#### State of Kansas

# Department of Health and Environment

### Notice of Hearing on Proposed

## **Administrative Regulations**

The Kansas Department of Health and Environment, Division of Public Health, Bureau of Community Health Systems, will conduct a public hearing at 10:00 a.m. Thursday, November 2, 2017, in the Azure Conference Room, fourth floor, Curtis State Office Building, 1000 SW Jackson, Topeka, to consider the adoption of proposed amended regulations K.A.R. 28-35-135a, 28-35-135c, 28-35-135i, 28-35-135s, 28-35-135u, 28-35-140, 28-35-177a, 28-35-178i, 28-35-179a, 28-35-180a, 28-35-180b, 28-35-181h, 28-35-181i, 28-35-181k, 28-35-181m, 28-35-181o, 28-35-184a, 28-35-192a, 28-35-192c, 28-35-192g, 28-35-205b, 28-35-217b, 28-35-221a, 28-35-221b, 28-35-264, 28-35-288, 28-35-343, 28-35-344, 28-35-347, 28-35-362, and 28-35-504; the adoption of proposed new regulations K.A.R. 28-35-181t, 28-35-192h, 28-35-197b, and 28-35-700; and the proposed revocation of K.A.R. 28-35-197a and 28-35-230d, all regarding radiation control.

A summary of the proposed regulations and the estimated economic impact follows: Summary of Regulations:

K.A.R. 28-35-135a. Definitions. Amended to meet Nuclear Regulatory Commission (NRC) compatibility requirements by removing the definition of "becquerel" and "curie," defined in 28-35-135b and 28-35-135c respectively, under the term "activity."

K.A.R. 28-35-135c. Definitions. Adds the definition of "consortium" for compatibility with NRC regulations.

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**K.A.R. 28-35-135i. Definitions.** Adds the definitions of "Indian tribe" and "Indian tribal official" for compatibility with NRC regulations.

**K.A.R. 28-35-135s. Definitions.** Clarifies the definition of "survey" for compatibility with NRC regulations.

K.A.R. 28-35-135u. Definitions. Adds a description of "processing" to the definition of "unrefined or unprocessed ore" for compatibility with NRC regulations.

**K.A.R. 28-35-140. Exemptions.** Specifies exemptions for carriers for compatibility with NRC regulations.

K.A.R. 28-35-177a. General licenses; source material. Adopts the wording of the federal requirements for a general license for uranium and thorium in certain forms and quantities for compatibility with NRC regulations.

K.A.R. 28-35-178i. General licenses for certain units of radium-226. Adds descriptions of types of products that are issued a general license for certain units of radium-226 and clarifies language related to reports of damage, abandonment, disposal, export, and fee waiver for compatibility with NRC regulations.

K.A.R. 28-35-179a. Application for specific license; renewal or amendment. Adds essential information required for the license of a sealed source or device containing a sealed source for compatibility with NRC regulations.

K.A.R. 28-35-180a. General requirements for the issuance of specific licenses. Adds a description of minimization of introduction of residual radioactivity regulation for compatibility with NRC regulations.

K.A.R. 28-35-180b. Financial assurance for decommissioning, Adds descriptive

information defining the criteria of a cost estimate, periodic adjustment timeframe of no longer than three years, and descriptor of prepayment terms for compatibility with NRC regulations.

K.A.R. 28-35-181h. Specific licenses to manufacture and distribute the devices specified in K.A.R. 28-35-178b. Adds the requirement to list certain devices or sources in the sealed source and device registry for compatibility with NRC regulations.

K.A.R. 28-35-181i. Special license to manufacture, distribute, assemble, or repair luminous safety devices for use in aircraft. Adopts by reference the comparable NRC regulation for compatibility with NRC regulations.

K.A.R. 28-35-181k. Specific licenses to manufacture and distribute ice detection devices. Adopts by reference the comparable NRC regulation for compatibility with NRC regulations.

K.A.R. 28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use. Clarifies wording for designation of an authorized nuclear pharmacist, including positron emission tomography (PET) radioactive drugs for compatibility with NRC regulations.

K.A.R. 28-35-1810. Specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or reference source or for certain medical uses. Adds the requirement to list certain devices or sources in the sealed source and device registry for compatibility with NRC regulations.

K.A.R. 28-35-181t. Requirements for license to initially transfer source material for use under the small quantities of source material general license. New regulation that adds requirements for transfer of source material for compatibility with NRC regulations.

K.A.R. 28-35-184a, Specific conditions on all licenses. Adds criteria for transfer of a

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license for compatibility with NRC regulations.

K.A.R. 28-35-192a. Exemptions; source material. Clarifies exemptions, adds a two percent by weight criteria for glassware, and adopts NRC regulatory language for depleted uranium for compatibility with NRC regulations.

K.A.R. 28-35-192c. Exceptions; other radioactive material. Replaces an incorrect reference to K.A.R. 28-35-197a with K.A.R. 28-35-197b for compatibility with NRC regulations.

K.A.R. 28-35-192g. Exemptions; exempt quantities. Replaces incorrect references to K.A.R. 28-35-197a with K.A.R. 28-35-198b and adds the word "owns" for compatibility with NRC regulations.

K.A.R. 28-35-192h. Certain industrial devices. New regulation that describes exemptions for certain industrial devices for compatibility with NRC regulations.

K.A.R. 28-35-197a. Schedule B; exempt quantities of radioactive material. Revoked to allow for adoption of the NRC Schedule B in K.A.R. 28-35-197b for compatibility with NRC regulations.

K.A.R. 28-35-197b. Schedule B; exempt quantities of radioactive material. New regulation that adopts by reference Schedule B for compatibility with NRC regulations.

K.A.R. 28-35-205b. Alternate criteria for license termination. Adds a reference to financial assurance for compatibility with NRC regulations.

K.A.R. 28-35-217b. General monitoring requirements. Clarifies criteria for surveys and adds requirements for personnel dosimeters for compatibility with NRC regulations.

K.A.R. 28-35-221a. Procedures for picking up, transporting, receiving, and opening packages. Adds criteria for transporting radioactive material for compatibility with NRC

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regulations.

K.A.R. 28-35-221b. Appendix A; determination of  $A_1$ ,  $A_2$  and B quantities. Removes the table used to calculate activity limits that are used to regulate the transportation of radioactive materials and adopts by reference the NRC tables for compatibility with NRC regulations.

**K.A.R. 28-35-230d. Reports of individual monitoring.** Revoked to reflect programmatic updates to eliminate redundant and conflicting requirements for individual monitoring.

K.A.R. 28-35-264. General requirements. Corrects an adoption by reference date.

K.A.R. 28-35-288. Special requirements and exemptions for enclosed radiography.
Corrects an error in numbering.

K.A.R. 28-35-343. Storage precautions. Deletes a portion of the regulation that was duplicated in K.A.R. 28-35-344.

K.A.R. 28-35-344. Transport precautions. Updates the wording for security requirements for transport of licensed materials for compatibility with NRC regulations.

K.A.R. 28-35-347. In-person inventory. Corrects programmatic inconsistency and sets the inventory period to six months.

K.A.R. 28-35-362. Notification of incidents, abandonment, and lost sources. Removes a reference to K.A.R. 28-35-364.

K.A.R. 28-35-504. Advance notification of shipment of certain types of licensed or registered material. Adds the requirement for notification of Indian tribes of shipments that cross the tribal boundaries for compatibility with NRC regulations.

K.A.R. 28-35-700. General requirements. Adopts by reference the NRC regulations for physical protection of by-product material for compatibility with NRC regulations.

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## **Economic Impact**

Cost to the agency: The estimated increased annual cost to the agency to implement these regulations is \$2,993.00. The additional cost to the agency will be funded by fees received from licensees.

Cost to the public and regulated community: The estimated annual cost to the Kansas licensees who must implement the requirements of these regulations is \$37,763.00. There is also an additional cost of \$2,322.00 that will occur once every ten years for a licensee to perform a background reinvestigation of each of their employees who are allowed unescorted access to the sources.

Cost to other governmental agencies or units: There are two state agencies that will have increased costs similar to those of the regulated community.

The time period between the publication of this notice and the scheduled hearing constitutes a 60-day public comment period for the purpose of receiving written public comments on the proposed regulations. All interested parties may submit written comments prior to 5:00 p.m. on the day of the hearing to Kimberly Steves, Kansas Department of Health and Environment, Bureau of Community Health Systems, Radiation Control Program, 1000 SW Jackson, Suite 330, Topeka, 66612-1365, by email to Kim.Steves@ks.gov, or by fax to 785-296-0984. During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed regulations as well as an opportunity to submit their written comments. In order to give each individual an opportunity to present their views, it may be necessary for the hearing officer to request that each presenter limit an oral presentation to an appropriate time frame.

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Complete copies of the proposed regulations and the corresponding regulatory impact statement may be obtained from the Radiation Control Program website at <a href="http://www.kdheks.gov/radiation/radpubnotice.html">http://www.kdheks.gov/radiation/radpubnotice.html</a> or by contacting Kimberly Steves at the address above, 785-296-4359 or fax 785-296-0984. Questions pertaining to the proposed

regulations should be directed to Kimberly Steves at the contact information above.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations and the regulatory impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting Kimberly Steves.

Susan Mosier, MD, MBA, FACS

Secretary and State Health Officer

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- 28-35-135a. **Definitions.** As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation: (a) "A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a type A package.
- (b) "A<sub>2</sub>" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a type A package. These values either are listed in table I in K.A.R. 28-35-221b or may be derived in accordance with the procedure specified in K.A.R. 28-35-221b of these regulations.
- (c) "Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The units of absorbed dose are the rad and the gray (Gy).
- (d) "Absorbed dose rate" means the absorbed dose per unit of time or, for linear accelerators, the dose monitor unit per unit of time.
- (e) "Accelerator-produced material" means any material made radioactive by exposing it in a particle accelerator.
- (f) "Accessible surface" means the surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.
- (g) "Accident" means an unintended event, including an operating error, equipment failure, and other mishap, that could result in either of the following:
  - (1) A dose in excess of regulatory limits on site or for the public; or
- (2) consequences or potential consequences that cannot be ignored from the point of view of protection or safety, including an actual or potential substantial degradation of the level of protection or safety of the facility or the release of radioactive material in sufficient quantity to

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warrant consideration of protective actions.

- (h) "Act" means the "nuclear energy development and radiation control act," K.S.A. 48-1601 et seq., and amendments thereto.
- (i) "Activity" means the rate of disintegration, transformation, or decay of radioactive material. Activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or the multiples of either unit, or disintegrations or transformations per unit of time as follows:
- (1) One becquerel (Bq) equals one disintegration or transformation per second (dps or tps); and
- (2) one curie (Ci) equals 3.7E+10 disintegrations or transformations per second (dps or tps). One curie also equals 3.7E+10 becquerels (Bq).
  - (j) "Added filter" means the filter added to the inherent filtration.
- (k) "Address of use" means the building or buildings that are identified on the license and each location where radioactive material could be produced, prepared, received, used, or stored.
  - (1) "Adult" means an individual who is 18 or more years of age.
- (m) (1)"Agreement state" means any state with which the United States nuclear regulatory commission (NRC) enters, or has entered, into an effective agreement pursuant to 42 U.S.C.\2021, as in effect on January 4, 1995 subsection 274b of the atomic energy act of 1954, 68 Stat. 919, as amended.
  - (2) "Non-agreement state" means any other state.
  - (n) "Airborne radioactive area" means the following:

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- (1) Any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the derived air concentrations (DAC) specified in "appendices to part 4: standards for protection against radiation," effective April 1994, published by the department and hereby adopted by reference; or
- (2) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations such that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the ALI or 12 DAC-hours.
- (o) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dust, fumes, mists, vapors, or gases.
- (p) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation.

  Kerma is determined by dividing 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).
- (q) "Alert" means a period during which one of the following could lead to a release of radioactive material that is not expected to require a response by off-site response organizations to protect persons off-site:
  - (1) Conditions have arisen that could cause an event.
  - (2) An event is in progress.
  - (3) An event has occurred.

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K.A.R. 28-35-135a, page 4

- (r) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy that affords the same attenuation, under specified conditions, as that of the material in question. The nominal chemical composition of type 1100 aluminum alloy is a minimum of 99.00 percent aluminum and 0.12 percent copper.
- (s) "Amendment" means any change to a license or registration issued under these regulations.
- (t) "Analytical X-ray system" means a group of local and remote components utilizing X-rays to determine the elemental composition or to examine the microstructure of materials.
- (1) Local components shall include those components that are struck by X-rays, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding.
- (2) Remote components may include power supplies, transformers, amplifiers, readout devices, and control panels.
- (u) "Annual limit on intake (ALI)" means and "ALI" mean 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 intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are specified in appendix B, table I, published in "appendices to part 4: standards for protection against radiation," which is adopted by reference in this regulation.

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- (v) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, at a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.
  - (w) "ANSI" means the American national standards institute.
- (x) "Applicator" means a structure that determines the extent of the treatment field at a given distance from the virtual source.
- (y) "Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.
- (z) "As low as is reasonably achievable (ALARA)," and "ALARA," when used to describe exposures to radiation workers, means mean that every reasonable effort has been made to maintain exposures to radiation workers as far below the dose limits specified in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking the following into account:
  - (1) The state of technology;
  - (2) the economics of improvements in relation to the state of technology;
- (3) the economics of improvements in relation to benefits to public health and safety and to other societal and socioeconomic considerations; and
- (4) the economics of improvements in relation to the utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

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K.A.R. 28-35-135a, page 6

(aa) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term shall include the owner of an X-ray system or any employee or agent of the owner who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

(bb) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device that makes radiographic exposures and that drives, guides, or comes in contact with the source.

(cc) "Attenuation block" means a block or stack, with dimensions of 20 cm by 20 cm by 3.8 cm, made of type 1100 aluminum alloy or other materials having equivalent attenuation.

(dd) "Authorized user" means an individual who is identified as an authorized user on a license issued by the department for the use of radioactive material or an individual who is designated by a registered facility as a user of X-ray machines or accelerators. This term shall not apply to part 6 of these regulations.

(ee) "Automatic exposure control" means a device that automatically controls one or more technique factors in order to obtain a required quantity of radiation, at one or more preselected locations. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2016 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended July 27, 2007; amended P-

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28-35-135c. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation: (a) "Cabinet radiography using radiation machines" means industrial radiography that is conducted in an enclosed, interlocked cabinet that prevents the radiation machine from operating unless all openings are securely closed and that is sufficiently shielded so that every location on the cabinet's exterior meets the conditions for an unrestricted area as specified in K.A.R. 28-35-214a.

- (b) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure, called a "cabinet," that is independent from existing architectural structures except the floor on which the cabinet could be placed. The cabinet is intended for the following purposes:
  - (1) To contain at least that portion of a material being irradiated;
  - (2) to provide radiation attenuation; and
  - (3) to exclude personnel from the interior of the cabinet during the generation of X-rays.

Cabinet X-ray systems may This term shall include all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube that is used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, shall not be considered a cabinet X-ray system.

(c) "Calendar quarter" means at least 12 but not more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January. Subsequent calendar quarters shall be arranged so that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. A licensee or registrant shall not change the method of determining and observing calendar quarters for purposes of these regulations except

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at the beginning of a calendar year.

- (d) "Calibration" means the determination of either of the following:
- (1) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
  - (2) the strength of a source of radiation relative to a standard.
  - (e) "Camera" means a radiographic exposure device.
- (f) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.
- (g) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (h) "Certifiable cabinet X-ray system" means an existing, uncertified X-ray system that has been modified to meet the certification requirements specified in 21 CFR C.F.R. 1020.40, as in effect on April 30, 1984.
- (i) "Certified cabinet X-ray system" means a cabinet X-ray system that has been certified as manufactured and assembled as specified in 21 CFR C.F.R. 1020.40, as in effect on April 30, 1984.
- (j) "Certified components" means the components of X-ray systems that are subject to regulations promulgated under public law 90-602, the radiation control for health and safety act of 1968 and amendments thereto as amended.
  - (k) "Certified system" means any X-ray system that has one or more certified components.
  - (1) "Certifying entity" means an independent certifying organization or state regulatory

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program meeting the requirements in K.A.R. 28-35-292 28-35-293.

- (m) "Changeable filter" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.
- (n) "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acids, and polycarboxylic acids.
- (o) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For the purposes of these regulations, "lung class" and "inhalation class" shall be considered equivalent terms. Materials are classified as D, W, or Y, which applies to the following range of clearance half-times:
  - (1) For class D, fewer than 10 days;
  - (2) for class W, from 10 through 100 days; and
  - (3) for class Y, more than 100 days.
- (p) "Coefficient of variation" or <u>and</u> "C" means <u>mean</u> the ratio of the standard deviation to the mean value of a population of observations. This ratio is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left( \sum_{i=1}^{n} \frac{(x_i - \bar{x})^2}{n-1} \right)^{\frac{1}{2}}$$

where

s = Estimated standard deviation of the population.

 $\bar{x}$  = Mean value of observations in sample.

 $x_i$  = ith observation in sample

(q) "Collective dose" means the sum of the individual doses received in a given period of

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· time by a specified population from exposure to a specified source of radiation.

- (r) "Collimator" means a radiation shield that is placed at the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.
- (s) "Committed dose equivalent ( $H_{T,50}$ )" means and " $H_{T,50}$ " mean 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 50-year period following the intake.
- (t) "Committed effective dose equivalent ( $H_{E,50}$ )" means and " $H_{E,50}$ " mean 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 each of these organs or tissues ( $H_{E,50} = \sum w_T H_{T,50}$ ).
- (u) "Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.
- (v) "Consortium" means an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use.
- (w) "Contact therapy" means therapy in which the X-ray tube port is put in contact with, or within five centimeters of, the surface being treated.
- (w) (x) "Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than five centimeters.

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K.A.R. 28-35-135c, page 5

(x) (y) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(y) (z) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

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

(aa) (bb) "Control panel" means that part of the X-ray system where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are mounted.

(bb) (cc) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

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

(dd) (ee) "Curie" means a unit of activity. One curie (Ci) is the quantity of radioactive material that decays at the rate of  $3.7 \times 10^{10}$  transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie ( $_{\rm m}$ Ci) = 0.001 curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) = 0.000001 curie =  $3.7 \times 10^4$  tps. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2016 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended P-

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28-35-135i. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation: (a) "Image intensifier" means a device that instantaneously converts, by means of photoemissive surfaces and electronic circuitry, an X-ray pattern into a light pattern of greater intensity than would have been provided by the original X-ray pattern.

- (b) "Image receptor" means any device, including a fluorescent screen and radiographic film, that transforms incident X-ray photons into a visible image or into another form that can be made into a visible image by further transformations.
- (c) "Image receptor support," for mammographic systems, means that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.
- (d) "Immediate" means within not more than 15 minutes or as otherwise defined in a license condition.
- (e) "Incident" means an individual event or series of related events that caused or threatened to cause any violation of these regulations or license conditions. For the purposes of part 13, "incident" means shall mean any unintended event involving radioactive material for which the public dose is a fraction of regulatory limits and safety provisions are sufficient, but further degradation of safety systems could lead to an accident.
- (f) "Independent certifying organization" means an independent organization that meets all of the criteria specified in K.A.R. 28-35-292 28-35-293.
  - (g) "Indian tribe" and "tribe" mean any Indian tribe, band, nation, or other organized

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K.A.R. 28-35-135i, page 2

group or community of Indians recognized as eligible for the services provided to Indians by the secretary of the United States department of the interior because of their status as Indians.

