or (1)(b)1 and 2 or (2)(a) or (3)(a) 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** **(5)** 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[**~~type(s)~~**]** of use for which the licensee is seeking approval. [~~(b) Has obtained written certification, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in subsection (2)(a) 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 or~~ (~~c) 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.~~]		(a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) 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** **(e)** 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(s) of use for which the licensee is seeking approval.
Section 65. Training for an Authorized Medical Physicist. Except as provided in Section 67 [~~68~~] of this administrative regulation the licensee shall require the authorized medical physicist to be an individual who: **(1)** Is certified by a specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state and who meets the [~~includes all of the training and experience~~] requirements in subsection (2)(b) and (3) of		**§ 35.51 Training for an authorized medical physicist.** Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who— **(a)** Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's

this section [~~and whose certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or another agreement state~~]. To have its certification process recognized, a specialty board shall require all candidates for certification to: **(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 a two (2) years of full-time practical training**, two (2) years of supervised experience in medical physics, or two (2) years of a combination of full-time practical training and[**~~and/or~~**]** supervised experience in medical physics: **1.** 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 equivalent agreement state; **OR** **2.** 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 of authorized users in Section 67, 74, or 77 of this administrative regulation, **AND** **(c)** 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** **(2)(a)** Holds a master's or doctor's degree in physics, [~~biophysics, radiological physics,~~] medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;[~~or health physics~~] and has completed one (1) year of full-		Web page.) 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 2 years of full-time practical training and/or 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 Commission or an Agreement State; **OR** **(ii)** In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; **AND** **(3)** Pass an examination, administered by diplomates 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)(1)** 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 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(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons

time training in medical physics [~~therapeutic radiological 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[**~~type(s)~~**]** 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)(b)** Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3), and (1)(a) and (b), or subsection (2)(a) and (3) 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, U.S. Nuclear Regulatory Commission, or equivalent 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[**~~type(s)~~**]** of use for which authorization is		and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include: **(i)** Performing sealed source leak tests and inventories; **(ii)** Performing decay corrections; **(iii)** Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and **(iv)** Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; **AND** **(b)(2)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) 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 must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent 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** **(c)** Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may 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(s) of use for which the individual is seeking authorization.

sought that includes hands-on device operation, safety operations, clinical use, and the operation of a treatment planning system. This training requirement **shall[**~~may~~**]** 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[**~~type(s)~~**]** of use for which the individual is seeking authorization. [~~at a medical institution that includes the tasks listed in Sections 24, 43, 52, 53, 54, 55, 56, 57 and 59 of this administrative regulation as applicable; and~~ ~~(3) Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (2)(a) 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 certification shall be signed by a preceptor authorized medical physicist who meets the requirements of this section or equivalent 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.~~]		
Section 66. Training for an Authorized Nuclear Pharmacist. Except as provided in Section 67 [~~68~~] of this administrative regulation the licensee shall require the authorized nuclear pharmacist to be a pharmacist who: **(1)** Is certified [~~as a nuclear pharmacist~~] by a specialty board whose certification process [~~includes all of the requirements in subsection (2) of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~another~~] 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:		**§ 35.55 Training for an authorized nuclear pharmacist.** Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who-- **(a)** Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)** Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or

(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[**~~4000~~**]** hours of training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than **2,000[**~~2000~~**]** 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 [~~Didactic~~] 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		have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination; **(2)** Hold a current, active license to practice pharmacy; **(3)** Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and **(4)** Pass an examination in nuclear pharmacy administered by diplomates 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** **(b)(1)** Has completed 700 hours in a structured educational program consisting of **BOTH**: **(i)** 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 byproduct material for medical use; and **(E)** Radiation biology; **AND** **(ii)** 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

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** **(2)(b)** [~~(c)~~] Has obtained written attestation [~~certification~~], 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) [~~subsection (2)(a)~~] of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.		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 byproduct material; and **(E)** Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; **AND** **(b)(2)** Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.
Section 67. [~~68.~~] Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, [~~and~~] 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 equivalent [~~another~~] agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~another~~] agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, ~~2005~~ 2002 shall not be required to comply with the training		**§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.** **(a)(1)** An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. **(a)(2)** An individual identified as a Radiation Safety Officer, an

requirements of Section 64, 65, or 66, [~~or 67~~] 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 equivalent agreement state license or a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or 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[**~~need not~~**]** 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 equivalent [~~another~~] agreement state, a permit issued by a Commission master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~another~~] agreement state broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002 [~~2005~~] 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 [~~69~~] 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 equivalent agreement state, a permit issued by a master material licensee, a permit issued by the cabinet, U.S. Nuclear Regulatory Commission or agreement state broad scope licensee or a permit issued by a U.S. Nuclear Regulatory 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.		authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. **(a)(3)** A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter. **(b)(1)** Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or 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 need not comply with the training requirements of Subparts D through H of this part. **(b)(2)** Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a

(3) Individuals who is not required to comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agreement State licenses for the same uses for which these individuals are authorized.		Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part. **(b)(3)** Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter. **(c)** Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.
Section 68. Training for Uptake, Dilution, and Excretion Studies. Except as provided in Section 67 [~~68~~] of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Section 30 of this administrative regulation to be a physician who: **(1)(a)** Is certified by a medical specialty board whose certification process ~~includes all of the requirements in subsection (3)(b) of this section and who~~ [~~whose certification~~] ~~has been recognized by the cabinet,~~ has been recognized by the cabinet, U.S. Nuclear Regulatory		**§ 35.190 Training for uptake, dilution, and excretion studies.** Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who— **(a)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted

Commission, or equivalent [~~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: **1.** 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 **and[**~~through~~**]** 2.f. of this section; **AND** **2.** Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; **OR** **(2)** Is an authorized user under Section 69 or 70 [~~or 71~~], of this administrative regulation or U.S. Nuclear Regulatory Commission or equivalent 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,		on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)** Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; **AND** **(2)** Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; **OR** **(b)** Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; **OR (c)(1)*** **(c)(1)** Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include— **(i)** 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 byproduct material for medical use; and **(E)** Radiation biology; **AND** **(ii)** Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving—

[~~or 71~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements, involving: **a.** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; **b.** Performing quality control procedures on [~~Calibrating~~] 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** **(3)(b)** Has obtained written attestation [~~certification~~], signed by a preceptor authorized user who meets the requirements in Section 67, 68, 69, or 70 [~~, or 71~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a)1. 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 under Section 30 of this administrative regulation.		**(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 byproduct material; **(E)** Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and **(F)** Administering dosages of radioactive drugs to patients or human research subjects; **AND** **(c)(2)** Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.
Section 69. Training for Imaging and Localization Studies. Except as		**§ 35.290 Training for imaging and localization studies.**

provided in Section 67 [~~68~~] of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Section 31 of this administrative regulation to be a physician who: **(1)** Is certified by a medical specialty board whose certification process [~~includes all of the requirements in subsection (3)(b) of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~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 basi~~s~~c 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 2.g 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; **OR** **(2)** Is an authorized user under Section 70 [~~71~~] of this administrative regulation and meets the requirements in subsection (3)(a)2.g of this section, U.S. Nuclear Regulatory Commission, or equivalent 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;		Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who— **(a)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)** Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; **AND** **(2)** Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; **OR** **(b)** Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; **OR** **(c)(1)** Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum— **(i)** 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, [~~or Section 71~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements, involving: **a.** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; **b.** Performing quality control procedures on [~~Calibrating~~] 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;		**(C)** Mathematics pertaining to the use and measurement of radioactivity; **(D)** Chemistry of byproduct material for medical use; **(E)** Radiation biology; **AND** **(ii)** Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent 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 byproduct 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** **(c)(2)** Has obtained written attestation, signed by a preceptor

AND **(3)(b)** Has obtained written attestation [~~certification~~], signed by a preceptor authorized user who meets the requirements in Sections 67, 69, or 70 ~~or~~ and Section 69(3)(a)2.g [~~71~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under Sections 30 and 31 of this administrative regulation		authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.
Section 70.[~~71.~~] Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required. Except as provided in Section 67 [~~68~~] of this administrative regulation the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Section 33 of this administrative regulation to be a physician who: **(1)** Is certified by a medical specialty board whose certification process [~~includes all of the requirements in subsection (2)(a)2.g. and (2)(b) [(3)] of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or equivalent [~~another~~] agreement state, and who meets the requirements in subsection (2)(a)2.f and (2)(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: [~~; or~~] **1.** Residency Review Committee of the Accreditation Council for Graduate Medical Education;		**§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.** Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who— **(a)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to: **(1)** 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 must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on

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 of Sections 67 and or 70 of this administrative regulation, or [subsections (1) and (2) of this section,] U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in Section 70[71](2) of this administrative regulation, shall have experience in administering dosages in the same dosage category or categories (**[**i.e.,**]**Section 70[71](2)(a)2.f[g(i), (ii),		Post-Graduate Training of the American Osteopathic Association; **AND** **(2)** Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; **OR** **(b)(1)** 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 byproduct material requiring a written directive. The training and experience must include— **(i)** 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 byproduct material for medical use; and **(E)** Radiation biology; **AND** **(ii)** Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve— **(A)** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