- (h) "Indian tribal official" and "tribal official" mean the highest-ranking individual who represents tribal leadership, including the chief, president, and tribal council leader.
  - (i) "Individual" means any human being.
  - (h) (j) "Individual monitoring" means the assessment of either of the following:
- (1) A dose equivalent by the use of individual-monitoring devices or by the use of survey data; or
- (2) a committed effective dose equivalent determined by bioassay or by computation of the number of DAC-hours to which an individual is exposed.
- (i) (k) "Individual-monitoring device" means any device designed to be worn by a single individual for the assessment of dose equivalent. "Individual-monitoring device" shall include any film badge, thermoluminescent dosimeter (TLD), optically stimulated dosimeter, pocket ionization chamber, and personal air-sampling device. For purposes of these regulations, "personnel dosimeter" and "dosimeter" shall be considered terms equivalent to "individual-monitoring device."
- (j) (l) "Industrial radiography" means the examination of the structure of materials by nondestructive methods utilizing sources of radiation.
- (k) (m) "Inherent filtration" means the filtration permanently mounted in the useful beam, including the window of the X-ray tube and any permanent tube or source enclosure.
  - (1) (n) "Injection tool" means a device used for controlled subsurface injection of

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radioactive tracer material.

(m) (o) "Inspection" means an official examination or observation that may include tests, surveys, and monitoring to determine compliance with federal rules, state regulations, orders, requirements, and license and registration conditions.

(n) (p) "Installation" means the location where one or more sources of radiation are used, operated, or stored.

(e) (q) "Interlock" means a device for precluding access by an individual to an area of radiation hazard without warning, either by preventing admission or by automatically removing the hazards.

(p) (r) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(q) (s) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without the resetting of operating conditions at the control panel.

(r) (t) "Ionizing radiation" means radiation capable of producing an ionization event, including gamma rays and X-rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(s) (u) "Irradiation" means the exposure of matter to ionizing radiation.

(t) (v) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type. This term shall not include any irradiator in which both the sealed source and the

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area subject to irradiation are contained within a device and are not accessible to personnel.

(u) (w) "Irradiator operator" means an individual who has successfully completed the required training and testing and is authorized by the terms of the license to operate an irradiator without a supervisor present.

(v) (x) "Irretrievable well-logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

(w) (y) "Isocenter" means a fixed point in space that is located at the center of the smallest sphere through which the central axis of the beams passes under all conditions. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2016 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_\_\_\_.)

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28-35-135s. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation: (a) "Sanitary sewerage" means a system of public sewers to carry off waste water and refuse. This term shall exclude sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

- (b) "Scattered radiation" means radiation that, during its passage through matter, is deviated in direction.
- (c) "Sealed source" means any radioactive material that is permanently encased in a capsule designed to prevent the leakage or escape of the radioactive material.
- (d) "Secondary dose-monitoring system" means a system that terminates irradiation if the primary system fails.
- (e) "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.
  - (f) "Secretary" means the secretary of the department of health and environment.
- (g) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. geological survey.
- (h) "Shallow dose equivalent (H<sub>s</sub>);" and "H<sub>s</sub>," which applies apply to the external exposure of the skin or an extremity, means mean the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>) averaged over an area of one square centimeter.
- (i) "Sheltering" means using a structure for radiation protection from an airborne plume containing radioactive material.
  - (i) "Shielded position" means the location within the radiographic exposure device or

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storage container that, by the manufacturer's design, is the proper location for storage of the sealed source.

- (k) "Shielded-room radiography using radiation machines" means industrial radiography using radiation machines that meets the following conditions:
- (1) Is conducted in an enclosed room, the interior of which is not occupied during radiographic operations;
- (2) is shielded so that every location on the exterior meets the conditions specified in K.A.R. 28-35-214a; and
- (3) is accessible only through openings that are interlocked so that the radiation machine will not operate unless all openings are securely closed.
  - (1) "SI" means the abbreviation for the international system of units.
- (m) "Shutter" means a device attached to an X-ray tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.
- (n) "Sievert" means the SI unit of any of the quantities expressed as a dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sy = 100 rem).
- (o) "Site area emergency" means an event that could occur, is in progress, or has occurred, that could lead to a significant release of radioactive material, and that could require a response by off-site response organizations to protect persons off-site.
  - (p) "Site boundary" means that line beyond which the land or property is not owned,

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leased, or otherwise controlled by the licensee or registrant.

- (q) "Source" means the focal spot of the X-ray tube.
- (r) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable.
- (s) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those devices also used for transporting and storaging sealed sources.
- (t) "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 in well-logging operations.
- (u) "Source-image receptor distance" and "SID" mean the distance from the source to the center of the input surface of the image receptor.
  - (v) "Source material" means the following:
- (1) Uranium or thorium, or any combination of these, in any physical or chemical form; or
- (2) orcs that contain, by weight, 0.05 percent or more of uranium, thorium, or any combination of these.

The term "source material" shall not include special nuclear material.

- (w) "Source material milling" means any activity that results in the production of byproduct material.
  - (x) "Source of radiation" means any material, device, or equipment that emits or is

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capable of producing radiation.

- (y) "Source-to-skin distance" and "SSD" mean the distance between the source and the patient's skin.
- (z) "Special form" means any licensed material that meets either of the following conditions:
  - (1)(A) Is in solid form;
  - (B) has at least one dimension measuring at least five millimeters;
  - (C) does not melt, sublime, or ignite in air at a temperature of 1,000°F;
- (D) does not shatter or crumble if subjected to the percussion test described in K.A.R. 28-35-144; and
- (E) is not dissolved or converted into dispensable form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F or in air at 86°F; or
  - (2)(A) Is in any physical form securely contained in a capsule;
  - (B) has at least one dimension measuring at least five millimeters;
  - (C) will retain its contents if subjected to the tests described in K.A.R. 28-35-144; and
- (D) is constructed of materials that do not melt, sublime, or ignite in air at 1,475°F and do not dissolve or convert into dispensable form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F or in air at 86°F.
  - (aa) "Special nuclear material" means either of the following:
- (1) Plutonium, uranium-223, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the department declares by order to be special nuclear material

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after the U.S. nuclear regulatory commission (NRC), pursuant to the provisions of section 51 of the atomic energy act of 1954, has determined the material to be special nuclear material, except for source material; or

- (2) any material artificially enriched as specified in paragraph (aa)(1), except for source material.
- (bb) "Special nuclear material in quantities not sufficient to form a critical mass" means any of the following:
- (1) Uranium enriched in the isotope U-235, in quantities not exceeding 350 grams of contained U-235;
- (2) uranium enriched in the isotope uranium-233, in quantities not exceeding 200 grams of contained U-233;
  - (3) plutonium not exceeding 200 grams; or
- (4) any combination of these special nuclear materials in accordance with the following formula:

The sum of the ratios for all of the kinds of special nuclear material in combination shall not exceed one.

(cc) "Spot check" means a procedure that is performed to ensure that a previous

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calibration continues to be valid.

- (dd) "Spot film" means a radiograph that is made during a fluoroscopic examination or radiation therapy treatment to permanently record conditions that exist during the procedure.
- (ee) "Spot-film device" means a device intended either to transport and position a radiographic image receptor between the radiation source and image receptor or to position a radiographic image receptor between the radiation source and image receptor. This term shall include a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- (ff) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.
- (gg) "Stationary X-ray equipment" means X-ray equipment that is installed in a fixed location.
- (hh) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.
- (ii) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the occurrence of the effect, rather than the severity of the effect, is assumed to be a linear function of dose without threshold. For purposes of these regulations, "probabilistic effect" shall be considered an equivalent term.
- (jj) "Storage area" means any location, facility, or vehicle that is used to store, transport, or secure a radiographic exposure device, radiation machine, storage container, or sealed source when not in use. Each storage area shall be locked or have physical barriers to prevent accidental exposure,

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tampering, or unauthorized removal of the device, machine, sealed source, or container.

- (kk) "Storage container" means a device in which radioactive materials are transported or stored.
  - (II) "Stray radiation" means the sum of leakage radiation and scattered radiation.
- (mm) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
- (nn) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.
  - (00) "Subsurface studies" means the evaluation of parameters below the surface of the earth.
- (pp) "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.

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28-35-135u. Definitions. As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation: (a) "Underwater irradiator" means an irradiator in which the sources always remain shielded underwater and humans do not have access to the sealed sources or the space that is subject to irradiation without entering the pool.

- (b) "Underwater radiography" means industrial radiography performed when the radiographic exposure device or the related equipment is beneath the surface of the water.
- (c) "Unit dose" means a dosage prepared for medical use for administration to a patient or human research subject as a single dosage, without any further manipulation of the dosage after the dosage is initially prepared.
- (d) "Unrefined and unprocessed ore" means ore in its natural form before any processing, including grinding, roasting, beneficiating, or and refining. "Processing" shall not include sieving or the encapsulation of ore or preparation of samples for laboratory analysis.
- (e) "Unrestricted area" means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" shall be considered an equivalent term.
- (f) "Useful beam" means the part of the radiation that passes through a window, aperture, cone, or other collimating device. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2016

  Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_\_\_.)

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28-35-140. Exemptions. (a) General provision. The secretary, upon application for an exemption or upon the secretary's own initiative, may grant exemptions or exceptions from the requirements of these regulations, if it is determined that the exemption will not result in an undue hazard to public health and safety, or to property.

(b) Carriers. Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. department of transportation or the U.S. postal service (39 CFR Parts 14 and 15), shall be exempt from these regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another. Private earriers who are subject to the rules and regulations of the U.S. department of transportation shall be exempt from these regulations to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the U.S. department of transportation or the U.S. postal service shall be subject to applicable sections of these regulations. Each common carrier, each contract carrier, each freight forwarder, and each U.S. postal service carrier that only transports or stores radioactive material in the regular course of carriage or storage shall be exempt from parts 3, 4, 6, 7, 10, 11, and 12 of these regulations and from K.A.R. 28-35-700.

(e) (b) U.S. department of energy contractors and U.S. nuclear regulatory commission contractors. Any Each U.S. department of energy contractor or subcontractor and any each U.S. nuclear regulatory commission contractor or subcontractor operating within this state in Kansas shall be exempt from these regulations to the extent that the contractor or subcontractor, under the contract, receives, possesses, uses, transfers, or acquires sources of radiation; and if the contractor or subcontractor is included in one of the following categories:

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- (1) Prime contractors performing work for the U.S. department of energy at <u>sites owned</u> or <u>controlled by the U.S. government-owned or controlled sites government</u>, including the transportation of sources of radiation to or from <u>such these</u> sites and the performance of contract services during temporary interruptions of <u>such</u> transportation;
- (2) prime contractors of the U.S. department of energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components of atomic weapons;
- (3) prime contractors of the U.S. department of energy using or operating nuclear reactors or other nuclear devices in a United States U.S. government-owned vehicle or vessel; and

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28-35-177a. General licenses; source material. (a)(1) Each of the following persons shall be deemed to have been issued a general license authorizing the acquisition, possession, use, and transfer of not more than 15 pounds (6.8 kg) of source material at any one time or the receipt of a total of 150 pounds (68.2 kg) of source material in any calendar year if the source material is used for research, development, education, commercial, or operational purposes:

- (A) Any commercial or industrial firm;
- (B) any research, educational, or medical institution; and
- (C) any state or local governmental agency.
- (2) Each person who acquires, possesses, uses, or transfers source material pursuant to the general license specified in subsection (a) shall be exempt from parts 4 and 10 of these regulations to the extent that the acquisition, possession, use, or transfer is within the terms of the general license. This exemption shall not apply to any person who is also in possession of source material under a specific license issued pursuant to these regulations.
- (3) Each person who receives, possesses, uses, or transfers source material pursuant to the general license specified in subsection (a) shall be prohibited from administering source material or the radiation, either externally or internally, to human beings except as may be authorized in a specific license.
- (b) Each person receiving title to source material shall be deemed to have been issued a general license without regard to quantity. This general license shall not authorize any person to receive, possess, use, or transfer source material.
- (c)(1) Each person who meets the requirements of paragraphs (2), (3), and (4) of this subsection shall be deemed to have been issued a general license to acquire, possess, use, or

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transfer depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2)(A) Each person who acquires, possesses, or uses depleted uranium pursuant to the general license issued in this subsection shall file a form specified by the department. The form shall be filed with the department within 30 days of the date on which the depleted uranium is received or acquired. Each person filing a form shall provide all the information requested by the form.

(B) If any change in circumstances renders any information provided on the form inaccurate, the department shall be provided with a written notice of the change within 30 days of the date of the change.

(3) A person who acquires, possesses, or uses depleted uranium pursuant to the general license specified in this subsection shall not perform any of the following:

(A) Introduce depleted uranium, in any-form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for the repair or restoration of any plating or other covering of the depleted uranium;

(B) abandon depleted uranium; or

(C) export depleted uranium, except in accordance with a license issued by the U.S. nuclear regulatory commission.

(4)(A) Each person possessing depleted uranium pursuant to the general license specified in this subsection shall transfer or dispose of the depleted uranium only by transfer in accordance with K.A.R. 28-35-190a.

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- (B) When depleted uranium is transferred to any person in this state, the transferor shall provide a copy of this regulation and the required form to the transferee.
- (C) When depleted uranium is transferred to any person outside this state, the transferor shall furnish the transferee with a copy of this regulation, the required form, and a written notice that possession or use of the depleted uranium is regulated by the U.S. nuclear regulatory commission or the state in which the person is located, under requirements substantially the same as those in this regulation.
- (D) Each person who transfers depleted uranium pursuant to this subsection shall give written notice to the department of the name and address of the person to whom the depleted uranium was transferred. The notice shall be filed within 30 days of the date of transfer.
- (5) The general license specified in this subsection shall apply only to industrial products or devices that have been manufactured or initially transferred in accordance with a specific license that authorizes the manufacture of the products or devices for distribution to persons generally licensed by the NRC or an agreement state.
- (d) Each person who acquires, possesses, uses, or transfers depleted uranium pursuant to subsection (c) shall be exempt from parts 4 and 10 of these regulations with respect to the depleted uranium acquired, possessed, used, or transferred by that person. A general license is hereby issued authorizing commercial and industrial firms, research, educational, and medical institutions, and federal, state, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in any of

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the following forms and quantities:

(1) Uranium and thorium in the following quantities and forms:

(A) Not more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms, including gases, liquids, and powders, at any one time. All material processed by the general licensee that alters the chemical or physical form of the material containing source material shall be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph shall not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

(B) not more than 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph shall not receive more than 70 kg (154 lb) of uranium and thorium in any one calendar year. A person shall not alter the chemical or physical form of the source material possessed under this paragraph unless the source material is accounted for under the limits of paragraph (a)(1);

(2) not more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person shall not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(3) not more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph shall not receive more than 70 kg (154 lb) of source material in any one

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calendar year.

(b)(1) Each person who receives, possesses, uses, or transfers source material in accordance with the general license in subsection (a) shall be prohibited from the following:

(A) Administering source material, or the radiation from the source material, either externally or internally, to human beings except as authorized by a specific license issued by the department;

(B) abandoning the source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year by a person authorized to receive, possess, use, and transfer source material under the general license to persons receiving the material for permanent disposal. The recipient of source material transferred under this paragraph shall be exempt from the requirements to obtain a license under part 3 of these regulations to the extent that the source material is permanently disposed of. This exemption shall not apply to any person who is in possession of source material under a specific license issued by the department; or

(ii) source material may be disposed in accordance with K.A.R. 28-35-190a; and

(C) exporting the source material to another country except in accordance with a license issued by the nuclear regulatory commission (NRC).

(2) Each person specified in paragraph (b)(1) shall respond to each written request from the department to provide information relating to the general license within 30 calendar days of the date of the request or other time specified in the request. If the person cannot provide the

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requested information within the required time, the person shall, within the same time period, request a longer period to supply the information by providing the department with a written justification for the request.

(c) Each person who receives, possesses, uses, or transfers source material in accordance with subsection (a) shall minimize contamination of the facility and the environment. When activities involving source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the department about the contamination and may consult with the department regarding the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in these regulations.

(d) Each person who receives, possesses, uses, or transfers source material in accordance with the general license granted in subsection (a) shall be exempt from parts 4 and 10 of these regulations to the extent that the receipt, possession, use, and transfer are within the terms of this general license, except that the person shall meet the requirements of paragraph (b)(1)(B) and subsection (c). This exemption shall not apply to any person who also holds a specific license issued by the department.

(e) No person shall initially transfer or distribute source material to persons generally licensed under paragraph (a)(1) or (2) or equivalent regulations of an agreement state, unless authorized by a specific license issued by the NRC or equivalent provisions of an agreement state. This subsection shall not apply to analytical laboratories returning any processed sample to

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the client who initially provided the sample.	(Authorized by and implementing K.S.A. 48-1607;
effective, T-86-37, Dec. 11, 1985; effective	May 1, 1986; amended Dec. 30, 2005; amended July
27, 2007; amended P	)

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28-35-178i. General licenses for certain units of radium-226. (a) Subject to the limitations prescribed in subsection subsections (b), (c) and (d) of this regulation, a general license is hereby issued to commercial and industrial firms, and to research, educational, medical and governmental institutions, any person to acquire, possess, use, and transfer radium-226 in units not exceeding 0.1 microcuric each. contained in the following products if manufactured before the effective date of this regulation:

- (1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, "antiquities" shall mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, including radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;
- (2) intact timepieces containing more than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;
  - (3) luminous items installed in air, marine, or land vehicles;
- (4) all other luminous products not listed in this subsection, if not more than 100 items are used or stored at the same location at any one time; and
- (5) small radium sources containing not more than 0.037 megabecquerel (1 microcurie) of radium-226.
- (b) A person shall not acquire, possess, use, or transfer radium-226 pursuant to the general license issued in subsection (a) of this regulation until the person has filed form RH-37 with the secretary and has received from the secretary a validated copy of the form, with a certification number assigned. Each person filing a form RH-37 shall provide all the information required by that form.

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- (c) Each general licensee under this regulation: Each person who acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license issued in subsection (a) shall meet the following requirements:
- (1) Shall not possess, at any one time and at any one location of storage or use, a total amount of radium-226 in excess of five microcuries. Notify the department of any indication of possible damage to the product that indicates a potential loss of the radioactive material. A report containing a brief description of the event and the remedial action taken shall be provided to the department within 30 days of the incident;
- (2) shall store the radium-226, until used, in the original shipping container or in a container providing equivalent radiation protection not abandon any products containing radium-226. The product and any radioactive material from the product shall be disposed of only according to K.A.R. 28-35-165 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the department;
- (3) shall transfer the radioactive material only to a person who is authorized to receive it pursuant to a license issued by the secretary, the United States nuclear regulatory commission or an agreement state not export any products containing radium-226 except in accordance with K.A.R. 28-35-178b; and
- (4) shall not transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the shipper. dispose of any products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the solid waste disposal act of 1965,

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42 U.S.C. 6901 through 6992k as amended, as authorized under 42 U.S.C. 15801 et seq., by transfer to a person authorized to receive radium-226 by a specific license issued under K.A.R. 28-35-180a or equivalent regulations of an agreement state, or as otherwise approved by the department; and

- (5) respond to any written request from the department to provide information relating to the general license within 30 calendar days of the date of the request or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, that licensee shall, within that same time period, request a longer period to supply the information by submitting a letter to the department and shall provide written justification as to why the person cannot comply.
- (d) Each general licensec under this regulation shall file with the secretary a written report with the secretary of any changes in the information filed in form RH-37. The report shall be furnished within 30 days after the effective date of the change.
- (e) Each general licensec under this regulation shall be exempt from the requirements of parts 4 and 10 of these regulations with respect to the radioactive material covered by the general license.
- (f) The general license issued in this regulation shall not authorize the manufacture, eommercial distribution or human use of radium-226. The general license specified in subsection (a) shall not authorize the manufacture, assembly, disassembly, repair, or import of any products containing radium-226, except that timepieces may be disassembled and repaired.