~~(iii), or (iv~~)]) 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 [~~Calibrating~~] 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.** [~~Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and~~ ~~g.~~] 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;		**(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 byproduct material; **(E)** Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; **(F)** [Reserved] **(G)** Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status— ***(1)*** 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; ***(2)*** Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[2]; ***(3)*** 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; AND/OR ***(4)*** Parenteral administration of any other radionuclide, for which a written directive is required;

(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[**~~and/or~~**]** **(iv)** Parenteral administration of any other radionuclide, for which a written directive is required; **AND** **(2)(b)** Has obtained written attestation [~~certification~~] that the individual has satisfactorily completed the requirements in subsection (1)[~~(2)~~](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 under Section 33 of this administrative regulation. The written attestation [~~certification~~] shall be signed by a preceptor authorized user who meets the requirements [~~of subsections (1) and (2)~~] of this section, ~~and~~ or section 67 of this administrative regulation or U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. The preceptor authorized user, who meets the requirements in [~~of~~] subsection (2) of this section, shall have experience in administering dosages in the same dosage category or categories (**[**~~i.e.,~~**]**Section 70[~~71~~](2)(a)2.f[~~g(i), (ii), (iii), or (iv)~~]) of this administrative regulation as the individual requesting authorized user status.		**AND** **(b)(2)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. [2] Experience with at least 3 cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*)
Section 71.[~~72.~~] 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[~~68~~] 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		**§ 35.392 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 § 35.57, 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— **(a)** Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and

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 equivalent [another] agreement state and who meets the requirements in subsection (3)(c) of this section; **OR (missing)** **(2)** Is an authorized user under Section 70 [71(1), 71(2)] of this administrative regulation for uses listed in Section 70[71](2)(a)2.f[g](i) [or (ii)]or (ii), or Section 72 of this administrative regulation, [or] U.S. Nuclear Regulatory Commission, or equivalent 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** **(3)(b)** Has work experience, under the supervision of an authorized user who meets the requirements in Section 67, 70, 71,[(1), 71(2)], or 72[, 73] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in Section 70 [71](2)(a) of this administrative regulation shall have experience in administering dosages as specified in Section 70[71](2)(a)2.f.[g.](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;		(c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); **OR** **(b)** Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; **OR** **(c)(1)** Has successfully completed 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 must include— **(i)** Radiation physics and instrumentation; **(ii)** Radiation protection; **(iii)** Mathematics pertaining to the use and measurement of radioactivity; **(iv)** Chemistry of byproduct material for medical use; and **(v)** Radiation biology; **AND** **(c)(2)** Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve— **(i)** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; **(ii)** Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

2. Performing quality control procedures on [~~Calibrating~~] 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** **(3)(c)** Has obtained written attestation [~~certification~~] that the individual has satisfactorily completed the requirements in subsection (3)[~~paragraphs~~](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 under Section 33 of this administrative regulation. The written attestation [~~certification~~] shall be signed by a preceptor authorized user who meets the requirements in Section 67, 70, 71 [~~(1), 71(2)~~], or 72[~~, 73~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A preceptor authorized user, who meets the requirement in Section 70[~~71~~](2) of this administrative regulation shall also have experience in administering dosages as specified in Section 70(2)(a)2.f.[~~g.~~](i) or (ii) of this administrative regulation.		**(iii)** Calculating, measuring, and safely preparing patient or human research subject dosages; **(iv)** Using administrative controls to prevent a medical event involving the use of byproduct material; **(v)** Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and **(vi)** Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; **AND** **(c)(3)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(*2*).

Section 72.[~~73.~~] 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 [~~68~~] 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 equivalent [~~another~~] agreement state and who meets the requirements in subsection of (3)(c) of this section; **OR** **(2)** Is an authorized user under Section 70 [~~71(1), 71(2)~~] of this administrative regulation for uses listed in Section 70(2)(a)2.f.[~~g.~~](ii) of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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; **AND (missing)** **(3)(b)** Has work experience, under the supervision of an authorized user who meets the requirements in Section 67, 70 ~~and~~ or 72 [~~71(1),~~		**§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).** Except as provided in 35.57, 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— **(a)** Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); **OR** **(b)** Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; **OR** **(c)(1)** Has successfully completed 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 must include— **(i)** Radiation physics and instrumentation; **(ii)** Radiation protection; **(iii)** Mathematics pertaining to the use and measurement of radioactivity; **(iv)** Chemistry of byproduct material for medical use; and **(v)** Radiation biology; **AND** **(c)(2)** Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have

~~71(2), 73~~] of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in Section 70[~~71~~](2) of this administrative regulation, shall also have experience in administering dosages as specified in Section 70[~~71~~](2)(a)2.f.(ii) [~~g.(i)~~] 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 [~~Calibrating~~] 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 [~~certification~~] that the individual has satisfactorily completed the requirements in subsection (3)[~~paragraphs~~](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 under Section 33 of this administrative regulation. The written attestation [~~certification~~] shall be signed by a preceptor authorized user who meets the requirements in Section 67, 70 or 72 [~~71(1), 71(2), 72, 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[~~71~~](2) of this		experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve— **(i)** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; **(ii)** Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; **(iii)** Calculating, measuring, and safely preparing patient or human research subject dosages; **(iv)** Using administrative controls to prevent a medical event involving the use of byproduct material; (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and **(vi)** Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; **AND** **(c)(3)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*).

administrative regulation, shall have experience in administering dosages as specified in [~~902 KAR 100:072,~~] Section 70(2)(a)2.f.[~~g.~~](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 under Section 70 for uses listed in Section 70(2)(a)2.f.(iii) or Section 70(2)(a)2.f.(iv) ~~or~~ of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state regulations; **[~~or~~] (deleted)** **(2)** Is an authorized user under Sections 74 or 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state and who meets the requirements in subsection (4) of this section; **[~~or~~] (deleted)** **(3)** Is certified by a medical specialty board whose certification process has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent agreement state under Sections 74 or 77 of this administrative regulation; and who meets the requirements in subsection (4) of this section**;** **OR[:] (does not belong)** **(4)(a)** Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less that 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training shall include: **1.** Radiation physics and instrumentation; 2 Radiation protection; **3.** Mathematics pertaining to the use and measurement of		**§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.** Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who-- **(a)** Is an authorized user under § 35.390 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; **OR** **(b)** Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; **OR** **(c)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section. **(d)(1)** Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include-- **(i)** Radiation physics and instrumentation; **(ii)** Radiation protection; **(iii)** Mathematics pertaining to the use and measurement of radioactivity; **(iv)** Chemistry of byproduct material for medical use; and **(v)** Radiation biology;

radioactivity; **4.** Chemistry of radioactive material for medical use; and **5.** Radiation biology; **AND** **(4)(b)** Has work experience, under the supervision of an authorized user who meets the requirements in Sections 67, 70, ~~and~~ or 73 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Section 70 shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) and/or Section 70(2)(a)2.f.(iv). 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 of survey meters; **3.** Calculating, measuring, and safely preparing patient or human research subjects dosages; **4.** Using administrative controls to prevent a medical event involving the use of unsealed 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 include at least three (3) cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three (3) cases involving the parenteral administration of any other radionuclide, for which a written directive is required; **AND**		**AND** **(d)(2)** Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve— **(i)** Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys; **(ii)** Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; **(iii)** Calculating, measuring, and safely preparing patient or human research subject dosages; **(iv)** Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; **(v)** Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and **(vi)** Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; **AND** **(d)(3)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to

(4)(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (2) or (3) of this section, 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. A preceptor authorized user, who meets the requirements in Section 70, shall have experience in administering dosages as specified in Section 70(2)(a)2.f.(iii) and/or Section 70(2)(a)2.f.(iv) of this administrative regulation.		function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(*4*).
Section 74. [~~75.~~] Training for Use of Manual Brachytherapy Sources. Except as provided in Section 67 [~~68~~] of this administrative regulation, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Section 37 of this administrative regulation to be a physician who: **(1)** Is certified by a medical specialty board whose certification process [~~includes all of the requirements in subsection (2)(c) of this section and whose certification~~] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [~~another~~] 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**		**§ 35.490 Training for use of manual brachytherapy sources.** TOP Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who— **(a)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)** Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education **OR** the Royal College of Physicians and Surgeons of Canada **OR** the Committee on Post-Graduate Training of the American Osteopathic