(g) Any general licensee under this regulation who is an individual member of the public

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may submit an application to the department for a waiver from the general license fee prescribe
in K.A.R. 28-35-147a. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective
T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-

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28-35-179a. Application for specific license; renewal or amendment. (a) Any person may file a written application with the secretary for a specific license to acquire, possess, use, or transfer radioactive material, and. Each person shall file a written application with the secretary to renew or amend any specific license. Each application for a specific license, or a renewal or an amendment of an existing license, shall be made submitted on the appropriate form prescribed and furnished by the secretary. Each person filing an application shall provide all the information requested on the application form, and any additional relevant information requested by the secretary.

- (b) Each application filed with the secretary shall be signed by the applicant or licensee, or by a person authorized to act for or on behalf of the applicant or licensee.
- (c) Any application may incorporate, by reference, information provided in applications, reports, or other documents previously filed with the secretary. Any <u>Each</u> reference to information previously filed with the secretary shall be clear and specific.
- (d) An Any application for a specific license may include a request for a license authorizing activity at one or more installations or locations.
- (e) Except as provided in subsections (f), (g), and (h), each application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall include either of the following:
- (1) Identification of the sealed source or device by manufacturer and model number as registered with the department, nuclear regulatory commission (NRC), or an agreement state; or
- (2) sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property. For a device, the application shall also include sufficient

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information about installation, service and maintenance, operating and safety instructions, and potential hazards, to provide reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property.

(f) For any sealed source or device manufactured before October 23, 2012 that is not registered with the department, NRC, or an agreement state and for which the applicant is unable to provide the information specified in this regulation, the application shall include the following:

(1) All available information specified in K.A.R. 28-35-181e, concerning the sealed source, and, if applicable, the device; and

(2) sufficient additional information to demonstrate reasonable assurance that the radiation safety properties of the sealed source or device are adequate to protect health and minimize danger to life and property. The information shall include a description of the sealed source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of the most recent leak test.

(g) For sealed sources and devices allowed to be distributed without the registration of safety information as required in this regulation, the applicant may supply only the name of the manufacturer, model number, and radionuclide quantity.

(h) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which the sealed sources and devices will be used, instead of identifying each sealed source and device. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-\_\_\_\_\_\_\_.)

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28-35-180a. General requirements for the issuance of specific licenses. Each application for a specific license shall be approved only if the application meets the requirements of these regulations.

- (a) Each applicant shall be required to be qualified by reason of training and experience to use the material in question for the purpose requested, in accordance with these regulations, and in a manner that will protect public health and safety and the environment.
- (b) The proposed equipment, facilities, and procedures used by each applicant shall protect public health and safety and the environment.
- (c) A specific license shall be approved only if the secretary determines that the specific license will not be a detriment to the health and safety of the public.
- (d) Each applicant shall meet the requirements prescribed in these regulations for the particular license sought.
- (e) (d)(1) Each application for a license for commercial waste disposal, source material milling, or any other operation that the secretary determines will affect the environment shall meet the requirement specified in this paragraph. Each application shall include information that permits the secretary to weigh the environmental, economic, technical, and other benefits against the environmental costs and alternatives to ensure the protection of public health and safety and the environment.
- (2) The approval of each application specified in paragraph (e)(1) (d)(1) shall be based upon the following:
- (A) The information specified in paragraph (e)(1) (d)(1) and other information as necessary; and
- (B) the applicable portions of information required by 10 CFR part 51, subpart A, § C.F.R. 51.45, as in effect on April 30, 1992.

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(f) (e) Each applicant shall be authorized to begin construction only after the issuance of the license. Commencement of construction before issuance of the license shall be grounds for denial of the license application. "Commencement of construction," as used in this regulation, shall mean any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site.

(g) (f) Each applicant for a license, other than a renewal, shall describe in the application how the facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(h) (g) Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source manufactured by the licensee. Each serial number shall be composed only of alphanumeric characters.

(h) Each licensee shall conduct operations to minimize the introduction of residual radioactivity into the facility out to the site boundary, including the subsurface, in accordance with the existing radiation protection requirements and radiological criteria for license termination in these regulations. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Sept. 20, 1993; amended Nov. 1, 1996; amended Dec. 30, 2005; amended July 27, 2007; amended P-

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28-35-180b. Financial assurance for decommissioning. (a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10<sup>5</sup> times the applicable quantities specified in K.A.R. 28-35-201 shall submit a decommissioning funding plan as described in K.A.R. 28-35-180b(e) subsection (e) of this regulation. Each applicant shall also submit the decommissioning funding plan if a combination of isotopes is involved and if R divided by 10<sup>5</sup> is greater than one, where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value specified in K.A.R. 28-35-201.

- (b) Each applicant for a specific license authorizing the possession and use of radioactive material with a half-life greater than 120 days and in quantities specified in table I shall submit either of the following:
  - (1) A decommissioning funding plan as described in subsection (e); or
- (2) a certification that financial assurance for decommissioning has been provided in the amount prescribed by table I, using one of the methods described in subsection (f). The certification may state that the appropriate assurance is to be obtained after the application has been approved and the license has been issued, but before the receipt of licensed material. If the applicant defers execution of the financial instrument required under subsection (f) until after the license has been issued, a signed original of the financial instrument shall be submitted to the department before the applicant receives the licensed material. If the applicant does not defer execution of the financial instrument required under subsection (f), the applicant shall submit to the department, as part of the certification, a signed original of the financial instrument.
  - (c) Each holder of a specific license that is a type specified in subsection (a) or (b) shall

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provide financial assurance for decommissioning in accordance with the following requirements:

- (1) Each holder of a specific license that is a type specified in subsection (a) shall submit a decommissioning funding plan as specified in subsection (e) or a certification of financial assurance for decommissioning in an amount equal to at least \$1,125,000.00. Each licensee shall submit the plan or certification to the department in accordance with the criteria specified in this regulation. If the licensee submits a certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.
- (2) Each holder of a specific license that is a type specified in subsection (b) shall submit a decommissioning funding plan as specified in subsection (e) or a certification of financial assurance for decommissioning. Each licensee shall submit the plan or certification to the department, in accordance with the requirements specified in this regulation.
- (d) The amounts of financial assurance required for decommissioning, by quantity of material, shall be those specified in table I.

## Table I

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by $10^5$ is equal to or less than one	\$1,125,000.00	
If the possession limit is greater than 10 <sup>3</sup> but less than or equal to		
10 <sup>4</sup> times the applicable quantities specified in K.A.R. 28-35-201,		
in unsealed form	\$225,000.00	
For a combination of isotopes, in unsealed form, if R, as defined		
in subsection (a), divided by 10 <sup>3</sup> is greater than one, but R divided		
by $10^4$ is less than or equal to one	\$225,000.00	
If the possession limit is greater than 10 <sup>10</sup> times the applicable		
quantities specified in K.A.R. 28-35-201, in sealed sources		
or foils	\$113,000.00	
For a combination of isotopes, in sealed sources or foils, if R,		
as defined in subsection (a), divided by 10 <sup>10</sup> is greater than one	\$113,000.00	
(e) Each decommissioning funding plan shall contain the following:		
(1) A cost estimate for decommissioning; in an amount including the following:		
(A) The cost of an independent contractor to perform all decommissioning activities;		

(C) the volume of on-site subsurface material containing residual radioactivity that will require remediation to meet the requirements for license termination; and

(B) the cost of meeting the requirements for unrestricted use specified in K.A.R. 28-35-

205. However, if the applicant or licensee can demonstrate the ability to meet the provisions of

K.A.R. 28-35-205a, the cost estimate may be based on meeting the requirements in K.A.R. 28-

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(D) a contingency factor;

(2) a description of the method of ensuring funds for decommissioning, selected from the methods specified in subsection (f) identification of and justification for using the key assumptions contained in the decommissioning cost estimate;

(3) a description of the means for periodically a description of the method of ensuring funds for decommissioning from subsection (f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(4) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(5) a signed original of the financial instrument obtained to satisfy the requirements specified in subsection (f): and

(6) at the time of license renewal and at intervals not longer than three years, the decommissioning funding plan with adjustments necessary to account for changes in costs and the extent of contamination. The amount of financial assurance shall not be reduced without first obtaining the approval of an updated decommissioning funding plan. The decommissioning funding plan shall update the information submitted with the original or prior approved plan and shall specifically consider the effect of the following events on decommissioning costs:

(A) Spills of radioactive material producing additional residual radioactivity in on-site subsurface material;

(B) waste inventory exceeding the amount previously estimated;

(C) waste disposal costs exceeding the amount previously estimated;

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(D) facility modifications;

(E) changes in authorized possession limits;

(F) actual remediation costs exceeding the previous cost estimate;

(G) on-site disposal; and

(H) use of a settling pond.

(f) Each licensee shall provide financial assurance for decommissioning by one or more of the following methods:

(1) Prepayment. "Prepayment" shall mean the deposit of cash or liquid assets that meet the following criteria:

(A) before the start of operation, are deposited into an a trust account acceptable to the secretary that is segregated from the licensee's assets and outside of the licensee's administrative control; and

(B) . The deposit shall consist of an amount that is sufficient to pay decommissioning costs. The adequacy of the trust funds shall be based on an assumed annual rate of return of one percent on the funds deposited into the trust.

The prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety instrument, insurance policy, or other guarantee method. The licensee may use a surety instrument, insurance policy, or other similar means to guarantee that decommissioning costs will be paid. A surety instrument may be in the form of a surety bond, letter of credit, or line of credit. A parent company's guarantee of funds for decommissioning costs based on a financial

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test may be used if the guarantee and test meet the requirements of K.A.R. 28-35-203. A parent company's guarantee shall not be used in combination with other financial methods to meet the requirements in this regulation. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test meet the requirements of K.A.R. 28-35-203. A guarantee by the applicant or licensee shall not be used in combination with any other financial methods to meet the requirements in this regulation or in any situation in which a parent company of the applicant or licensee holds majority control of the voting stock of the company. Each surety instrument or insurance policy used to provide financial assurance for decommissioning shall contain the following requirements:

- (A) The surety instrument or insurance policy shall be open-ended or, if written for a specified term, shall be renewed automatically, unless 90 days or more before the renewal date, the insurer notifies the department, the beneficiary, and the licensee of the insurer's intention not to renew. The surety instrument or insurance policy shall also provide that the full face amount will be paid to the beneficiary automatically before the expiration without proof of forfeiture if the licensee fails to provide a replacement that meets the requirements of this regulation within 30 days after receipt of notification of cancellation.
- (B) The surety instrument or insurance policy shall be payable to an approved trust established for decommissioning costs. The trustee may include an appropriate state or federal agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.
  - (C) The surety instrument or insurance policy shall remain in effect until the license is

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terminated by the department.

- (3) External sinking fund. A licensee may provide financial assurance for decommissioning through an external sinking fund in which deposits are made at least annually, coupled with a surety instrument or insurance policy. The value of the surety instrument or insurance policy may decrease by the amount accumulated in the sinking fund. "External sinking fund" shall mean a fund that meets both of the following conditions:
- (A) Is established and maintained by setting aside funds periodically in an account segregated from the licensee's assets and outside the licensee's administrative control; and
- (B) contains a total amount of funds sufficient to pay the decommissioning costs when termination of the operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall meet the requirements specified in this subsection.
- (4) Statement of intent. Any federal, state, or local government licensee may submit a statement of intent containing a cost estimate for decommissioning or an amount based on table I of this regulation and indicating that funds for decommissioning will be obtained when necessary.
- (g) Each person licensed under subsections (a) through (g) (f) shall keep records of all information that is relevant to the safe and effective decommissioning of the facility. The records shall be kept in an identified location until the license is terminated by the department. If records of relevant information are kept for other purposes, the licensee may refer to these records and the location of these records within the records kept pursuant to this subsection.

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- (h) Each licensee shall maintain decommissioning records, which shall consist of the following information:
- (1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to records of instances in which contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants could have spread to inaccessible areas. These records shall include any known information identifying the nuclides, quantities, forms, and concentrations involved in the spill or occurrence;
  - (2) drawings of the following, both as originally built and, if applicable, as modified:
- (A) The structures and equipment in restricted areas where radioactive materials are used or stored, or both; and
- (B) the locations of possible inaccessible contamination. If the licensee refers to required drawings other than those kept pursuant to this regulation, the licensee shall not be required to index each relevant document individually. If drawings are not available, the licensee shall substitute available information concerning these areas and locations;
- (3) a list of the following information, which shall be contained in a single document and updated every two years:
  - (A) All areas designated and formerly designated as restricted areas;
- (B) all areas outside of restricted areas that require the documentation specified in this subsection;
  - (C) all areas outside of restricted areas where current and previous wastes have been

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buried and documented as specified in K.A.R. 28-35-227j; and

(D) all areas outside of restricted areas that contain material so that, if the license expired, the licensee would be required either to decontaminate the area to unrestricted release levels or to apply for approval for disposal as specified in K.A.R. 28-35-225a.

Those areas containing sealed sources only shall not be included in the list if the sources have not leaked, no contamination remains in the area after any leak, or the area contains only radioactive materials having half-lives of less than 65 days; and

- (4) the following records:
- (A) Records of the cost estimate performed for the decommissioning funding plan or records of the amount certified for decommissioning; and
- (B) if either a funding plan or certification is used, records of the funding method used for assuring funds.
- (i) Each applicant for a specific license shall make arrangements for a long-term care fund pursuant to K.S.A. 48-1623, and amendments thereto available a long-term care fund necessary to provide for the long-term surveillance and care of the radioactive material or waste. Each applicant for any of the following types of specific licenses shall establish the long-term care fund before the issuance of the license or before the termination of the license if the applicant chooses, at the time of licensure, to provide by providing a surety instrument in lieu of a long-term care fund:
  - (1) Waste-handling licenses;
  - (2) source material milling licenses; and

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(3) licenses for any facilities formerly licensed by the U.S. atomic energy commission or the nuclear regulatory commission (NRC), if required.

(j)(1) Each applicant shall agree to notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11, bankruptcy, of the United States code by or against any of the following:

- (A) The licensee;
- (B) any person controlling the licensee or listing the licensee as property of the estate; or
  - (C) any affiliate of the licensee.
  - (2) The bankruptcy notification shall indicate the following:
  - (A) The name of the bankruptcy court in which the petition for bankruptcy was filed; and
  - (B) the date on which the petition was filed. (Authorized by and implementing K.S.A.

48-1607; effective Dec. 30, 2005; amended March 18, 2011; amended

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28-35-181h. Specific licenses to manufacture and distribute the devices specified in K.A.R. 28-35-178b. An application for a specific license to manufacture and distribute one or more of the devices specified in K.A.R. 28-35-178b shall not be approved unless the applicant meets the requirements of subsections (a) and (b) of this regulation in addition to meeting all of the additional applicable requirements specified in these regulations.

- (a) Each applicant shall submit information about the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that the following conditions are met:
- (1) The device can be safely operated by individuals not having training in radiological protection;
- (2) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any individual will receive a dose in excess of 10 percent of the limits specified in K.A.R. 28-35-212a; and
- (3) under accident conditions, including fire and explosion, associated with handling, storage, and use of the device, it is unlikely that any individual will receive an external radiation dose or dose commitment in excess of the following organ doses:
- (A) Whole body; head and trunk; active blood-forming

  15 rems

  organs; gonads; or lens of eye
- (B) Hands and forearms; feet and ankles; localized 200 rems areas of skin averaged over areas no larger than 1 square centimeter

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(C) Other organs

50 rems.

- (b)(1) Each device shall bear a durable, legible, clearly visible label or labels that contain, in clearly identified and separate statements, the following information:
- (A) Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Operating and service manuals may be identified in the label and used to provide this information;
- (B) specification of whether or not leak testing or testing of any on-off mechanism and indicator is required. The information shall include the maximum allowable time intervals between tests and shall identify the radioactive material by isotope, quantity of radioactivity, and date that the quantity was determined; and
- (C) the information required in one of the following statements, as appropriate, in the same or a substantially similar form:

(i) "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 a state with which the U.S. nuclear regulatory commission has entered
into an agreement for the exercise of regulatory authority. This label shall be maintained on the
device in a legible condition. Removal of this label is prohibited.

CAUTION—RA	DIOACTIVE 1	MATERIAL
(Name of manul	facturer or dist	ributor)"; o

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(ii) "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 a licensing
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)"

- (2) The model, serial number, and name of the manufacturer or distributor may be omitted from the requirements specified in paragraphs (b)(1)(C)(i) and (ii) if the information is elsewhere specified in labeling affixed to the device.
- (3) Each device having a separate source housing that provides the primary shielding for the source shall also bear, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "Caution Radioactive Material," the radiation symbol described in part 4 of these regulations, and the name of the manufacturer or initial distributor.
- (4) Each device containing at least 370 Mbq (10 mCi) of cesium-137, 3.7 Mbq (0.1 mCi) of strontium-90, 37 Mbq (1 mCi) of americium-241 or any other transuranic element based on the activity indicated on the label shall meet the following criteria:
- (A)(i) Bear a permanent label affixed to the source housing if the source housing is separable, including the words "Caution Radioactive Material"; or
  - (ii) bear a permanent label affixed to the device if the source housing is not separable,

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including the words "Caution — Radioactive Material"; and

- (B) if practicable, bear the radiation symbol described in part 4 of these regulations.
- (c) If the device is required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by the performance characteristics of the device or of similar devices and by 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. In determining the acceptable interval for the test for leakage of radioactive material, the applicant shall address the following in the application:
  - (1) The primary containment of the source capsule;
  - (2) protection of the primary containment;
  - (3) the methods of sealing the primary containment;
  - (4) the containment construction materials;
  - (5) the form of contained radioactive material;
  - (6) the maximum temperature withstood during prototype tests;
  - (7) the maximum pressure withstood during prototype tests;
  - (8) the maximum quantity of contained radioactive material;
  - (9) the radiotoxicity of contained radioactive material; and
- (10) any prior operating experience with identical devices or similarly designed and constructed devices.

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(d) If the general licensee under K.A.R. 28-35-181b 28-35-178b, or under equivalent regulations of an agreement state, is authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the onoff mechanism and indicator, or remove the device, the applicant shall include in the application the written instructions to be followed by the general licensee, the estimated calendar-quarter doses associated with each operation, and the bases for the estimates. The submitted information shall demonstrate that performance of the specified operations by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in part 4 of these regulations.

(e) Each device shall be listed on the nuclear regulatory commission's sealed source and device registry. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended P-\_\_\_\_\_\_\_.)

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28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use. An application for a specific license to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material and used by persons as specified in part 6 of these regulations shall not be approved unless the applicant meets the requirements of this regulation and all other applicable requirements of these regulations.