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 Sections 67 ~~and~~ or74 of this administrative regulation, [~~of this section~~] U.S. Nuclear Regulatory Commission, or equivalent 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; [~~and~~]		Association; **AND** **(2)** Pass an examination, administered by diplomates 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** **(b)(1)** Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes— **(i)** 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** **(ii)** 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent 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 byproduct material; **(F)** Using emergency procedures to control byproduct material;

f. Using emergency procedures to control radioactive material; **AND** **(2)(b)** Has completed [~~obtained~~] three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in sections 67 ~~and~~ or 74 of this administrative regulation [~~of this section~~], U.S. Nuclear Regulatory Commission, or equivalent 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** **(2)(c)** Has obtained written attestation [~~certification~~], signed by a preceptor authorized user who meets the requirements of ~~this section and~~ Sections 67 ~~and~~ or 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent 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 under Section 37 of this administrative regulation.		**AND** **(b)(2)** Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent 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 paragraph (b)(1)(ii) of this section; **AND** **(b)(3)** Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), 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 under § 35.400.
Section 75. Training for Ophthalmic Use of Strontium-90. Except as provided in Section 67 [~~68~~] 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 under Section 74 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;		**§ 35.491 Training for ophthalmic use of strontium-90.** Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who— **(a)** Is an authorized user under § 35.490 or equivalent Agreement State requirements; **OR**

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 [~~certification~~], signed by a preceptor authorized user who meets the requirements in Sections 67, 74, ~~and~~ or 75 of this administrative regulation, U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in subsection[~~subsections (1) and~~] (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.		**(b)(1)** Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include— **(i)** Radiation physics and instrumentation; **(ii)** Radiation protection; **(iii)** Mathematics pertaining to the use and measurement of radioactivity; and **(iv)** Radiation biology; **AND** **(b)(2)** 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 individuals. This supervised clinical training must involve— **(i)** Examination of each individual to be treated; **(ii)** Calculation of the dose to be administered; **(iii)** Administration of the dose; and **(iv)** Follow up and review of each individual's case history; **AND** **(b)(3)** Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) 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 [~~68~~] of this administrative regulation, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Section		**§ 35.590 Training for use of sealed sources for diagnosis.** Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist

45 of this administrative regulation to be a physician, dentist, or podiatrist who: **(1)** Is certified by a specialty board whose certification process includes all of the requirements in subsection (2) and (3) of this section and whose certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [another] agreement state; **OR** **(2)** Has completed [had] 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: **(a)** Radiation physics and instrumentation; **(b)** Radiation protection; **(c)** Mathematics pertaining to the use and measurement of radioactivity; and **(d)** Radiation biology; **AND** **(3)** Has completed [(c)] training in the use of the device for the uses requested.		who-- **(a)** Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); **OR** **(b)** Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include— **(1)** Radiation physics and instrumentation; **(2)** Radiation protection; **(3)** Mathematics pertaining to the use and measurement of radioactivity; and **(4)** Radiation biology; **AND** **(c)** 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. Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in Section 67 [68] of this administrative regulation, the licensee shall require an authorized user of a sealed source for a use authorized under Section 46 of this administrative regulation to be a physician who: **(1)** Is certified by a medical specialty board whose certification process [includes all of the requirements in subsection (2) of this section and whose certification] has been recognized by the cabinet, U.S. Nuclear Regulatory Commission, or equivalent [another] agreement state and who meets the requirements in (2)(c) and (3) of this section. To have its certification recognized, a specialty board		**§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.** Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who— **(a)** Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: **(1)** Successfully complete a minimum of 3 years of residency

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 Sections 67 ~~and~~ or 77 of this administrative regulation [~~of this section~~], U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements at a medical institution, involving: **a.** Reviewing full calibration measurements and periodic spot-checks; **b.** Preparing treatment plans and calculating		training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; **AND** **(2)** Pass an examination, administered by diplomates 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** **(b)(1)** 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— **(i)** 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** **(ii)** 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent 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

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** **(2)(b)** Has completed three (3) years of supervised clinical experience in radiation therapy [~~oncology~~], under an authorized user who meets the requirements in Sections 67 ~~and~~ or 77 of this administrative regulation, U.S. Nuclear Regulatory Commission, [~~of this~~] or equivalent 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** **(2)(c)** Has obtained written attestation [~~certification~~] that the individual has satisfactorily completed the requirements in subsection (1)(a) or (2)(a) and (b), and (3) [~~(2)(a) and (b)~~] 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 [~~certification~~] shall be signed by a preceptor authorized user who meets the requirements in Sections 67 ~~and~~ or 77 of this administrative regulation [~~of this section~~], U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements for an authorized user for each type of therapeutic		event involving the use of byproduct 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)(2)** Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent 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 paragraph (b)(1)(ii) of this section; **AND** **(b)(3)** Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), 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 must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; **AND** **(c)** Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory

medical unit for which the individual is requesting authorized user status; **AND** **(3)[~~3.~~]** Has received training in device operation, safety procedures, and clinical use for the **type[~~type(s)~~]** 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[~~type(s)~~]** of use for which the individual is seeking authorization.		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(s) of use for which the individual is seeking authorization.

902 KAR 100:165. Notices, reports, and instructions to employees.
http://www.lrc.ky.gov/kar/902/100/165.htm

RELATES TO: KRS 211.842 - 211.852, 211.990(4), 10 C.F.R. 19.11 to 19.17, 30.7, 30.10

STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health and Family Services to provide by administrative regulation 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 notices, instructions, and reports for the protection of workers who may be exposed to radiation in their employment.

Section 1. Posting of Notices to Workers.
(1) A licensee or registrant shall post current copies of the following documents:
- (a) This administrative regulation and 902 KAR 100:019, relating to standards for protection against radiation;
- (b) The license, certificate of registration, conditions or documents incorporated into the license by reference, and amendments to the license;
- (c) The operating procedures for work under the license or registration; and
- (d) A notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued as authorized by 902 KAR 100:170, and responses from the licensee or registrant.

(2) If posting of a document specified in subsection (1)(a), (b), or (c) of this section is not practical, the licensee or registrant shall post a notice that describes the document and states where it may be examined.
(3) Cabinet form KR-441, Notice to Employees, shall be prominently posted by a licensee or registrant.
(4) Documents, notices, or forms posted as required by this section shall:
- (a) Appear in a sufficient number of places to permit an individual engaged in work under the license or registration to observe them on the way to or from a particular work location to which the document applies;
- (b) Be conspicuous; and
- (c) Be replaced if defaced or altered.

(5)(a) Cabinet documents posted as required by subsection (1)(d) of this section shall be posted within two (2) working days after receipt of the documents from the cabinet;
- (b) The licensee's or registrant's response shall be posted within two (2) working days after dispatch from the licensee or registrant; and
- (c) The documents shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

Section 2. Instructions to Workers.
(1) An individual likely to receive in a year, during the course of employment, an occupational dose in excess of 100 millirems (one (1) mSV) shall be:

(a) Kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;
(b) Informed of health protection problems, to the individual and potential offspring, associated with exposure to radioactive material or radiation, and instructed in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed;
(c) Instructed in, and instructed to observe, to the extent within the worker's control, the applicable requirements of 902 KAR Chapter 100 and licenses issued thereunder for the protection of personnel from exposures to radiation or radioactive material;
(d) Instructed of their responsibility to report promptly to the licensee or registrant a condition that may lead to or cause a violation of the Act, 902 KAR Chapter 100 or license conditions, or unnecessary exposure to radiation or radioactive material;
(e) Instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
(f) Informed of the radiation exposure reports that workers may request as authorized by Section 3 of this administrative regulation.

(2) In determining the individuals subject to the requirements of this section, a licensee or registrant shall take into consideration assigned activities during normal and abnormal situations involving exposure to radioactive material or radiation that can reasonably be expected to occur during the life of a licensed or registered facility. The extent of the instructions shall be commensurate with potential radiological health protection problems in the workplace.

Section 3. Notifications and Reports to Individuals.

(1) Radiation exposure data for an individual and the results of measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual.

(2) The information reported shall include data and results obtained as required by 902 KAR Chapter 100, orders, or license conditions as shown in records maintained by the licensee or registrant as required by 902 KAR 100:019, Section 34.

(3) Each notification and report shall:
(a) Be in writing;
(b) Include the following identifying data:
1. The name of the licensee or registrant;
2. The name of the individual; and
3. The individual's identification or Social Security number.
(c) Include the individual's exposure information; and
(d) Contain the following statement: "This report is furnished to you under the provisions of the Kentucky Cabinet for Health and Family Services' radiation administrative regulations, 902 KAR 100:165. Preserve this report for further reference."

(4) A licensee or registrant shall advise the worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant required by 902 KAR 100:019, Section 34.
(5) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, a licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. The report shall:
(a) Be furnished within thirty (30) days from the time request is made, or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;
(b) Cover the period of time the worker's activities involved exposure to radiation from radioactive materials licensed by, or radiation machines registered with, the cabinet; and
(c) Include the dates and locations of work under the license or registration in which the worker participated during this period.
(6) If a licensee or registrant is required, pursuant to 902 KAR 100:019, Sections 40, 41, and 42, to report to the cabinet an exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included in the report to the cabinet. The reports shall be transmitted to the individual at a time not later than the transmittal to the cabinet.
(7)(a) At the request of a worker who is terminating employment in work involving exposure to radiation or radioactive material during the current year, the licensee or registrant shall provide to the worker, or to the worker's designee, at termination a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof.
(b) If the most recent individual personnel monitoring results are not available at the time of termination, a written estimate of the dose shall be provided.
(c) Estimated doses shall be clearly indicated as estimated doses.