- (a) Each applicant shall meet the requirements specified in K.A.R. 28-35-180a.
- (b) Each applicant shall submit evidence of either of the following:
- (1) The radiopharmaceutical containing radioactive material is subject to the federal food, drug and cosmetic act or the public health service act and will be manufactured, labeled, and packaged in accordance with a new drug application (NDA) approved by the food and drug administration (FDA), a biologic product license issued by the FDA, or a "notice of claimed investigational exemption for a new drug" (IND) accepted by the FDA.
- (2) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal food, drug, and cosmetic act or the public health service act.
  - (c) Each applicant shall submit evidence of at least one of the following:
- (1) The applicant is registered or licensed with the U.S. food and drug administration as a drug manufacturer.
  - (2) The applicant is registered or licensed with a state agency as a drug manufacturer.
  - (3) The applicant is licensed as a pharmacy by the state board of pharmacy.
  - (4) The applicant is operating as a nuclear pharmacy within a federal medical institution.
  - (5) The applicant is operating a positron emission tomography (PET) drug production

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- (d) Each applicant shall submit the following information on the radionuclide:
- (1) The chemical and physical form of the material;
- (2) the packaging in which the radionuclide is shipped, including the maximum activity per package; and
- (3) evidence that the shielding provided by the packaging of the radioactive material is appropriate for the safe handling and storage of radiopharmaceuticals by group licensees.
  - (e)(1) Each applicant shall submit a description of the following:
- (A) A label that shall be affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the following:
- (i) The radiation symbol and the words "CAUTION RADIOACTIVE MATERIAL" or "DANGER RADIOACTIVE MATERIAL";
  - (ii) the name of the radioactive drug and the abbreviation; and
- (iii) 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; and
- (B) a label that shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION RADIOACTIVE MATERIAL" or "DANGER RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

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(2) The labels, leaflets, or brochures required by this regulation shall be made in addition to the labeling required by the FDA. The labels, leaflets, or brochures may be separate from the FDA labeling, or with the approval of the FDA, the labeling may be combined with the labeling required by the FDA.

(f) All of the following shall apply to each licensee described in paragraph (c)(3) or (c)(4), or both:

(1) The licensee may prepare radioactive drugs for medical use, if each radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (2) and (4) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist.

(2) The licensee may allow a pharmacist to work as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The pharmacist qualifies as an authorized nuclear pharmacist.

(B) The pharmacist meets the requirements specified in 10 CFR C.F.R. 35.55(b) and 35.59 as adopted by reference in K.A.R. 28-35-264, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(C) (B) The pharmacist is designated as an authorized nuclear pharmacist in accordance with paragraph (4) of this subsection.

(3) The actions authorized in paragraphs (1) and (2) of this subsection shall be permitted in spite of more restrictive language in license conditions.

(4) The licensee may designate a pharmacist as an authorized nuclear pharmacist if the individual is a nuclear pharmacist preparing radioactive drugs and identified as an "authorized

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user" on a nuclear pharmacy license issued under this part. at least one of the following conditions is met:

- (A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material.
- (B) The individual practiced at a government agency or federally recognized Indian tribe pharmacy before November 30, 2007 or at any other pharmacy before August 8, 2009.
- (5) Each licensee shall provide a copy of the state pharmacy license or registration for an individual to work as an authorized nuclear pharmacist and one of the following documents to the department no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(A) and (2)(C) of this subsection, the individual to work as an authorized nuclear pharmacist:
- (A) A copy of each individual's certification by a specialty-board whose certification process has been recognized as specified in 10 CFR 35.55(a), as adopted by reference in K.A.R. 28-35-264, the department or agreement state license, the permit issued by a licensee of broad scope, or nuclear regulatory commission master materials permittee; and
- (B) a copy of the state pharmacy license or registration. The individual's certification by a specialty board whose certification process has been recognized as specified in 10 C.F.R. 35.55(a), as adopted by reference in K.A.R. 28-35-264;
- (B) a department, NRC, or agreement state license listing the individual as an authorized nuclear pharmacist;

(C) an NRC master materials licensee permit listing the individual as an authorized nuclear pharmacist;

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(D) a permit issued by a licensee of broad scope or an NRC master materials permittee or the authorization from a commercial nuclear pharmacy that is authorized to list its own authorized nuclear pharmacist; or

(E) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear phannacy 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 noticed by the NRC as permitted by 10 C.F.R. 35.13(b)(5).

- (g) Each licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. Each licensee shall have procedures for using the instrumentation. Each licensee shall 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 before transfer for commercial distribution. Each licensee shall meet the following requirements:
- (1) Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments if necessary; and
- (2) check each instrument for constancy and proper operation at the beginning of each day of use.
- (h) Each application from a medical facility, an educational institution, or a federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees within the applicant's consortium authorized for medical use under part 6 of

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these regulations or equivalent agreement state requirements shall include the following:

- (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under these regulations or equivalent NRC or agreement state requirements for a PET radionuclide production facility within the applicant's consortium from which the applicant receives PET radionuclides;
- (2) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting the requirements of this regulation;
- (3) the name of each individual authorized to prepare PET radioactive drugs if the applicant is a pharmacy and documentation that each individual meets the requirements of an authorized nuclear pharmacist; and
- (4) the name of each PET radioactive drug for production and noncommercial distribution to the applicant's consortium, including the chemical and physical form of each drug.

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28-35-1810. Specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or reference source or for certain medical uses. (a) Each application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as specified in K.A.R. 28-35-181d for use as a calibration, transmission, or reference source or for one or more of the uses listed in 10 CFR C.F.R. 35.400, 35.500, 35.600, and 35.1000, as adopted by reference in K.A.R. 28-35-264, shall include the following information regarding each type of source or device:

- (1) The radioactive material contained, its chemical and physical form, and amount;
- (2) details of design and construction of the source or device;
- (3) 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 in accidents;
- (4) for devices containing radioactive material, the radiation profile for a prototype device;
- (5) details of quality control procedures to ensure that the production sources and devices meet the standards of the design and prototype tests;
  - (6) procedures and standards for calibrating sources and devices;
  - (7) legend and methods for labeling sources and devices as to their radioactive content;
- (8) radiation safety instructions for handling and storing the source or device. These instructions shall be included on a durable label attached to the source or device. However, instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label; and
  - (9) the label that is to be affixed to the source or device or to the permanent storage

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container for the source or device. The label shall contain information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the department for distribution to persons licensed under K.A.R. 28-35-181d or under an equivalent license of the nuclear regulatory commission (NRC) or an agreement state. Labeling for sources that do not require long-term storage may be on a leaflet or brochure that is to accompany the source; and

- (10) documentation that the source or device is listed on the nuclear regulatory commission's sealed source and device registry.
- (b)(1) If the applicant wants to have the source or device required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device, or similar sources or devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.
- (2) In determining the acceptable interval between tests for leakage of radioactive material, information that includes the following shall be considered by the secretary:
  - (A) The nature of the primary containment;
  - (B) the method for protection of the primary containment;
  - (C) the method of sealing the containment;
  - (D) containment construction materials;
  - (E) the form of the contained radioactive material;
  - (F) the maximum temperature withstood during prototype tests;

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- (H) the maximum quantity of contained radioactive material;
- (I) the radiotoxicity of contained radioactive material; and

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28-35-181t. Requirements for license to initially transfer source material for use under the small quantities of source material general license. (a) Each person submitting an application for a specific license to initially transfer source material for use in accordance with K.A.R. 28-35-177a, or equivalent regulations of an agreement state or the nuclear regulatory commission (NRC), shall meet the following requirements:

- (1) Meet the general requirements specified in K.A.R. 28-35-190a; and
- (2) provide information documenting that the NRC approves the methods for quality control, labeling, and providing safety instructions to recipients.
  - (b) Each person licensed under this regulation shall meet the following requirements:
- (1) Label the immediate container of each quantity of source material with the type of source material, the quantity of source material, and the words "radioactive material";
- (2) ensure that the quantities and concentrations of source material are labeled and indicated in any transfer records;
- (3) provide the following information to each person to whom source material is transferred for use under K.A.R. 28-35-177a or equivalent regulations of an agreement state or the NRC before the source material is transferred for the first time in each calendar year to each person:
- (A) A copy of K.A.R. 28-35-177a and K.A.R. 28-35-190a or relevant equivalent regulations of an agreement state or the NRC; and
- (B) appropriate radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the material;

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- (4) report transfers as follows, on or before January 31 of each year covering all transfers for the previous calendar year:
  - (A) File a report with the department. The report shall include the following information:
- (i) The name, address, and license number of the person who transferred the source material;
- (ii) the name and address of the general licensee to whom source material is distributed, a responsible agent by name or position, or both, the phone number of the general licensee to whom the material was sent, and the type, physical form, and quantity of source material transferred; and
- (iii) the total quantity of each type and physical form of source material transferred in the reporting period to all generally licensed recipients; and
- (B) file a report with each agreement state or the NRC if the transfer is to a person licensed by the NRC that identifies all persons operating under provisions equivalent to K.A.R. 28-35-177a to whom more than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information:
- (i) The name, address, and license number of the person who transferred the source material;
- (ii) the name and address of the general licensee to whom source material was distributed, a responsible agent by name or position, or both, the phone number of the general licensee to whom the material was sent, and the type, physical form, and quantity of source material transferred; and

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- (iii) the total quantity of each type and physical form of source material transferred in the reporting period to each generally licensed recipient within the agreement state; and
- (5) maintain all information that supports the reports required by this subsection concerning each transfer to a general licensee for one year after the transfer is included in a report to the NRC or to an agreement state.

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28-35-184a. Specific conditions on all licenses. (a) No license and no right under any license shall be assigned or otherwise transferred except as authorized under the act or these regulations and approved by the secretary in writing. Each request to assign or transfer a license shall include the following:

- (1) The name and the technical and financial qualifications of the proposed transferee; and
- (2) the financial assurance for decommissioning information required by K.A.R. 28-35-180b.
- (b) Each person authorized under these regulations shall confine the use and possession of the radioactive material licensed to the locations and purposes authorized in the license.
- (c) No person shall introduce radioactive material into any product or material knowing or having reason to believe that the product or material will be transferred to a person exempt from these regulations under K.A.R. 28-35-192a, 28-35-192b, 28-35-192c, 28-35-192d, 28-35-192e, 28-35-192f, or 28-35-192g or the equivalent regulations of the United States nuclear regulatory commission (NRC) or an agreement state, except in accordance with a specific license issued under K.A.R. 28-35-181f or the general license issued under K.A.R. 28-35-194a.
- (d) Each licensee shall file written notice with the secretary 30 days before vacating any facility when the licensee decides to permanently discontinue all activities involving licensed materials authorized in that facility under the license.
- (e) Each licensee authorized under K.A.R. 28-35-181h to distribute devices to generally licensed persons shall perform the following:
  - (1) Report to the department all sales or transfers of those devices to persons

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generally licensed under K.A.R. 28-35-178b. The report shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device. A report shall be submitted within 90 days of the sale or transfer; and

- (2) furnish, to each general licensee to whom the licensee transfers any such device, a copy of the general license issued under K.A.R. 28-35-178b.
- (f)(1) Each general licensee that is required by this part to register and each specific licensee shall notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11, bankruptcy, of the United States code by or against any of the following:
  - (A) The licensee;
- (B) any person controlling the licensee or listing the licensee or licensee as property of the estate; or
  - (C) any affiliate of the licensee.
  - (2) The notification specified in paragraph (f)(1) shall indicate the following:
- (A) The name of the bankruptcy court in which the petition for bankruptcy was filed; and
  - (B) the date of the filing of the petition.
- (g) Each portable gauge licensee shall use at least two independent physical controls that form tangible barriers to secure each portable gauge from unauthorized removal whenever the portable gauge is not under the control and constant surveillance of the licensee. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11,

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28-35-192a. Exemptions; source material. (a) Any Each person shall be exempt from these regulations to the extent the person who only acquires, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material, by weight, is less than 0.05 percent of the mixture, compound, solution, or alloy shall be exempt from these regulations.

- (b) Any Each person shall be exempt from these regulations to the extent the person who only acquires, possesses, uses, or transfers unrefined and unprocessed ore containing source material and does not refine or process the ore shall be exempt from these regulations.
- (c) Any Each person shall be exempt from these regulations to the extent the person who only acquires, possesses, uses, or transfers any of the following shall be exempt from the requirements for a license in part 3 of these regulations and the requirements of parts 4 and 10 of these regulations:
  - (1) Any quantities of thorium contained in any of the following:
  - (A) Incandescent gas mantles;
  - (B) vacuum tubes;
  - (C) welding rods;
- (D) electric lamps for illuminating purposes, if each lamp does not contain more than 50 milligrams of thorium;
- (E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, if each lamp does not contain more than two grams of thorium;
- (F) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent thorium or uranium, or both, by weight; or

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- (G) personnel neutron dosimeters, if each dosimeter does not contain more than 50 milligrams of thorium;
  - (2) source material contained in any of the following:
- (A) Glazed ceramic tableware, if the glaze contains not more than 20 percent source material, by weight;
- (B) glassware, containing not more than two percent of source material by weight or, for glassware manufactured before August 27, 2013, 10 percent of source material by weight. This exemption shall not include commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction; and
- (C) glass enamel or glass enamel frit that contains not more than 10 percent of source material, by weight, and that was imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or
- (D) piezoelectric ceramic containing not more than two percent of source material by weight;
  - (3) photograhic film, negatives, and prints containing uranium or thorium;
- (4) any finished product or part of a product fabricated of, or containing, tungsten or magnesium-thorium alloys if the thorium content of the alloy does not exceed four percent, by weight. The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any product or part of a product;
- (5) uranium contained in counterweights installed in aircraft, rockets, projectiles or missiles or stored or handled in connection with installation or removal of these counterweights

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when:

- (A) the counterweights are manufactured in accordance with the specifications contained in a specific license issued by the secretary, the United States nuclear regulatory commission or an agreement state, and when distribution by the licensee is authorized pursuant to this paragraph or an equivalent provision of the regulations of the United States nuclear regulatory commission or an agreement state;
- (B) each counterweight has been impressed in a manner that is clearly legible through any plating or covering with the following legend: "DEPLETED URANIUM"; and
- (C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer, and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED". The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any counterweights, other than repair or restoration of any plating or other covering;
- (6) uranium used as shielding and constituting part of any shipping container. The uranium shielding shall be conspicuously and legible legibly impressed with the legend words "CAUTION—RADIOACTIVE SHIELDING—URANIUM" and shall be enclosed in mild steel containing no more than 0.25 percent carbon, or another equally fire-resistant metal, with a minimum wall thickness of one-eighth inch (3.2 mm);
- (7) (6) thorium or uranium contained in finished optical lenses, if each lens does not contain more than 30 percent of thorium or uranium by weight or, if manufactured after August 27, 2013, 10 percent of thorium or uranium by weight. The exemption contained in this

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paragraph shall not be deemed to authorize either of the following:

- (A) The shaping, grinding, or polishing of the lens or any manufacturing processes other than the assembly of the lens into optical systems and devices without any alteration of the lens; or
- (B) the receipt, possession, use, or transfer of thorium <u>or uranium</u> contained in contact lenses, or in <del>spectacles</del> <u>eyeglasses</u>, or in eyepicces in binoculars or other optical instruments;
- (8) (7) uranium contained in detector heads for use in fire detection units, if each detector head contains not more than 0.005 microcurie of uranium; and or
- (9) (8) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, if both of the following conditions are met:
- (A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and
  - (B) the thorium content in the nickel-thoria alloy does not exceed four percent by weight.
- (d) The exemptions provided in this regulation shall not authorize the manufacture, processing or production of any of the products described in this regulation.
- (1) Each person who acquires, possesses, uses, or transfers uranium contained in counterweights installed in aircraft, rockets, projectiles or missiles or stored or handled in connection with installation or removal of these counterweights, except counterweights manufactured before December 31, 1969 under a specific license issued by the atomic energy commission and impressed with the legend required by that license, shall be exempt from the requirements for a license in part 3 of these regulations and the requirements of parts 4 and

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10 of these regulations if both of the following conditions are met:

- (A) Each counterweight has been impressed in a manner that is clearly legible through any plating or covering with the following words: "DEPLETED URANIUM."
- (B) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the following words: "UNAUTHORIZED ALTERATIONS

  PROHIBITED."
- (2) The exemption specified in this subsection shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any counterweights, other than repair or restoration of any plating or other covering.
- (e)(1) No person shall initially transfer for sale or distribution a product containing source material to any persons exempt under subsections (c) and (d) or equivalent regulations of an agreement state, unless authorized by a license issued by the nuclear regulatory commission (NRC) to initially transfer the products for sale or distribution.
- (2) Each person authorized by an agreement state to manufacture, process, or produce materials or products containing source material and each person who imports finished products or parts for sale or distribution shall be authorized by a license issued by the NRC for distribution only. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-\_\_\_\_\_\_\_\_.)

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28-35-192c. Exceptions; other radioactive material. Except for persons who apply tritium, promethium-147, or radium to, or persons who incorporate tritium, promethium-147, or radium into, the products listed in this regulation, any each person shall be exempt from these regulations to the extent that the person who only acquires, possesses, uses, or transfers any of the following products shall be exempt from these regulations:

- (a) Timepieces or hands or dials containing radium, or timepieces, hands, or dials containing not more than the following specified quantities of other radioactive materials:
  - (1) 25 millicuries of tritium per timepiece;
  - (2) 5 millicuries of tritium per hand;
- (3) 15 millicuries of tritium per dial. Bezels, when used, shall be considered as part of the dial:
- (4) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;
- (5) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per hand on other timepieces;
- (6) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per dial on other timepieces. Bezels, when used, shall be considered as part of the dial. The levels of radiation from hands and dials containing promethium-147 shall not exceed the following, when measured through 50 milligrams per square centimeter of absorber:
  - (A) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;
  - (B) for pocket watches, 0.1 millirad per hour at one centimeter from any surface; and
  - (C) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface;

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and

- (7) for intact timepieces manufactured before November 30, 2007, 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece;
- (b) balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;
- (c) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;
- (d) ionization chamber smoke detectors containing not more than one microcurie (µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires;
- (e) electron tubes. The levels of radiation from each electron tube containing radioactive material shall not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this subsection, "electron tubes" shall include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents. An electron tube shall not contain more than one of the following specified quantities of radioactive material:
- (1) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;
  - (2) I microcurie cobalt-60;

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- (3) 5 microcuries nickel-63;
- (4) 30 microcuries krypton-85;
- (5) 5 microcuries cesium-137; or
- (6) 30 microcuries promethium-147; and
- (f) ionizing radiation-measuring instruments containing, for purposes of internal calibration or standardization, sources of radioactive material. No source shall exceed the applicable quantity set forth specified in K.A.R. 28-35-197a 28-35-197b. No single instrument shall contain more than 10 sources. For the purposes of this subsection, 0.05 μCi of Am-241 shall be considered an exempt quantity. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended March 18, 2011; amended P-\_\_\_\_\_\_\_\_\_.)

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28-35-192g. Exemptions; exempt quantities. (a) Except as provided in subsections (c) through (e), each person who acquires, possesses, uses, owns, receives, or transfers radioactive material in individual quantities that do not exceed the applicable quantity specified in K.A.R. 28-35-197a 28-35-197b shall be exempt from these regulations.

- (b) Each person who possesses radioactive material received or acquired before January 1, 1972 under the general license then provided in K.A.R. 28-35-178a shall be exempt from these regulations to the extent that the person possesses, uses, owns, or transfers that radioactive material. This exemption shall not apply to radium-226.
- (c) This regulation shall not authorize the production, packaging, repackaging, or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
- (d) No person shall, for purposes of commercial distribution, transfer radioactive material in the individual quantities specified in K.A.R. 28-35-197a 28-35-197b knowing, or having reason to believe, that those quantities of radioactive material will be transferred to a person exempt under this regulation or an equivalent regulation of the nuclear regulatory commission (NRC) or an agreement state, except in accordance with a specific license issued by the secretary under K.A.R. 28-35-181r, an equivalent regulation of the nuclear regulatory commission NRC, or an equivalent regulation of an agreement state.
- (e) No person shall, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the individual quantities specified in K.A.R. 28-35-197a 28-35-197b. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986;

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28-35-192h. Certain industrial devices. (a) Except as specified in subsections (b) and (c), each person who receives, possesses, uses, transfers, owns, or acquires any industrial device containing by-product material designed and manufactured for either of the following purposes shall be exempt from these regulations:

- (1) Detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition; or
- (2) producing an ionized atmosphere if the industrial device is manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the nuclear regulatory commission (NRC).
- (b) Each person who manufactures, processes, produces, or initially transfers for sale or distribution any industrial device containing by-product material designed and manufactured for either of the following purposes shall be excluded from the exemption in subsection (a):
- (1) Detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition; or
  - (2) producing an ionized atmosphere.
- (c) The exemption in subsection (a) shall exclude any source not incorporated into an industrial device, including calibration and reference sources.
- (d) Each person who manufactures, processes, produces, or initially transfers for sale or distribution any industrial device containing by-product material for use under subsection (a) shall apply for a license and a certificate of registration from the NRC. (Authorized by and implementing K.S.A. 48-1607; effective P-\_\_\_\_\_\_\_.)