Section 4. Presence of Representatives of Licensees or Registrants and Workers during Inspection.
(1) A licensee or registrant shall afford to the cabinet at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records required by 902 KAR Chapter 100.
(2) During an inspection, cabinet inspectors may consult privately with workers as specified in Section 5 of this administrative regulation. The licensee or registrant may accompany cabinet inspectors during other phases of an inspection.
(3) If, during the inspection, an individual has been authorized by the workers to represent them during cabinet inspections, the licensee or registrant shall notify the inspectors of the authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
(4) The workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in Section 2 of this administrative regulation.
(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting

interference with the conduct of an inspection. However, only one (1) workers' representative at a time may accompany the inspectors.
(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany cabinet inspectors during
the inspection of physical working conditions.
(7) A cabinet inspector shall refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection.
(8) Unless specifically authorized, an individual accompanying an inspector shall not have access to an area containing information classified by an agency of the U.S. government as a national security interest.
(9) Unless previously authorized by the licensee or registrant, a worker's representative shall not have access to an area containing proprietary information.

Section 5. Consultation with Workers during Inspection.
(1) If necessary to conduct an effective and thorough inspection, a cabinet inspector may consult privately with a worker concerning a matter of occupational radiation protection or other matter related to 902 KAR Chapter 100, licenses, or registrations.
(2) During the course of an inspection, a worker may bring to the attention of the inspectors, either orally or in writing, a past or present condition that he has reason to believe may have contributed to or caused a violation of the Act, 902 KAR Chapter 100, or license condition, or an unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. A written notice shall comply with the requirements of Section 6(1) of this administrative regulation.
(3) The requirements of subsection (2) of this section shall not be interpreted as authorization to disregard instructions required by Section 2 of this administrative regulation.

Section 6. Requests by Workers for Inspections. (1)(a) A worker or representative of workers who believes that a violation of the Act, 902 KAR Chapter 100, or a license condition exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Cabinet for Health and Family Services, Radiation Health Branch.

(b) The notice shall:

1. Be in writing;
2. Set forth the specific grounds for the notice; and
3. Be signed by the worker or representative of the workers.

(c) A copy shall be provided to the licensee or registrant by the cabinet no later than at the time of inspection. If the worker giving the notice requests, his name and the name of individuals referred to in the notice shall not appear in the copy or on a record published, released, or made available by the cabinet, except for good cause shown.

(2) In accordance with 49 C.F.R. 19.16, if, upon receipt of the notice, the Manager, Radiation Health Branch, determines that the complaint meets the requirements established in subsection (1) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the manager of the Radiation and Health Branch shall cause an inspection to be made as soon as practicable, to determine if the alleged violation exists or has occurred. An inspection authorized by this section may not be limited to matters referred to in the complaint.
(3) A licensee, registrant, contractor, or subcontractor of a licensee or registrant, shall not discharge or discriminate against a worker because the worker has:

(a) Filed a complaint;
(b) Instituted or caused to be instituted a proceeding under 902 KAR 100:170;
(c) Testified or is about to testify in a proceeding; or
(d) Exercised an option on behalf of himself or others afforded by this administrative regulation.

Section 7. Inspections not Warranted; Informal Review.
(1)(a) If the Cabinet for Health and Family Services, Radiation Health Branch determines, with respect to a complaint under Section 6 of this administrative regulation, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the cabinet shall notify the complainant in writing of the determination.
(b) The complainant may obtain a review of the determination by submitting a written statement of position with the Commissioner, Department for Public Health. The commissioner shall provide the licensee or registrant with a copy of the statement by certified mail excluding, at the request of the complainant, the name of the complainant.
(c) The licensee or registrant may submit an opposing written statement of position with the commissioner, who shall provide the complainant with a copy of the statement by certified mail.
(2) Upon the request of the complainant, the commissioner shall hold an administrative hearing in accordance with 902 KAR 1:400.
(3) If the Radiation Health Branch determines that an inspection is not warranted because the requirements of Section 6(1) of this administrative regulation have not been met, the complainant shall be notified, in writing, of the determination. The determination shall be without prejudice to the filing of a new complaint meeting the requirements of Section 6(1) of this administrative regulation.