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28-35-197a. (Authorized by and implementing K.S.A	. 1984 Supp.	48-1607; effective	e, T-
86-37, Dec. 11, 1985; effective May 1, 1986; revoked P-			.)

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28-35-1976. Schedule B; exempt q	uantities of radioactive material. The provisions of
10 C.F.R. 30.71, as in effect on October 1, 2	2007, are hereby adopted by reference, except that the
word "byproduct" shall be replaced with "ra	adioactive." (Authorized by and implementing K.S.A
48-1607; effective P-	.)

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28-35-205b. Alternate criteria for license termination. (a) A license shall be terminated by the secretary using alternate criteria greater than the dose criteria specified in K.A.R. 28-35-205a(d) only if the licensee provides all of the following information:

- (1) (a) Evidence that public health and safety and the environment would continue to be protected and that it is unlikely that the dose from all manmade sources combined, other than medical, could be more than the limit of one millisievert per year or 100 mrem per year specified in part 4 of these regulations, by submitting an analysis of the possible sources of exposure;
- (2) (b) restrictions, to the extent practical, on site use according to the provisions of K.A.R. 28-35-205a to minimize exposure at the site;
- (3) (c) evidence that doses have been reduced to ALARA levels, taking into consideration any detriment, including any traffic accidents that could result from decontamination and waste disposal; and
- (4) (d) a decommissioning plan indicating the licensee's intent to decommission in accordance with this part and specifying that the licensee proposes to decommission by the use of alternate criteria. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who might be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking this advice, the licensee shall provide for the following:
- (A) (1) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;
- (B) (2) an opportunity for comprehensive, collective discussions of the issues by the participants represented; and

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(C) (3) a publicly available summary of the results of all the discussions specified in paragraph (4)(B) of this subsection (d)(2), including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues among the participants; and

(e) sufficient financial assurance, as specified in K.A.R. 28-35-180b, to enable an independent third party, including a governmental custodian of a site, to assume and carry out the responsibilities for any necessary control and maintenance of the site.

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28-35-217b. General monitoring requirements. (a) Each licensee or registrant shall make, or cause to be made, surveys of each area of use, including the subsurface, that meet the following requirements:

- (1) Provide measurements or evaluations demonstrating compliance with these regulations; and
  - (2) are necessary under the circumstances to evaluate the following:
  - (A) Radiation and radiological contamination levels;
  - (B) concentrations or quantities of radioactive material; and
  - (C) the potential radiological hazards that could be present.
- (b) Records from surveys describing the location and amount of subsurface residual radioactivity identified at the facility out to the site boundary shall be kept on file with records required for decommissioning.
- (c) The Each licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, are calibrated at intervals not to exceed 12 months, for the type of radiation measured.
- (c) (d) The Each licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual\_monitoring device.
- (e) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities that require processing to determine the radiation dose and are used by licensees to comply with these regulations or with conditions specified in a license, shall be processed and evaluated by a dosimetry processor that meets the following requirements:

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(1) Holds current personnel dosimetry accreditation from the national voluntary

laboratory accreditation program (NVLAP) of the national institute of standards and technology;

and

(2) is accredited for the type of radiation or radiations included in the NVLAP program
that most closely approximates the type of radiation or radiations for which the individual
wearing the dosimeter is monitored. (Authorized by and implementing K.S.A. 1993 Supp. 48-
1607; effective Oct. 17, 1994; amended P)

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28-35-221a. Procedures for picking up, <u>transporting</u>, receiving, and opening packages. (a)(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of the type A quantities specified in K.A.R. 28-35-221b shall meet one of the following requirements:

- (A) If the package is to be delivered to the licensee's or registrant's facility by the carrier, shall make arrangements to receive the package when it is offered for delivery by the carrier; or
- (B) if the package is to be picked up by the licensee or registrant at the carrier's terminal, shall make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.
- (2) Each licensee or registrant who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its the arrival of the package.
- (b) Each licensee or registrant shall ensure that external radiation levels around any package specified in subsection (a) and, if applicable, external radiation levels around the vehicle transporting the package do not exceed 200 millirems per hour (2 mSv/hr) at any point on the external surface of the package or vehicle at any time during transportation. The transport index shall not exceed 10.
- (c)(1) For the purpose of this subsection, "exclusive use" shall have the meaning specified in 10 C.F.R. 71.4, dated January 1, 2015 and hereby adopted by reference.
- (2) For each package specified in subsection (a) and transported in exclusive use, radiation levels external to the package may exceed the limits specified in subsection (d) but shall not exceed any of the following:

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(A) 200 millirems per hour (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit shall be 1,000 millirems per hour (10 mSv/hr):

(i) The shipment is made in a closed transport vehicle. For the purposes of this subsection, "closed transport vehicle" shall mean a vehicle or conveyance equipped with a securely attached exterior enclosure that, during normal transportation, restricts the access of unauthorized persons to the cargo space containing a package specified in subsection (a). The enclosure can be either temporary or permanent and, in the case of packaged materials, can be the see-through type that limits access from top, sides, and bottom;

(ii) the package is secured so that its position within the closed transport vehicle remains fixed during transportation; and

(iii) no loading or unloading operations occur between the beginning and end of the transportation;

(B) 200 millirems per hour (2 mSv/hr) at any point on the outer surface of the closed transport vehicle, including the upper and lower surfaces, or for a flatbed-style closed transport vehicle with a personnel barrier, at any point on the vertical planes projected from the outer edges of the closed transport vehicle, on the upper surface of the load, and on the lower external surface of the closed transport vehicle;

(C)10 millirems per hour (0.1 mSv/hr) at any point two meters from the vertical planes represented by the outer lateral surfaces of the closed transport vehicle, or, in the case of a flatbed-style closed transport vehicle, at any point two meters from the vertical planes projected from the

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outer edges of the closed transport vehicle; or

(D) two millirems per hour (0.02 mSv/hr) in any normally occupied positions in the closed transport vehicle, except that this paragraph shall not apply to private motor carriers if each person occupying any of these positions in the closed transport vehicle is provided with a personnel-monitoring device and training in accordance with K.A.R. 28-35-333.

(d) Each licensee or registrant, upon receipt of a any package of radioactive material, shall monitor the external surfaces of each package labeled with the U.S. department of transportation radioactive white I<sub>5</sub> or radioactive yellow II or III labels, as specified in 49 CFR C.F.R. 172.403 and 172.436-440 in effect January 1, 1993, for radioactive contamination caused by leakage of the radioactive contents. Each licensee or registrant shall also monitor for radiation levels on of each package containing quantities of radioactive materials that are equal to or more than or equal to the type A quantity defined specified in K.A.R. 28-35-221b. Each licensee or registrant shall monitor each package known to contain radioactive materials for radioactive contamination and radiation levels if there is evidence of degradation of package integrity. The monitoring shall be performed as soon as practicable after receipt, but not later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours or three hours from the beginning of the next working day if received after normal working hours. The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the department when under either of the following conditions:

(A) (1) Removable radioactive surface contamination exceeds the limits of K.A.R. 28-35-

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## 221b table V of these regulations; or the following maximum permissible limits:

Contaminant	Maximum Permissible Limits			
	Bq/cm <sup>2</sup>	uCi/cm <sup>2</sup>	dpm/cm <sup>2</sup>	
Beta and gamma emitters and low-toxicity	<u>′</u>			
alpha emitters	<u>4</u>	10-4	220	
All other alpha-emitting radionuclides	<u>0.4</u>	10-5	<u>22</u>	

- (B) (2) External radiation levels exceed the limits of specified in K.A.R. 28-35-221b(e) and (f).
- (c) Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall assure can that these procedures are followed and that due consideration is given to special instructions any special instructions are followed for the type of package being opened.

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28-35-221b. Appendix A; determination of  $A_{1_2}$  and  $A_{2_3}$  and B quantities. (a) Single-radionuclides.

- (1) For a single radionuclide of known identity, the values of  $A_1$  and  $A_2$  shall be taken from Table I if listed there. The values  $A_1$  and  $A_2$  in Table I shall also be applicable for the radionuclide contained in  $(\propto, n)$  or  $(\gamma, n)$  neutron-sources.
- (2) For any single radionuclide whose identity is known but which is not listed in Table I, the value of  $A_1$  and  $A_2$  shall be determined according to the following procedure:
- (Λ) If the radionuclide emits only one type of radiation, Λ<sub>1</sub>-shall be determined according to the following method. For radionuclides emitting different kinds of radiation, the value of Λ<sub>1</sub>-shall be the most restrictive value of those determined for each kind of radiation. However, in either case, Λ<sub>1</sub>-shall be no more than 1000 curies (37 TBq). If a parent nuclide decays into a shorter lived daughter with a half-life not greater than 10 days, Λ<sub>1</sub>-shall be calculated for both the parent and the daughter, and the more limiting of the two values shall be assigned to the parent nuclide.
  - (i) For gamma emitters, A<sub>1</sub>-shall be determined by the expression:

$$A_1 = \underline{9}$$
 curies

where  $\Gamma$  is the gamma-ray constant, corresponding to the dose in roentgens per curie-hour at one meter, and the number nine results from the choice of one rem per hour at a distance of three meters as the reference dose equivalent rate.

(ii) For x-ray emitters, A<sub>1</sub>-shall be determined by the atomic number of the nuclide:

for 
$$Z > 55$$
,  $A_1 = 200 \text{ Ci } (7.4 \text{ TBq})$ 

where Z is the atomic number of the nuclide.

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(iii) For beta emitters, A<sub>1</sub> shall be determined by the maximum beta energy (E<sub>max</sub>) according to Table II; and

(iv) For alpha emitters, A<sub>1</sub> shall be determined by the expression:

 $A_1 = 1000 - A_2$ 

where A: is the value listed in Table III;

- (B) A₂ is the more restrictive of the following two values:
- (i) The corresponding  $A_1$ ; and
- (ii) The value A3-obtained from Table III.
- (3) For any single radionuclide whose identity is unknown, the value of Λ<sub>1</sub> shall be taken to be 2 Ci (74 GBq) and the value of Λ<sub>2</sub> shall be taken to be 0.002 Ci (74 MBq). However, if the atomic number of the radionuclide is known to be less than 82, the value of Λ<sub>1</sub>, shall be taken to be 10 Ci (370 GBq) and the value of Λ<sub>2</sub> shall be taken to be 0.4 Ci (14.8 GBq).
  - (b) Mixtures of radionuclides, including radioactive decay chains.
- (1) For mixed fission products, the following activity limit shall be assumed if a detailed analysis of the mixture is not carried out.

 $A_1 = 10 \text{ Ci } (370 \text{ GBq})$ 

 $A_2 = 0.4 \text{ Ci } (14.8 \text{ GBa})$ 

(2) A single radioactive decay chain shall be considered to be a radionuclide when the radionuclides are present in their naturally occurring proportions and no daughter nuclide has a half-life either longer than ten days or longer than that of the parent nuclide. The activity to be taken into account and the  $A_1$ -or  $A_2$ -value from table I to be applied are those corresponding to the parent nuclide of that chain. When calculating  $A_1$  or  $A_2$ -values, radiation

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emitted by daughters shall be considered. However, in the case of radioactive decay chains in which any daughter nuclide has a half life either longer than ten days or greater than that of the parent nuclide, the parent and daughter nuclides shall be considered to be mixtures of different nuclides.

(3) In the case of a mixture of different radionuclides, where the identity and activity of each radionuclide are known, the permissible activity of each radionuclide  $R_1$ ,  $R_2 \dots R_n$  is such that  $F_1$ ,  $F_2 + \dots F_n$  is not greater than unity, where:

$$F_{1} = \frac{\text{total activity of } R_{1}}{A_{1}(R_{1})}$$

$$F_{2} = \frac{\text{total activity of } R_{2}}{A_{1}(R_{2})}$$

$$F_{n} = \frac{\text{total activity of } R_{2n}}{A_{1}(R_{n})}$$

 $A_1$  ( $R_1$ ,  $R_2$  . . . .  $R_n$ ) is the value of  $A_1$  or  $A_2$  as appropriate for the nuclide  $R_1$ ,  $R_2$  . . . .  $R_n$ 

(4)-When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the formula given in paragraph three shall be applied to establish the values of  $A_1$  or  $A_2$  as appropriate. All the radionuclides whose individual activities are not known (their total activity will, however, be known) shall be classed in a single group and the most restrictive value of  $A_1$  or  $A_2$  applicable to any one of them shall be used as the value of  $A_1$  or  $A_2$  in the denominator of the fraction.

(5) Where the identity of each radionuclide is known but the individual activity of none of the radionuclides is known, the most restrictive value of  $A_1$  or  $A_2$ -applicable to any one of the radionuclides present shall be adopted as the applicable value.

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(6) When the identity of none of the nuclides is known, the value of  $\Lambda_1$ -shall be taken to be 2 Ci (74 GBq) and the value of  $\Lambda_2$ -shall be taken to be 0.002 Ci (74 MBq). However, if alpha emitters are known to be absent, the value of  $\Lambda_2$ -shall be taken to be 0.4 Ci (14.8 GBq).

Table I

A<sub>1</sub>-and A<sub>2</sub>-Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A <sub>l</sub> ( <del>Ci)</del>	A₂( <del>Ci)</del>	Specifie Activity (Ci/g)
Ac-227	Actinium (89)	1000	0.003	$7.2 \times 10^{1}$
Ac 228		10	4	$2.2 \times 10^{6}$
Aq-105	Silver (47)	<del>40</del>	40	$3.1 \times 10^4$
<del>Aq-110m</del>		7	7	$4.7 \times 10^{3}$
Aq-111		100	<del>20</del>	$1.6 \times 10^{5}$
Am-241	Americium (95)	8	800.0	3.2
Am-243		8	0.008	$1.9 \times 10^{-1}$
Ar 37 (compressed or uncompressed)*	Argon (18)	1000	1000	$1.0\times10^{5}$
Ar-41 (uncompressed)*		<del>20</del>	<del>20</del>	$4.3 \times 10^{2}$
Ar-41-(compressed)*		4	1	$4.3\times10^{7}$
As 73	Arsenie (33)	1000	400	$2.4 \times 10^4$
As 74		20	20	1.0×10 <sup>-5</sup>
As 76		10	10	$1.6 \times 10^{6}$
As 77		300	20	$1.1 \times 10^{6}$
At-211	Astatine (85)	200	7	$2.1 \times 10^{6}$

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Cd-109	<del>Cadmium (48)</del>	1000	<del>70</del>	$2.6 \times 10^{3}$
<del>Ca 47</del>		<del>20</del>	<del>20</del>	5.9 × 10 <sup>5</sup>
<del>Ca-45</del>	<del>Caleium (20)</del>	1000	<del>25</del>	$1.9 \times 10^4$
C-14		1000	<del>60</del>	4.6
C-11	<del>Carbon (6)</del>	20	. 20	$8.4 \times 10^{8}$
Br-82		6	6	$1.1 \times 10^{6}$
Br-77	Bromine (35)	<del>70</del>	<del>25</del>	$7.1 \times 10^{5}$
Bk-249	<del>Berkelium (97)</del>	1000	1	$1.8\times10^3$
Bi-212		6	6	$1.5\times10^{7}$
Bi-210 (RaE)		100	4	$1.2 \times 10^{5}$
Bi-207		10	10	$2.2 \times 10^{2}$
Bi 206	Bismuth (83)	5	5	9.9 × 10 <sup>4</sup>
Be-7	<del>Beryllium (4)</del>	<del>300</del>	300	$3.5 \times 10^{5}$
<del>Ba-140</del>		20	<del>20</del>	$7.3 \times 10^4$
<del>Ba-133</del>		40	40	$4.0 \times 10^{2}$
<del>Ba-131</del>	<del>Barium (56)</del>	40	40	8.7 ×10⁴
AU-199		200	<del>25</del>	$2.1 \times 10^{5}$
Symbol of radionuclide	Element and atomic number	A <sub>I</sub> (Ci)	A₂ <del>(Ci)</del>	<del>Specific</del> <del>Activity</del> <del>(Ci/g)</del>
7xu 170	Table I (C	Sontinued 2)	<del>≟∀</del>	<del>2.3 / 10</del>
Au 198		<del>30</del>	<del>20</del>	$\frac{1.2 \times 10}{2.5 \times 10^5}$
Au 196	Gold (75)	30	3 <del>0</del>	1.2 ×10 <sup>5</sup>
<del>Au 193</del>	Go <del>ld (79)</del>	<del>200</del>	200	9.3 × 10 <sup>5</sup>
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Cd-115m		30	<del>30</del>	$2.6 \times 10^4$
Cd-115		80	<del>20</del>	$5.1 \times 10^{5}$
Ce-139	Cerium (58)	100	100	$6.5 \times 10^3$
Ce-141		300	<del>25</del>	$2.8 \times 10^4$
Ce-143	·	60	<del>20</del>	$6.6 \times 10^{5}$
Ce-144		10	7	$3.2 \times 10^3$
Cf-249	California (98)	2	0.002	3.1
	<del>Table I (C</del> e	entinued-3)		
Symbol of radionuclide	Element and atomic number	A <sub>1</sub> (Ci)	Ag <del>(Ci)</del>	Specific Activity (Ci/g)
Cf-250		7	0.007	$1.3 \times 10^{2}$
Cf-252		2	0.009	$6.5 \times 10^{2}$
Cl-36	Chlorine (17)	300	<del>10</del> .	$3.2 \times 10^{-2}$
<del>Cl-38</del>		10	10	$1.3 \times 10^{8}$
<del>Cm-242</del>	<del>Curium (96)</del>	<del>200</del>	0.2	$3.3 \times 10^3$
Cm-243		9	0.009	4.2 × 10 <sup>1</sup>
<del>Cm-244</del>		10	0.01	$8.2 \times 10^{1}$
Cm-245		6	0.006	$1.0 \times 10^{-1}$
Cm-246		6	0.006	$3.6 \times 10^{-1}$
<del>Co 5</del> 6	Cobalt (27)	5	5	$3.0 \times 10^4$
<del>Co-57</del>		90	90	$8.5 \times 10^3$
Co-58m		1000	1000	$5.9 \times 10^{6}$
<del>Co-58</del>	RECEIVED	<del>20</del>	20	$3.1 \times 10^4$
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<del>Co-60</del>			7	7	$1.1 \times 10^3$
<del>Cr-51</del>		Chromium (24)	600	600	$9.2 \times 10^4$
Cs-129		Cesium (55)	<del>40</del>	40	$7.6 \times 10^5$
Cs-131			1000	1000	$1.0 \times 10^{5}$
Cs-134m			1000	10	7.4 × 10 <sup>6</sup>
Cs-134			10	10	$1.2 \times 10^{3}$
Cs-135			1000	25	$8.8 \times 10^{-1}$
Cs-136			7	7	$7.4 \times 10^4$
Cs-137			30	10	$9.8 \times 10^{1}$
<del>Cu-6</del> 4		Copper (29)	80	<del>25</del>	$3.8 \times 10^{6}$
Cu-67			200	25	$7.9 \times 10^{5}$
		<del>Table-1-(Co</del>	ontinued-4)		
Symbol of radionuclide	<del>3</del>	Element and atomic number	A <sub>4</sub> ( <del>Ci)</del>	A <sub>2</sub> (Ci)	Specific Activity (Ci/g)
<del>Dy 165</del>		<del>Dysprosium (66)</del>	100	20	$8.2 \times 10^{6}$
<del>Dy 166</del>			1000	200	$2.3 \times 10^{5}$
<del>Er-169</del>		Erbium (68)	1000	<del>25</del>	$8.2 \times 10^4$
<del>Er-171</del>			50	20	$2.4 \times 10^6$
<del>Eu-152m</del>		Europium (63)	30	30	$2.2 \times 10^6$
<del>Eu-152</del>			20	10	$1.9 \times 10^2$
Eu-154			40	5	$1.5 \times 10^{2}$
Eu-155			400	60	$1.4 \times 10^3$
F-18		Fluorine (9)	20	20	9.3 × 10 <sup>7</sup>
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Fe-52	<del>Iron (26)</del>	<del>5</del>	5	$7.3 \times 10^{6}$			
Fe-55		1000	1000	$2.2 \times 10^{3}$			
Fe-59		10	40	4.9×10 <sup>4</sup>			
<del>Ga-67</del>	<del>Gallium (31)</del>	100	100	$6.0 \times 10^{5}$			
<del>Ga-68</del>		10	20	$4.0 \times 10^{7}$			
<del>Ga-72</del>		7	7	$3.1 \times 10^6$			
Gd-153	<del>Gadolinium (6</del> 4	) 200	100	$3.6 \times 10^{3}$			
Gd-159		300	<del>20</del>	$1.1 \times 10^{6}$			
Ge-68	<del>Germanium (32</del>	) 20	<del>10</del>	$7.0 \times 10^{3}$			
Ge-71		1000	1000	$1.6 \times 10^{5}$			
H-3	Hydrogen (1) see T-Tritium						
Hf-181	Hafnium (72)	30	<del>25</del>	$1.6 \times 10^4$			
Hg-197m	Mercury (80)	200	<del>20</del> 0	$6.6 \times 10^{5}$			
Hg-197		200	200	$2.5 \times 10^{3}$			
	<del>Table I</del>	(Continued-5)	i				
Symbol of radionuclide	Element and atomic number	A <sub>4</sub> ( <del>Ci)</del>	A <sub>2</sub> ( <del>Ci)</del>	<del>Specific</del> Activity ( <del>Ci/g)</del>			
Hg 203		80	<del>25</del>	$1.4 \times 10^4$			
<del>Ho 166</del>	Holmium (67)	<del>30</del>	<del>30</del>	$6.9 \times 10^{5}$			
1-123	Iodine (53)	<del>50</del>	<del>50</del>	$1.9 \times 10^{6}$			
I-125		1000	<del>70</del>	$1.7 \times 10^4$			
I-126		40	10	$7.8 \times 10^4$			
I <del>-129</del>		1000	2	$1.6 \times 10^{-4}$			
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<del>I 131</del>			40	<del>10</del>	$1.2 \times 10^5$
<del>I 132</del>			7	7	$1.1 \times 10^{7}$
I-133			<del>30</del>	10	$1.1 \times 10^{6}$
<del>I 13</del> 4			8	8	$2.7 \times 10^{7}$
<u>I-135</u>			10	10	$3.5 \times 10^{6}$
In-1-1-1		Indium (49)	30	<del>25</del>	$4.2 \times 10^{5}$
In-113m			60	60	$1.6 \times 10^{2}$
<del>In-114m</del>			30	<del>20</del>	$2.3 \times 10^4$
I <del>n-115m</del>			100	<del>20</del>	$6.1 \times 10^6$
<del>Ir-190</del>		<del>Iridium (77)</del>	10	<del>10</del>	$6.2 \times 10^4$
<del>Ir-192</del>			20	10	$9.1 \times 10^{3}$
Ir-194			10	10	8.5 × 10 <sup>5</sup>
<del>K-42</del>		Pottassium (19)	10	10	6.0 × 10 <sup>6</sup>
K-43			20	10	$3.3 \times 10^6$
Kr-85m (un	<del>.compressed)*</del>	Krypton (36)	100 ·	100	$8.4 \times 10^6$
Kr-85m (compressed)*			3	3	$8.4 \times 10^6$
Kr-85 (unco	<del>ompressed)*</del>		1000	1000	$4.0 \times 10^{2}$
<del>Kr 85 (com</del>	<del>pressed)*</del>		\$	5	$4.0\times10^2$
		<del>Table I (Co</del>	entinued 6)		
<del>Symbol of</del> radionuclide		Element and atomic number	A <sub>I</sub> (Ci)	A <sub>2</sub> (Ci)	<del>Specific</del> <del>Activity</del> <del>(Ci/g)</del>
Kr-87 (unce	ompressed)*		<del>20</del>	<del>20</del>	$2.8 \times 10^{7}$
Kr-87-(compressed)*			0.6	0.6	$2.8 \times 10^{7}$
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<del>La 140</del>	Lanthanum (57)	<del>30</del>	30	$5.6 \times 10^{5}$
<del>Lu-177</del>	Lutetium (71)	300	25	$1.1 \times 10^{\$}$
MFP	Mixed Fission- products	10	0.4	
Mg-28	Magnesium (12)	6	6	$5.2 \times 10^{6}$
Mn-52	Manganese (25)	5	5	4.4-×-10 <sup>5</sup>
Mn-54		<del>20</del>	20	$8.3 \times 10^{3}$
Mn-56		5	5	$2.2 \times 10^{7}$
Mo-99	Molybdenum (42)	100	<del>20</del>	$4.7 \times 10^{5}$
N-13	Nitrogen-(7)	<del>20</del>	10	$1.5 \times 10^{9}$
Na 22	Sodium (11)	8	8	$6.3 \times 10^{3}$
<del>Na 24</del>		5	<del>5</del>	$8.7 \times 10^{6}$
Nb-93m	Niobium (41)	1000	<del>200</del>	$1.1 \times 10^{3}$
Nb-95		20	<del>20</del>	$3.9 \times 10^4$
Nb-97		<del>20</del>	20	$2.6 \times 10^{7}$
Nd-147	Neodymium (60)	100	20	$8.0 \times 10^{4}$
Nd-149		<del>30</del>	20	$1.1 \times 10^{2}$
Ni 59	Nickel (28)	1000	900	8.1 ×10 <sup>-2</sup>
Ni-63		1000	100	4.6-×-10 <sup>1</sup>
Ni-65		10	10	$1.9 \times 10^{7}$
Np-237	Neptunium (93)	5	0.005	6 <del>.9 ×10 -1</del>
Np-239		200	25	$2.3 \times 10^{5}$

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# Table I (Continued 7)

Symbol of radionuclide	Element and atomic number	A <sub>4</sub> ( <del>Ci)</del>	A <sub>2</sub> <del>(Ci)</del>	S <del>pecific</del> Activity (Ci/g)
Os-185	Osmium (76)	20	20	$7.3 \times 10^3$
Os-191		600	<del>200</del>	4. <del>6 × 10</del> <sup>4</sup>
Os-191 m		<del>200</del>	<del>200</del>	$1.2 \times 10^{6}$
Os 193		100	20	$5.3 \times 10^{5}$
<del>P-32</del>	Phosphorus (15	<del>5)</del> 30	<del>30</del>	2.9 × 10 <sup>5</sup>
<del>Pa 230</del>	<del>Protactinium (</del> 9	<del>21)</del> 20	8.0	$3.2 \times 10^4$
Pa 231		2	0.002	$4.5 \times 10^{-2}$
<del>Pa 233</del>		100	100	2.1-×-10) <sup>4</sup>
Pb-201	<del>Lead (82)</del>	<del>20</del>	<del>20</del>	1.7×10 <sup>6</sup>
<del>Pb-210</del>		100	0.2	$8.8 \times 10^{1}$
Pb-212		6	5	1.4×10 <sup>6</sup>
<del>Pd-103</del>	<del>Palladium (46)</del>	1000	700	$7.5 \times 10^4$
<del>Pd-109</del>		100	<del>20</del>	$2.1 \times 10^{6}$
Pm-147	Promethium (6	<del>1)</del> 1000	25	$9.4 \times 10^{2}$
Pm-149		40	<del>20</del>	$4.2 \times 10^{5}$
Po-210	Polonium (84)	<del>200</del>	0.2	$4.5 \times 10^{3}$
Pr-142	Praseodymium	<del>(59)</del> <del>10</del>	10	$1.2 \times 10^4$
Pr-143		<del>300</del>	<del>20</del>	6.6 × 10 <sup>4</sup>
Pt 191	<del>Platinum (78)</del>	100	100	2.3 ×10 <sup>5</sup>
<del>Pt-193m</del>	Pote Viell the to	<del>200</del>	<del>200</del>	2.0-×10 <sup>5</sup>
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<del>Pt-197m</del>		<del>300</del> ·	<del>20</del>	$1.2 \times 10^{-2}$
Pt-197		<del>300</del>	<del>20</del>	$8.8 \times 10^{5}$
<del>Pu 238</del>	Plutonium (94)	3	0.003	$1.7 \times 10^{1}$
Pu-239		<del>2</del>	0.002	$6.2 \times 10^{-2}$
	Table I (Co	ontinued-8)		
Symbol of radionuclide	Element and atomic number	A <sub>1</sub> (Ci)	A₂ <del>(Ci)</del>	Specific Activity (Ci/g)
Pu-240		2	0.002	$2.3 \times 10^{-1}$
<del>Pu-241</del>		1000	0.1	$1.1 \times 10^{2}$
Pu-242		3	0.003	$3.9 \times 10^{-3}$
Ra-223	<del>Radium (88)</del>	<del>50</del>	0.2	5.0 ×-10 <sup>4</sup>
Ra-224		6	0.5	1.6 × 10 <sup>5</sup>
<del>Ra 226</del>		10	0.05	1.0
<del>Ra-228</del>		10	0.05	$2.3 \times 10^{2}$
<del>Rb-81</del>	Rubidium (37)	<del>30</del>	24	$8.2 \times 10^6$
Rb-86		<del>30</del>	30	$8.1 \times 10^{4}$
<del>Rb-87</del>		Unlimited	Unlimited	6.6 × 10 *
Rb (natural)		Unlimited	Unlimited	1.8 × 10 *
Re-186	Rhenium (75)	100	<del>20</del>	$1.9 \times 10^5$
Re-187		Unlimited	Unlimited	3.8 × 10 *
<del>Re-188</del>		10	10	1.0-x-10 <sup>6</sup>
Re (natural)		Unlimited	Unlimited	2.4×10*
Rh-103m	Rhodium (45)	1000	1000	$3.2 \times 10^{-2}$
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Rh-105		200	25	$8.2 \times 10^{5}$
Rn 222	Radon (86)	10	2	$1.5\times10^{5}$
<del>Ru-97</del>	Ruthenium (44)	80	80	$5.5\times10^5$
Ru-103		30	<del>25</del>	$3.2 \times 10^4$
Ru-105		<del>20</del>	20	6.6 × 10 <sup>6</sup>
<del>Ru-106</del>		10	7	$3.4 \times 10^3$
<del>S-35</del>	Sulphur (16)	1000	60	$4.3 \times 10^4$
Sb-122	Antimony (51)	<del>30</del>	<del>30</del>	$3.9\times10^{5}$
	<del>Table I (Co</del>	ontinued 9)		
Symbol of radionuclide	Element and atomic number	A <sub>I</sub> ( <del>Ci)</del>	A <sub>2</sub> ( <del>Ci)</del>	<del>Specit</del> ic <del>Activity</del> <del>(Ci/g)</del>
Sb 124		5	5	$1.8 \times 10^4$
Sb-125		40	25	$1.4 \times 10^3$
<del>Se-46</del>	Seandium (21)	8	8	$3.4 \times 10^4$
Se-47		<del>200</del>	20	$8.2 \times 10^{5}$
<del>Se-48</del>		5	5	$1.5\times10^{6}$
Se-75	S <del>eleni</del> um (34)	40	40	1.4×-10 <sup>4</sup>
Si-31	Silicon (14)	100	20	$3.9 \times 10^{2}$
S <del>m 147</del>	<del>Samarium (62)</del>	<del>Unlimited</del>	Unlimited	$2.0 \times 10^{-8}$
Sm-151		1000	90	$2.6 \times 10^{1}$
S <del>m-153</del>		300	<del>20</del>	$4.4 \times 10^5$
Sn-113	<del>Tin (50)</del>	<del>60</del>	<del>60</del>	1.0 × 10 <sup>4</sup>
<del>Sn-119m</del>	DEOFINE	100	100	$4.4 \times 10^{3}$
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Sn-125		<del>10</del>	10	1.1 × 10
<del>Sr-85m</del>	Strontium (38)	80	80	$3.2 \times 10^{2}$
<del>Sr-85</del>		<del>30</del>	30	$2.4 \times 10^4$
<del>Sr-85m</del>		<del>50</del>	<del>50</del>	$1.2 \times 10^{-7}$
<del>Sr 89</del>		100	10	$2.9 \times 10^4$
<del>Sr-90</del>		<del>10</del>	0.4	$1.5 \times 10^2$
Sr-91		10	10	$3.6 \times 10^{6}$
<del>Sr 92</del>		10	<del>10</del>	$1.3 \times 10^{7}$
T-(uncompressed)*	Tritium (1)	1000	1000	$9.7 \times 10^{3}$
<del>T-(compressed</del> )*		1000	1000	$9.7 \times 10^3$
T-(activated luminous paint)		1000	1000	9.7 × 10 <sup>3</sup>
	<del>Table I (Cc</del>	ontinued-10)		
Symbol of radionuclide	Element and atomic number	A <sub>I</sub> ( <del>Ci)</del>	A <u>a(Ci)</u>	S <del>pecific</del> Activity ( <del>Ci/g)</del>
T (absorbed on solid earrier)		1000	1000	$9.7 \times 10^3$
T-(tritiated-water)		1000	1000	$9.7 \times 10^{3}$
T-(other-forms)		20	<del>20</del>	$9.7 \times 10^{3}$
<del>Ta-182</del>	Tantalum (73)	<del>20</del>	<del>20</del>	$6.2 \times 10^{3}$
Tb-160	Terbium (65)	20	10	$1.1 \times 10^4$
<del>Tc-96m</del>	Technetium (43)	1000	1000	$3.8 \times 10^{2}$
<del>Tc-96</del>		6	6	$3.2 \times 10^{5}$
Te-97m		1000	200	$1.5 \times 10^4$
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Te-97		1000	400	1.4 × 10 <sup>-3</sup>
<del>Te-99m</del>		100	100	$5.2 \times 10^6$
<del>Te-99</del>		1000	25	$1.7 \times 10^{-2}$
<del>Te-125m</del>	<del>Tellurium (52)</del>	1000	100	1.8×10 <sup>4</sup>
<del>Te-127m</del>		300	20	$4.0 \times 10^4$
<del>Te-127</del>		300	20	2.6×10 <sup>6</sup>
<del>Te-129m</del>		<del>30</del>	10	$2.5 \times 10^4$
Te-129		100	20	$2.0 \times 10^{2}$
Te-131m		10	10	$8.0 \times 10^{5}$
Te-132		7	7	$3.1 \times 10^{5}$
Th-227	Thorium (90)	<del>20</del> 0	0.2	$3.2 \times 10^{4}$
Th-228		6	0.008	$8.3 \times 10^{2}$
Th-230		3	0.003	$1.9 \times 10^{-2}$
Th-231		1000	25	5.3 × 10 <sup>5</sup>
Th-232		Unlimited	Unlimited	1.1 × 10 <sup>-2</sup>
	<del>Table I ((</del>	Continued 11)		
Symbol of radionuclide	Element and atomic number	A <sub>t</sub> ( <del>Ci)</del>	A <sub>2</sub> ( <del>Ci)</del>	Specifie Activity (Ci <sup>'</sup> g)
Th-234		10	10	$2.3 \times 10^{4}$
Th (natural)		Unlimited	Unlimited	$2.2 \times 10^{-2}$
Th (irradiated	<del>1)**</del>	denum		
<del>T1-200</del>	Thallium (81)	20	20	$5.8 \times 10^{5}$
<del>T1-201</del>		200	200	$2.2 \times 10^{5}$
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<del>T1-202</del>		40	40	5.4×-10 <sup>4</sup>
<del>T1 204</del>		300	10	$4.3 \times 10^{2}$
<del>Tm-170</del>	Thulium (69)	<del>300</del>	10	$6.0 \times 10^3$
Tm-171		1000	100	$1.1 \times 10^{3}$
<del>U-230</del>	<del>Uranium (92)</del>	100	0.1	$2.7 \times 10^4$
<del>U 232</del>		<del>30</del>	0.03	$2.1 \times 10^{1}$
<del>U 233</del>		100	0.1	$9.5 \times 10^{-3}$
<del>U-23</del> 4		100	0.1	$6.2 \times 10^{-3}$
<del>U-235</del>	•	100	0.2	$2.1 \times 10^{-6}$
<del>U-236</del>		200	0.2	$6.3 \times 10^{-5}$
<del>U 238</del>		Unlimited	Unlimited	$3.3 \times 10^{-7}$
<del>U (natural)</del>		Unlimited	Unlimited	see Table IV)
U (enriched) ≤ 20%		Unlimited	Unlimited	see Table IV)
<del>20% or gr</del>	eater	100	0.1	see Table IV)
<del>U-(depleted)</del>		Unlimited	Unlimited	see Table IV)
U-(irradiated)***				
V-48	Vanadium (23)	6	6	$1.7 \times 10^{5}$
W-181	Tungsten (74)	<del>200</del>	100	$5.0\times10^3$
<del>W-185</del>		1000	25	$9.7 \times 10^{-3}$
	<del>Table I (Co</del>	ntinued-12)		
Symbol-of radionuclide	Element and atomic number	A <sub>1</sub> (Ci)	A <sub>2</sub> (Ci)	Specific Activity (Ci/g)
W-187		40	<del>20</del>	$7.0 \times 10^{5}$

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Xe-127-(uncompressed)*	Xenon (54)	<del>70</del>	<del>70</del>	$2.8 \times 10^{4}$
Xe-127 (compressed)*		5	5	$2.8 \times 10^{4}$
Xe-131m (compressed)*		10	10	$1.0 \times 10^{5}$
Xe-131m (uncompressed	<u>)*</u>	100	100	1.0×10 <sup>5</sup>
Xe-133 (uncompressed)*		1000	1000	$1.9 \times 10^{5}$
Xe-133 (compressed)*		5	5	$1.9 \times 10^{5}$
Xe-135 (uncompressed)*		70	<del>70</del>	$2.5 \times 10^{5}$
Xe-135 (compressed)*		2	2	2.5 × 10 <sup>5</sup>
<del>Y-87</del>	Yttrium (39)	20	20	4.5 × 10 <sup>1</sup>
<del>Y-90</del>		10	40	$2.5 \times 10^{5}$
<del>Y-91</del> m		30	30	$4.1 \times 10^{-2}$
<del>Y-91</del>		<del>30</del>	30	$2.5 \times 10^4$
<del>Y 92</del>		10	10	$9.5 \times 10^6$
<del>Y-93</del>		10	40	$3.2 \times 10^{6}$
Yb-169	<del>Ytterbium (70)</del>	80	<del>80</del> -	$2.3 \times 10^{5}$
¥b-175		400	25	$1.8 \times 10^{5}$
<del>Zn-65</del>	Zine-(30)	<del>30</del>	30	$8.0 \times 10^{3}$
<del>Zn 69m</del>		40	<del>20</del>	$3.3 \times 10^{6}$
<del>Zn 69</del>		300	<del>20</del>	$5.3 \times 10^{2}$
<del>Zr 93</del>	Zirconium (40)	1000	<del>200</del>	$3.5 \times 10^{-3}$
<del>Zr-95</del>		<del>20</del>	20	$2.1 \times 10^{4}$
<del>Zr 97</del>		<del>20</del>	20	$2.0 \times 10^{6}$

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- For the purpose of Table I, compressed gas means a gas at a pressure which exceeds the ambient atmospheric pressure at the location where the containment system was elosed:
- \*\* The values of A<sub>1</sub>-and A<sub>2</sub>-must be calculated in accordance with the procedure specified in Appendix A, paragraph II-3, taking into account the activity of the fission products and of the uranium 233 in addition to that of the thorium.
- \*\*\* The values of A<sub>1</sub> and A<sub>2</sub> must be calculated in accordance with the procedure specified in Appendix A, paragraph II-3, taking into account the activity of the fission products and plutonium isotopes in addition to that of the uranium.