Section 8. Employee Protection.
(1) Discrimination by a cabinet licensee, an applicant for a cabinet license, a registrant or a contractor or subcontractor of a cabinet licensee, registrant or applicant against an employee for engaging in protected activities shall be prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment.

(a) The protected activities include in part:
1. Providing the cabinet or his or her employer information about alleged violations or possible violations of requirements of 902 KAR Chapter 100;

2. Refusing to engage in a practice made unlawful under these requirements, if the employee has identified the alleged illegality to the employer;
3. Requesting the cabinet to institute action against his or her employer for enforcement of these requirements;
4. Testifying in a cabinet proceeding, before Congress, or at a federal or state proceeding regarding a provision, or proposed provision, of 902 KAR Chapter 100; and
5. Assisting or participating in, or is about to assist or participate in, a protected activity.

(b) A protected activity shall retain its protected status even if no formal proceeding is initiated as a result of the employee assistance or participation.

(c) This section shall not be applied to an employee alleging discrimination who, acting without direction from his or her employer or the employer's agent, deliberately causes a violation of the Act or the administrative regulations promulgated under the Act.

(2) An employee who believes that he or she has been discharged or discriminated against for engaging in a protected activity may seek a remedy through an administrative proceeding in the Department of Labor.

(a) The aggrieved employee shall file a complaint within 180 days after the occurrence of the alleged violation with the Kentucky Department of Labor, Employment Standards Administration, Wage and Hour Division.

(b) If warranted by the evidence presented, the Kentucky Department of Labor may order reinstatement, back pay, and compensatory damages as appropriate to the case.

(3) A violation of subsections (1) or (5) of this section or Section 1(3) of this administrative regulation by a cabinet licensee, an applicant for a cabinet license, or a contractor or subcontractor of a cabinet licensee or applicant shall constitute grounds for:

(a) Denial, revocation, or suspension of the license;

(b) Imposition of a penalty; or

(c) Other enforcement action.

(4)(a) An action taken by an employer or others that adversely affects an employee shall be predicated upon nondiscriminatory grounds.

(b) The prohibition applies if the adverse action occurs because the employee has engaged in a protected activity.

(c) An employee's engagement in a protected activity does not automatically render him or her immune from discharge or discipline for legitimate reasons, or from adverse action dictated by nonprohibited considerations.

(5) An agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor, shall not contain a provision that has the potential to prohibit, restrict, or discourage an employee from participating in protected activity, including providing information to the cabinet or to his or her employer on alleged violations or other matters within cabinet's regulatory responsibilities.

Section 9. Deliberate Misconduct.

(1) This section applies to:
(a) Licensee;
(b) Registrant;
(c) Certificate of registration holder;
(d) Applicant for a license, or certificate of registration;
(e) Employee of any person identified in this section; or
(f) Contractor, including a supplier, consultant, or subcontractor to any person identified in this section.

(2) Any person identified in subsection 1 of this section shall not:
(a) Engage in deliberate misconduct that causes or may have caused, if not detected, a licensee, registrant, certificate of registration holder, or applicant to be in violation of a rule, administrative regulation, order; term, condition, or limitation of a license issued by the cabinet; or
(b) Deliberately submit to the cabinet, a licensee, registrant, certificate of registration holder, an applicant, or a licensee's, certificate holder's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the cabinet.

(3) A person who violates subsection (2) of this section shall be subject to enforcement action in accordance with the procedures in 902 KAR 100:170.

(4) For the purposes of subsection (2)(a) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:
(a) May cause a licensee, registrant, certificate holder, or applicant for a license, registration, or certificate to be in violation of the rule, regulation, order or a term, condition, or limitation of a license, registration, or certificate issued by the cabinet; or
(b) Constitutes a violation or a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, certificate holder, applicant, or the contractor or subcontractor of any of them.

Section 10. Incorporation by Reference.

(1) Form KR-441, "Notice to Employees", edition 2/2011 is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m. (1 Ky.R. 420; eff. 2-5-75; Am. 3 Ky.R. 170; eff. 9-1-76; 12 Ky.R. 1073; eff. 1-3-86; 18 Ky.R. 1578; eff. 1-10-92; 24 Ky.R. 771; eff. 11-14-97; 26 Ky.R. 2418; 27 Ky.R. 991; eff. 10-16-2000; 37 Ky.R. 1863; 2651; eff. 6-3-11.)