Table 11
Relationship Between A<sub>1</sub> and E<sub>max</sub> for the Beta Emitters

E <sub>nex</sub> (MeV)	A <sub>I</sub> (Ci)
< 0.5	1000
0.5 < 1.0	300
1.0 < 1.5	100
1.5 < 2.0	30
>20	10

Table III

Relationship Between A<sub>1</sub> and the Atomic Number

of the Radionuclide

A

Atomie Number	Half-life less than 1000 days	Half-life_1000-days to-10°-years	Half-life greater than-10°-years
1-to-81	<del>3 Ci</del>	0.05-Ci	<del>3 Ci</del>
82 and above	<del>0.002 Ci</del>	<del>0.002 Ci</del>	<del>3 Ci</del>

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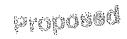


Table IV
Activity-Mass Relationships for Uranium/Thorium

Thorium and

Uranium Enrichment* Specific Activi		ivity
F	<del>Ci/g</del>	<del>g/Ci</del>
0.45	$5.0 \times 10^{-2}$	$2.0 \times 10^{6}$
0.72 (natural)	7.06 × 10 <sup>-7</sup>	1.42 × 10 <sup>6</sup>
Ŧ	able IV-(continued)	
Thorium and Uranium Enrichment* wt % U-235 present	· Specific Act	i <del>vity</del>
1.0	<del>7.6 × 10</del>	$1.3 \times 10^{6}$
1.5	1.0×10 <sup>-6</sup>	1.0 × 10"
5.0	$2.7 \times 10^{-6}$	$3.7 \times 10^{5}$
10.0	4.8 × 10.4	$2.1 \times 10^5$
20.0	$1.0 \times 10^{-5}$	$1.0 \times 10^{5}$
35.0	$2.0 \times 10^{-5}$	5.0 × 10 <sup>4</sup>
<del>50.0</del>	2.5×10 <sup>-5</sup>	$4.0 \times 10^{4}$
90.0	$5.8 \times 10^{-5}$	$1.7 \times 10^4$
93.0	7.0-×10 <sup>-5</sup>	$1.4 \times 10^4$
95.0	$9.1 \times 10^{-5}$	$1.1 \times 10^{4}$
Natural Thorium	$2.2 \times 10^{-2}$	4. <del>6 ×10</del> 6

<sup>\*</sup> The figures for uranium include representative values for the activity of the uranium 234 which is concentrated during the enrichment process. The activity for thorium includes the equilibrium concentration of thorium 228.

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(c) Type B quantity shall mean a quantity of radioactive materials greater than a type A quantity:

(d) The level of removable contamination on the external surfaces of each package shall. when averaged over the surface wiped, not exceed the limits given in table V below at any time during transport. The level of removable radioactive contamination shall be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Only in the case of packages transported as exclusive use shipment by rail or highway, may the removable radioactive contamination exceed the levels prescribed in table V. In this case, the levels shall not exceed 10 times the levels prescribed in tableV.

Table V Removable External Radioactive Contamination Wipe Limits

Maximum-Permissible

Limits

Contaminant

uCi′cm<sup>3</sup>

dpm/cm2

Beta-gamma emitting radionuclides;

all-radionuclides with half-lives

less than ten days; natural uranium;

natural thorium; uranium 235;

uranium-238; thorium-232; thorium-228

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- (e) External radiation-levels around the package and around the vehicle, if applicable, shall not exceed 200 millirems per hour (2 mSv/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.
- (f) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in K.A.R. 28-35-221b(d) but shall not exceed any of the following:
- (1) 200 millirems-per-hour (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit shall be 1000 millirem-per-hour (10 mSv/hr):
  - (A) The shipment is made in a closed transport vehicle;
- (B) provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and
- (C) there are no loading or unloading operations between the beginning and end of the transportation;
- (2) 200 millirems per hour (2 mSv/hr) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load, and on the lower external surface of the vehicle;

(3) 10 millirems per hour (0.1 mSv/hr) at any point 2 meters from the vertical planes

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represented by the outer lateral surfaces of the vehicle, or, in the case of a flat bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

- (4) 2 millirems per hour (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision shall not apply to private motor carriers when persons occupying these positions are provided with special health supervision personnel radiation exposure-monitoring devices, and training in accordance with K.A.R. 28-35-333. The provisions of 10 C.F.R. part 71, appendix A, as in effect on June 12, 2015, are hereby adopted by reference, with the changes specified in this regulation.
- (a) Wherever the term "commission" appears within 10 C.F.R. part 71, appendix A, that term shall be replaced with the term "department."

(b) In 10 C.F.R. part 71, appendix A, paragraph II(c) shall be replaced with the
following text: "The licensee shall submit requests for prior approval, described under
paragraphs II(a) and II(b) of this appendix, to the department." (Authorized by and
implementing K.S.A. <del>1993 Supp.</del> 48-1607; effective Sept. 20, 1993; amended Oct. 17, 1994
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<b>28-35-230d.</b> (Authorized by and implementing K.S.A. 48-1607; effective Oct.	17, 1994;
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28-35-264. General requirements. The provisions of 10 CFR C.F.R. part 35, as in effect on January 15, 2010 June 30, 2015, are hereby adopted by reference, with the changes specified in this regulation.

- (a) For the purposes of part 6, "byproduct material" shall mean all radioactive material regulated by the department.
  - (b) All reports required by this regulation shall be submitted to the department.
  - (c) The following sections shall be deleted:
  - (1) 10 CFR 35.1, "purpose and scope";
- (2) 10 CFR 35.2, "definitions," except that the definitions of the following terms shall be retained:
  - (A) "Authorized medical physicist";
  - (B) "authorized nuclear pharmacist";
  - (C) "authorized user";
  - (D) "medical event";
  - (E) "prescribed dose"; and
  - (F) "radiation safety officer";
  - (3) 10 CFR 35.8, "information collection requirements: OMB approval";
  - (4) 10 CFR 35.18, "license issuance";
  - (5) 10 CFR 35.19, "specific exemptions";
  - (6) 10 CFR 35.26(a)(1), "radiation protection program changes";
  - (7) 10 CFR 35.4001, "violations"; and
  - (8) <del>10 CFR</del> 35.4002, "criminal penalties."

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- (d) Wherever the following CFR C.F.R. references occur within 10 CFR C.F.R. part 35, these references shall be replaced with the specified references to regulations and parts in this article:
- (1) "10 CFR 19.12" shall be replaced with "K.A.R. 28-35-333, 'instructions to workers.'
- (2) "10 CFR part 20" shall be replaced with "part 4, 'standards for protection against radiation.'
- (3) "10 CFR 20.1101" shall be replaced with "K.A.R. 28-35-211d, 'radiation protection programs.'
  - (4) "10 CFR 20.1301(a)(1) and 20.1301(c)" shall be replaced with "K.A.R. 28-35-214a."
  - (5) "10 CFR 20.1501" shall be replaced with "K.A.R. 28-35-217b."
  - (6) "10 CFR part 30" shall be replaced with "part 3, 'licensing of sources of radiation.' "
- (7) "10 CFR 32.72" shall be replaced with "K.A.R. 28-35-181m, 'specific licenses to manufacture and distribute radiopharmaceuticals containing radioactive material for medical use under group licenses,' and K.A.R. 28-35-181n, 'specific licenses to manufacture and distribute generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material.'
- (8) "10 CFR 32.74" shall be replaced with "K.A.R. 28-35-1810, 'specific licenses to manufacture and distribute sources and devices for use as a calibration or reference source, or for certain medical uses.'
  - (9) "10 CFR 33.13" shall be replaced with "K.A.R. 28-35-182b, 'qualifications for a type

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- (e) Wherever the following terms occur within 10 CFR C.F.R. part 35, these terms shall be replaced with "department":
  - (1) "Commission";
  - (2) "NRC operation center"; and
  - (3) "NRC regional office."
  - (f) The following changes shall be made to the sections specified:
  - (1) 10 CFR 35.6(b)(1) and (c)(1) shall be replaced with the following text:

"Obtain review and approval of the research as specified in 45 CFR 46.111, 'criteria for IRB approval of research'; and".

- (2) 40 CFR 35.6(b)(2) and (c)(2) shall be replaced with the following text:
- "Obtain informed consent from the human research subject as specified in 45 CFR 46.116, 'general requirements for informed consent.'
  - (3) 10 CFR 35.10, subsection (a) shall be deleted.
- (4) In 10 CFR 35.10(d), the date "October 24, 2002" shall be replaced with "the effective date of these regulations, "and in 10 CFR 35.10(b) and (c), the date "October 25, 2005" shall be replaced with "two years from the effective date of these regulations."
- (5) 10 CFR 35.12(b)(1) and (c)(1)(i) shall be replaced with the following text: "submitting a form specified by the department that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized users, authorized physicists, and authorized pharmacists."

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- (6) 35.12(c)(1)(i) shall be replaced with the following text: "a form specified by the department that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized users, authorized physicists, and authorized pharmacists."
- (7) In 10 CFR 35.57(a)(1) and (b)(1), the date "October 24, 2002" shall be replaced with "the effective date of these regulations."
- (7) (8) In 10 CFR 35.57(a)(2) and (b)(2), the date "April 29, 2005" shall be replaced with "the effective date of these regulations."
- (8) (9) In 10 CFR 35.432(a), the date "October 24, 2002" shall be replaced with "the effective date of these regulations."
- (9) (10) In 40 CFR 35.3045, the footnote shall be deleted, and in subsection (a) the words "or any radiation-producing device" shall be added before the words "results in."
- (10) (11) 10 CFR 35.3047(d) shall be replaced with the following text: "The licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo or fetus, or nursing child that requires a report in paragraphs (a) or (b) in this section."
- (11) (12) In 10 CFR 35.3067, the phrase "with the department" shall be inserted after the word "report" in the first sentence, and the second sentence shall be deleted. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended March 18, 2011; amended P-

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28-35-288. Special requirements and exemptions for enclosed radiography. (a) Each licensee or registrant shall ensure that each system for enclosed radiography that is designed to allow the admittance of any individual meets the following requirements:

- (1) Meets all applicable requirements of this part and K.A.R. 28-35-214a if the system is not a certified cabinet X-ray system;
- (2) meets all applicable requirements of this part and has been certified by the <u>U.S. food</u> and <u>drug administration (FDA)</u> as compliant with the requirements <del>specified</del> in 21<del>CFR C.F.R.</del> 1020.40, if the system is a certified cabinet X-ray system; and
- (3) is evaluated, at intervals not to exceed one year, to ensure compliance with the applicable requirements specified in paragraphs (1) or (2) of this subsection. A record of each evaluation shall be maintained for two years after the evaluation.
- (b) Each cabinet X-ray system designed to exclude any individual shall be exempt from the requirements of K.A.R. 28-35-276, K.A.R. 28-35-278, K.A.R. 28-35-281, K.A.R. 28-35-282, K.A.R. 28-35-283, K.A.R. 28-35-284, K.A.R. 28-35-285, K.A.R. 28-35-286, and K.A.R. 28-35-289, with the following exceptions:
- (1) Operating personnel shall be provided with personnel-monitoring equipment as specified in K.A.R. 28-35-217a.
- (2) A registrant shall not permit any individual to operate a cabinet x-ray system until that individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. A record that demonstrates compliance with this paragraph shall be maintained for inspection by the department until disposition is authorized by the department.

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- (3) A test for proper operation of each high-radiation area control device or alarm system, where applicable, shall be conducted and recorded as specified in K.A.R. 28-35-288(e) 28-35-288.
- (c) Each permanent radiographic installation having any high-radiation area entrance control of the type specified in K.A.R. 28-35-219a shall also meet the following requirements:
- (1) Each entrance that is used for personnel access to the high-radiation area in a permanent radiographic installation shall have both a visible and an audible warning signal to warn of the presence of radiation.
- (2) The visible signal shall be activated by radiation whenever the source is exposed.

  The audible signal shall be activated if an attempt is made to enter the installation while the source is exposed.
- (e) (d) The control device or alarm system shall be tested for proper operation at the beginning of each period of use. A record of each test shall be prepared quarterly or before the first use after the end of the quarter. Each record shall be maintained for inspection by the department until the secretary authorizes disposal of the record. (Authorized by and implementing K.S.A. 48-1607; effective Jan. 1, 1970; amended, T-85-43, Dec. 19, 1984; amended May 1, 1985; amended Sept. 20, 1993; amended Dec. 30, 2005; amended P-

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28-35-343. Storage precautions. (a) Each source of radiation, except accelerators, shall be provided with a storage container and, if transported, a transport container. The same container may be used in both cases if the container meets the requirements for each use. The container shall be provided with a lock to prevent unauthorized removal of, or exposure to, the source of radiation.

- (b) Each source of radiation shall be stored in a manner that minimizes danger from explosion or fire.
- (c) Each licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle. (Authorized by and implementing K.S.A. 48-1607; effective Sept. 20, 1993; amended Dec. 30, 2005; amended P-

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28-35-344. Transport precautions. Each transport container shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal. Each licensee shall lock and physically secure each transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle. (Authorized by and implementing K.S.A. 1992 Supp. 48-1607; effective Sept. 20, 1993; amended P-\_\_\_\_\_\_\_\_.)

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28-35-347. Quarterly In-person inventory. Each licensee or registrant shall conduct a physical an in-person inventory to account for all sources of radiation once every three six months. A record of each inventory shall be maintained for two years from the date of the inventory for inspection by the department and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory. (Authorized by and implementing K.S.A. 1992 Supp. 48-1607; effective Sept. 20, 1993; amended P-\_\_\_\_\_\_\_.)

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- 28-35-362. Notification of incidents, abandonment, and lost sources. (a) The Each licensee shall notify the department of any incidents and any sources lost in other than downhole logging operations in accordance with K.A.R. 28-35-184b, 28-35-228a, 28-35-229a and 28-35-230a.
- (b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
- (1) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and .
- (2) (c) If the licensee knows or has reason to believe that a sealed source has been ruptured, the licensee shall notify the department immediately by telephone and subsequently, within 30 days, by confirmatory written report if the licensee knows or has reason to believe that a sealed source has been ruptured. This written report shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.
- (e) (d) If it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall eomply with meet the following requirements:
- (1) The licensee shall advise the well-operator well operator of the following requirements regarding the method of abandonment:
- (A) The well-operator well operator shall immobilize and seal the radioactive source in place with a cement plug.
- (B) The well-operator well operator shall set in place a whipstock or other deflection device.

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- (C) The well-operator well operator shall mount a permanent identification plaque at the surface of the well, containing the appropriate information required by this regulation.
- (2) The licensee shall notify the department by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures.
- (3) The licensee shall file a written report with the department within 30 days of the abandonment, setting forth providing the following information:
  - (A) The date of occurrence and a brief description of attempts to recover the source;
- (B) a description of the radioactive source involved, including the radionuclide, quantity, and chemical and physical form;
  - (C) a description of the surface location and identification of the well;
  - (D) the results of efforts to immobilize and set the source in place;
  - (E) the depth of the radioactive source;
  - (F) the depth of the top of the cement plug;
  - (G) the depth of the well; and
  - (H) the information contained on the permanent identification plaque.
- (d) (e) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque as described in K.A.R. 28 35 364 for posting on the well-bore. The plaque shall meet the following requirements:
- (1) Be constructed of long-lasting material, which may include stainless steel or Monel metal; and
  - (2) contain the following information engraved on its face:

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- (A) The word "CAUTION";
- (B) the radiation symbol, without the conventional color requirement;
- (C) the date of abandonment;
- (D) the name of the well operator or well owner;
- (E) the well name and the well identification number or numbers or other designation;
- (F) a description of the sealed source or sources, by radionuclide and quantity of activity;
- (G) the source depth and the depth to the top of the plug; and
- (H) an appropriate warning which that, depending on the specific circumstances of that abandonment, shall include one of the following:
  - (i) "Do not drill below plug back depth";
  - (ii) "do not enlarge casing"; or
- (iii) "do not reenter the hole before contacting the Kansas department of health and environment radiation control program"; and
- (3) be a minimum of at least seven inches square. The word "CAUTION" shall be written in ½-inch letters and all other information shall be written in ¼-inch letters.
- (e) (f) Each If the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source, the licensee shall immediately notify the department by telephone, and subsequently, within 30 days, by eonfirming confirmatory letter, if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. The notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such the

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loss, and explain efforts planned or b	being taken to mitigate these consequences. (Authorized by
and implementing K.S.A. 48-1607;	effective Sept. 20, 1993; amended Nov. 1, 1996; amended
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28-35-504. Advance notification of shipment of certain types of licensed or registered material. (a)(1) As specified in subsections (b), (c), and (d) of this regulation, each licensee shall provide advance notification to the governor, or the governor's designee, of each state of each shipment of licensed or registered material through or across the boundary of that governor's state. The licensee shall provide this advance notification before transporting, or delivering to a carrier for transport, any licensed or registered material outside the confines of the licensee's facility or other place of use or storage.

- (2) As specified in subsections (b), (c), and (d), each licensee shall provide advance notification to the Indian tribal official or tribal official of participating tribes referenced in subsection (c), or the official's designee, of the shipment of licensed material within or across the boundary of the tribe's reservation before the transport or delivery to a carrier for transport of licensed material outside the confines of the licensee's plant or other place of use or storage.
- (b)(1) The advance notification specified in subsection (a) shall be required for each shipment of irradiated reactor fuel containing 100 grams or less in net weight of irradiated fuel, exclusive of cladding and any other structural or packaging material, that has a total external radiation dose rate in excess of 100 rems per hour at a distance of three feet from any accessible surface without intervening shielding.
- (2) The advance notification specified in subsection (a) shall also be required for each shipment of licensed or registered material, other than irradiated fuel, meeting all of the following conditions:
- (A) The licensed or registered material is required to be shipped in a type B package for transportation as specified in this part.
- (B) The licensed or registered material is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal

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facility.

- (C) The quantity of licensed or registered material in a single package exceeds the smaller of the following:
- (i) 3,000 times the A<sub>1</sub> value of the radionuclides as specified in K.A.R. 28-35-221b for special form radioactive material or 3,000 times the  $\Lambda_2$  value of the radionuclides as specified in K.A.R. 28-35-221b for normal form radioactive material; and
  - (ii) 1,000 TBq (27,000 Ci).
  - (c) The notification specified in subsection (b) shall meet the following requirements:
- (1) The notification shall be submitted, in writing, to the office of each appropriate governor or governor's designee and each appropriate Indian tribal official and to the director of the division of nuclear security in the office of nuclear security and incident response. A list of names and addresses for the governor's designees can be obtained from one of the following sources:
  - (A) A list is published by the NRC annually in the federal register on or about June 30.
- (B) A list is available on request from the director of the office of state programs at the U.S. NRC.
- (2) Each notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated by the licensee to occur.
- (3) Each notification delivered by any means other than mail shall reach the office of each governor or governor's designee and each appropriate Indian tribal official at least four days before the beginning of the seven-day period during which departure of the shipment is estimated by the licensee to occur.

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- (4) Each licensee shall retain a copy of the notification as a record for three years.
- (d) Each advance notification of any shipment of irradiated reactor fuel or nuclear waste shall contain the following information:
- (1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;
- (2) a description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of the U.S. DOT <u>United States department of transportation</u>
  (USDOT) in 49 CFR C.F.R. 172.202 and 172.203(d);
  - (3) a shipment schedule, which shall include the following information:
- (A) The point of origin of the shipment and a specification of the seven-day period during which departure of the shipment is estimated by the licensee to occur;
- (B) a specification of the seven-day period during which arrival of the shipment at the state boundaries is estimated by the licensee to occur; and
- (C) the destination of the shipment and a specification of the seven-day period during which arrival of the shipment at the destination is estimated by the licensee to occur; and
- (4) the name of a contact person, including a telephone number, for current shipment information.
- (e) If any licensee finds out that the shipment schedule previously furnished to any governor, or governor's designee, or <u>Indian tribal official</u> in accordance with this regulation will not be met, that licensee shall perform the following:
- (1) Telephone a responsible individual in the office of the governor or governor's designee or the Indian tribal official as soon as practical after the licensee has found out that the shipment schedule will not be met and inform that individual of the revised schedule; and

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(2) maintain a record of the name of the responsible individual contacted and the date of this contact for three years.

(f) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for
which advance notification has been sent shall send a cancellation notice to the governor of each
state; or the governor's designee; or to the Indian tribal official who was previously notified and
to the director of the division of nuclear security in the office of nuclear security and incident
response. The licensee shall state in the notice that the notice is a cancellation and shall identify
the advance notification that is being canceled. The licensee shall retain a copy of the notice as a
record for three years. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30,
2005; amended P)

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28-35-700. General requirements. The provisions of 10 C.F.R. part 37, 78 fed. reg. 17007-17020 (2013), as in effect on May 20, 2013, are hereby adopted by reference, with the changes specified in this regulation.

changes specified in this regulation.			
(a) The following sections or portions of sections in 10 C.F.R. part 37 shall be			
deleted:			
(1) 37.1;			
(2) 37.3;			
(3) 37.7;			
(4) 37.9;			
(5) 37.11(a) and (b);			
(6) 37.13;			
(7) 37.43(d)(9);			
(8) in 37.81(g), the third sentence;			
(9) 37.105;			
(10) 37.107; and			
(11) 37.109.			
(b) In 10 C.F.R. 37.5, the following terms and the definition of each of these terms			
shall be deleted:			
(1) "Act";			
(2) "agreement state";			
(3) "becquerel";			
(4) "byproduct material";			
(5) "commission";			

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(6) "curie";

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(7) "government agency";				
(8) "license";				
(9) "lost or missing licensed material";				
(10) "person";	(10) "person";			
(11) "state"; and	(11) "state"; and			
(12) "United States."				
(c) Wherever the following words a	nd phrases occur within the portion	ns of 10 C.F.R.		
part 37 adopted in this regulation, these wo	rds and phrases shall be replaced w	vith		
"department":				
(1) "Appropriate NRC regional office	ce listed in §30.6(a)(2) of this chap	ter";		
(2) "Commission," except secs. 37.5	5, 37.27(a) and (c), 37.29(a) and 37	7.71;		
(3) "NRC," except secs. 37.25(b)(2)	), 37.27(c), 37.29(a), and 37.71;			
(4) "NRC regional office specified i	in §30.6 of this chapter";			
(5) "NRC's Operations Center"; and				
(6) "NRC's Operations Center (301-816-5100)."				
(d) The following changes shall be a	made wherever the following text o	occurs within		
the portions of 10 C.F.R. part 37 adopted in	this regulation:			
(1) "Part 73 of this chapter" shall be	replaced with "10 C.F.R. Part 73."	,		
(2) "71.97(b) of this chapter" and "71.97 of this chapter" shall be replaced with				
"K.A.R 28-35-504(b),"				
(3) "Governor's designee" shall be replaced with "division of emergency management				
of the office of the adjutant general." (Authorized by and implementing K.S.A. 48-1607;				
effective P)				
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## Kansas Department of Health and Environment

## Division of Public Health

Bureau of Community Health Systems

July 27, 2017

## **Economic Impact Statement**

Pursuant to K.S.A. 2016 Supp. 77-416

### PROPOSED AMENDED, NEW, AND REVOKED REGULATIONS:

Nuclear Energy Development and Radiation Control Act (K.S.A. 48, Article 16)

## Amended

K.A.R. 28-35-135a, 28-35-135c, 28-35-135i, 28-35-135s, 28-35-135u, 28-35-140, 28-35-177a, 28-35-178i, 28-35-179a, 28-35-180a, 28-35-180b, 28-35-181h, 28-35-181i, 28-35-181k, 28-35-181m, 28-35-181o, 28-35-184a, 28-35-192a, 28-35-192c, 28-35-192g, 28-35-205b, 28-35-217b, 28-35-221a, 28-35-221b, 28-35-264, 28-35-288, 28-35-343, 28-35-344, 28-35-347, 28-35-362, 28-35-504.

#### New

K.A.R. 28-35-181t, 28-35-192h, 28-35-197b, 28-35-700.

## Revoked

K.A.R. 28-35-197a, 28-35-230d.

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# Executive Summary of Proposed Amended, New, and Revoked Regulations

The Kansas Radiation Control Program operates within the Kansas Department of Health and Environment (KDHE) in the Bureau of Community Health Systems. The Kansas Radiation Control Program performs all functions and duties as necessary to meet the requirements set forth in the Nuclear Energy Development and Radiation Control Act (K.S.A. 48, Article 16). Protecting the health and environment of the citizens of Kansas permeates every activity conducted by the Kansas Radiation Control Program. Members of the staff provide for the regulation, licensing, registration and inspection of sources of radiation, whether they consist of radioactive materials or machine generated radiation. As specified in K.S.A. 48-1601(b), the program has the requirement "(b) to institute and maintain a regulatory program for sources of radiation so as to provide for (1) compatibility with the standards and regulatory programs of the federal government; (2) an integrated, effective system of regulation within the state; and (3) a system consonant insofar as possible with those of other states."

Pursuant to K.S.A. 48-1601 *et seq.*, the State of Kansas entered into an agreement with the Nuclear Regulatory Commission (NRC) in 1965 to regulate radioactive materials under the provisions of the federal Atomic Energy Act. Kansas has operated as an agreement state since that time. The regulated community in Kansas includes over 270 facilities licensed to use radioactive materials and over 2600 facilities registered to use x-ray equipment. These facilities include industrial operations, research labs, medical and dental facilities, and security screening operations. In order to assure appropriate protection of the public and operators, radiation exposures must be kept as low as reasonably achievable. The role of the radiation control program is to provide the appropriate oversight and regulation to assure this protection. K.S.A. 48-1601 requires that the state provide for compatibility with the standards and regulatory programs of the federal government.

The changes to the regulations included in the package fall into three broad categories. The first are changes that were made to maintain the compatibility of the Kansas regulations with the corresponding NRC regulations. Secondly, changes were also made to address minor programmatic updates or errors in the existing regulations. Finally, three new regulations were added to reflect the promulgation of new NRC regulations regarding physical protection of byproduct material.

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## Summary of Regulation Changes

## Amended

- **K.A.R. 28-35-135a. Definitions.** This regulation was amended to meet NRC compatibility requirements by removing the definition of "becquerel" and "curie," defined in 28-35-135b and 28-35-135c respectively, under the term "activity." The format of a reference to the atomic energy act was corrected.
- **K.A.R. 28-35-135c. Definitions.** This regulation was amended to meet NRC compatibility requirements by adding the definition of "consortium."
- **K.A.R. 28-35-135i. Definitions.** This regulation was amended to meet NRC compatibility requirements by adding the definitions of "Indian tribe" and "Indian tribal official."
- **K.A.R. 28-35-135s. Definitions.** This regulation was amended to meet NRC compatibility requirements by clarifying the definition of "survey."
- **K.A.R. 28-35-135u. Definitions.** This regulation was amended to meet NRC compatibility requirements by adding a description of "processing" to the definition of "unrefined or unprocessed ore."
- **K.A.R. 28-35-140. Exemptions.** This regulation was amended to meet NRC compatibility requirements by specifying exemptions for carriers.
- K.A.R. 28-35-177a. General licenses; source material. This regulation was amended to meet NRC compatibility requirements by adopting the wording of the federal requirements for a general license for uranium and thorium in certain forms and quantities.
- K.A.R. 28-35-178i. General licenses for certain units of radium-226. This regulation was amended to meet NRC compatibility requirements by adding descriptions of types of products that are issued a general license for certain units of radium-226, along with additional clarifying language related to reports of damage, abandonment, disposal, export, and fee waiver.
- K.A.R. 28-35-179a. Application for specific license; renewal or amendment. This regulation was amended to meet NRC compatibility requirements by adding essential information required for the licensing of a sealed source or device containing a sealed source.
- K.A.R. 28-35-180a. General requirements for the issuance of specific licenses. This regulation was amended to meet NRC compatibility requirements by adding a description of minimization of introduction of residual radioactivity.
- K.A.R. 28-35-180b. Financial assurance for decommissioning. This regulation was amended to meet NRC compatibility requirements by adding descriptive information defining

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the criteria of a cost estimate, periodic adjustment timeframe of no longer than three years, and descriptor of prepayment terms.

- K.A.R. 28-35-181h. Specific licenses to manufacture and distribute the devices specified in K.A.R. 28-35-178b. This regulation was amended to meet NRC compatibility requirements by adding the requirement to list certain devices or sources in the sealed source and device registry.
- K.A.R. 28-35-181i. Special license to manufacture, distribute, assemble, or repair luminous safety devices for use in aircraft. This regulation was amended to meet NRC compatibility requirements by adopting by reference the comparable NRC regulation.
- K.A.R. 28-35-181k. Specific licenses to manufacture and distribute ice detection devices. This regulation was amended to meet NRC compatibility requirements by adopting by reference the comparable NRC regulation.
- K.A.R. 28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use. This regulation was amended to meet NRC compatibility requirements by clarification of wording for designation of an authorized nuclear pharmacist including positron emission tomography (PET) radioactive drugs.
- K.A.R. 28-35-1810. Specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or reference source or for certain medical uses. This regulation was amended to meet NRC compatibility requirements by adding the requirement to list certain devices or sources in the sealed source and device registry.
- K.A.R. 28-35-184a. Specific conditions on all licenses. This regulation was amended to meet NRC compatibility requirements by adding criteria for transfer of a license.
- K.A.R. 28-35-192a. Exemptions; source material. This regulation was amended to meet NRC compatibility requirements by clarification of exemptions, addition of a two percent by weight criteria for glassware, and adoption of NRC regulatory language for depleted uranium.
- K.A.R. 28-35-192c. Exceptions; other radioactive material. This regulation was amended to meet NRC compatibility requirements by replacing an incorrect reference to K.A.R. 28-35-197a with K.A.R. 28-35-198b.
- K.A.R. 28-35-192g. Exemptions; exempt quantities. This regulation was amended to meet NRC compatibility requirements by replacing incorrect references to K.A.R. 28-35-197a with K.A.R. 28-35-198b and by adding the word "owns."
- **K.A.R. 28-35-205b.** Alternate criteria for license termination. This regulation was amended to meet NRC compatibility requirements by adding a reference to financial assurance.

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- **K.A.R. 28-35-217b.** General monitoring requirements. This regulation was amended to meet NRC compatibility requirements by clarifying criteria for surveys and adding requirements for personnel dosimeters.
- K.A.R. 28-35-221a. Procedures for picking up, transporting, receiving, and opening packages. This regulation was amended to include the U.S. Department of Transportation requirements for radioactive materials transport. Requirements pertaining to transportation previously contained in K.A.R. 28-35-221b was moved to this regulation.
- K.A.R. 28-35-221b. Appendix A; determination of  $A_1$ ,  $A_2$  and B quantities. This regulation was amended to meet NRC compatibility requirements by removing the table used to calculate activity limits that are used to regulate the transportation of radioactive materials and by adopting by reference the NRC table.
- **K.A.R. 28-35-264.** General requirements. This regulation was amended to meet NRC compatibility requirements by updating the adoption by reference date.
- K.A.R. 28-35-288. Special requirements and exemptions for enclosed radiography. This regulation was amended to correct an error in numbering.
- **K.A.R. 28-35-343. Storage precautions.** This regulation was amended to remove a portion that is duplicated in K.A.R. 28-35-344.
- **K.A.R. 28-35-344. Transport precautions.** This regulation was amended to meet NRC compatibility requirements by updating the wording for security requirements for transport of licensed materials.
- **K.A.R. 28-35-347. In-person inventory.** This regulation was amended to correct programmatic inconsistency and set the inventory period to six months.
- K.A.R. 28-35-362. Notification of incidents, abandonment, and lost sources. This regulation was amended to remove a reference to K.A.R. 28-35-364.
- K.A.R. 28-35-504. Advance notification of shipment of certain types of licensed or registered material. This regulation was amended to meet NRC compatibility requirements by adding the requirement for notification of Indian tribes of shipments that cross the tribal boundaries.

#### New

- K.A.R. 28-35-181t. Requirements for license to initially transfer source material for use under the small quantities of source material general license. This regulation was added to meet NRC compatibility requirements for transfer of source material.
- K.A.R. 28-35-192h. Certain industrial devices. This regulation was added to meet NRC compatibility requirements for the description of exemptions of certain industrial devices. **RECEIVED**

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K.A.R. 28-35-197b. Schedule B; exempt quantities of radioactive material. This regulation was added to meet NRC compatibility requirements by adoption by reference of Schedule B.

**K.A.R. 28-35-700. General requirements.** This regulation was added to meet NRC compatibility requirements by adopting by reference the NRC regulations for physical protection of by-product material.

## Revoked

K.A.R. 28-35-197a. Schedule B; exempt quantities of radioactive material. This regulation was revoked to allow for adoption of the NRC Schedule B in K.A.R. 28-35-197b.

**K.A.R. 28-35-230d. Reports of individual monitoring.** This regulation was revoked to reflect programmatic updates to eliminate redundant and conflicting requirements for individual monitoring.

Are these regulations mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?

Yes. Kansas became an agreement state with the NRC effective January 1, 1965. Under the Nuclear Regulatory Commission-Kansas delegation agreements, Kansas is required to adopt rules enforceable by the state which are compatible with federal rules in order to have the authority to regulate certain radioactive materials. Failure to maintain the program could result in the reinstatement of the NRC as the regulatory agency for certain types of radioactive materials in the state of Kansas. This would negatively impact Kansas licensees with increased fees. This compatibility is a statutory responsibility as required by K.S.A. 48-1601 "(b) to institute and maintain a regulatory program for sources of radiation so as to provide for (1) compatibility with the standards and regulatory programs of the federal government; (2) an integrated, effective system of regulation within the state; and (3) a system consonant insofar as possible with those of other states."

Do the proposed regulations exceed the requirements of applicable federal law?

No

### **Description of Costs:**

a. Cost to the agency:

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KRIS W. KOBACH SECRETARY OF STATE The estimated increased annual cost to the agency to implement these regulations is \$2,993.00. These costs fall under the new regulation K.A.R. 28-35-700.

There are no increased costs for any other amended regulation or new regulation included in this package.

b. Cost to persons who will bear the costs and those who will be affected, (i.e., private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

The estimated annual cost to the Kansas licensees who must implement the requirements of these regulations is \$37,763.00.

There is also an additional cost of \$2,332.00 that will occur once every ten years for a licensee to perform a background reinvestigation of each of their employees who are allowed unescorted access to the sources.

c. Costs to other governmental agencies or units:

There are two state agencies which will have increased costs as described in item b. above. However, due to the sensitive nature of the radioactive material security, those agency names may not be listed.

d. A detailed statement of the data and methodology used to estimate the costs used in the statement.

#### Cost to agency

The estimated increased annual cost to the agency to implement these regulations is \$2,993.00. This number was calculated using the following assumptions and is supported by data referenced from Appendix B of the NRC "Regulatory Analysis for Final Rule: Physical Protection of Byproduct Material (10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73)," December 2011.

There are currently 21 licensees in Kansas who will be affected by the implementation of increased controls. Six KDHE staff members each will require 40 hours of training one time. At this time, five of those staff already are trained. To calculate the annual estimated cost, an annual turnover of one staff member was conservatively estimated. The average hourly salary of the six KDHE staff members is \$34.41. The NRC estimates that an average of ten advance notifications will occur each year and that an increase of two hours of inspection time will be necessary to conduct the security-related aspects of the inspection.

Staff Training: 1 staff X 40 hours X \$34.41/hr = \$1,376.00 Advance Notifications (est. 10/ yr): .5 hr X \$34.41/hr X 10 = 172.00Inspection: 2 hours X \$34.41/hr = \$68.82/inspection X 21 licenses = \$1,445.00

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Total annual cost to agency = \$1,376.00 + \$172.00 + \$1,445.00 = \$2,993.00.

The additional cost to the agency will be funded by fees received from licensees.

#### Cost to licensees

Kansas licensees who are affected by these regulations have already implemented the initial requirements.

The estimated increased annual cost to the radioactive material licensees to meet the requirements of these regulations is \$37,763.00. There is also an additional cost once every ten years of \$2,332.00. These numbers were calculated as illustrated below and are supported by data referenced from Appendix A of the NRC "Regulatory Analysis for Final Rule: Physical Protection of Byproduct Material (10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73)," December 2011.

The calculations below use the assumption that the Kansas licensees fall into the "small" category as defined by the NRC, which means that there are 20 or less individuals requiring the background check and no more than two reviewing officials for each license. The actual cost to licensees in Kansas may be higher or lower based on many factors including:

- The number of individuals who are granted unescorted access
- The actual security measures which are implemented to meet requirements
- The extent of training
- The number of radioactive sources possessed by the licensee

#### Annual costs:

Performance Evaluation Security and Access Authorization Program: \$10,000

Refresher Training of personnel: \$2,530.00

Coordination with local law enforcement on security: \$303.00

Maintenance and testing of security systems: \$2,750.00

Records Retention: \$550.00

Access Authorization Program/New Employees: \$982.00

Report suspicious activities: \$1,375.00

Security Measures: \$15,000.00

Category 1 Shipments: (N/A – we do not have licensees shipping in Kansas)

Category 2 Shipments: \$4,272.80

(Kansas averages 5/month; with 15 licensees ~ 4/licensee/yr):

License Verification: .25 hr X \$55 X 4 = \$55.00

Preplanning and Coordination: .50 hr X \$55 X 4 = \$110.00

Notification of Shipping Licensee upon receipt: .16 X \$55 X 4 = \$35.00

Document preplanning/coordination:  $(.25 \times $55 \times 4) + (.08 \times $55 \times 4) = $73.00$ 

Protection of Category 2 shipments: \$1,000 X 4 = \$4,000

\$55 + \$110 + \$35.00 + \$73.00 + \$4.000 = \$4,273.00

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Reinvestigate employee background: \$2,332.00

Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the rules and regulations and why such methods were rejected in favor of the proposed rules and regulations.

There are no alternative methods of implementing the federal requirements that would be less costly or less intrusive.

Consultation with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.

The department does not anticipate that the proposed regulations will have any significant financial impact on these organizations. However, copies of the regulations, the economic impact statement, and the notice of hearing will be provided electronically to these organizations at the time of publication of the notice of hearing in the *Kansas Register*.

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