

902 KAR 100:045. Exemptions.

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. 30.15, 30.16, 30.19-30.21, 40.11, 40.13

STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090(3), 211.844

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires the Cabinet for Health Services to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes exemptions from the requirements of 902 KAR Chapter 100 for certain uses of radioactive material and for specific devices containing radioactive material.

Section 1. Exemption of Source Material. The exemptions in this section do not authorize manufacture of the products described. A person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, or transfers:

(1) Source material in a chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one (1) percent (0.05 percent) of the mixture, compound, solution, or alloy;

(2) Unrefined and unprocessed ore containing source material; except that, as authorized in a specific license, the person shall not refine or possess the ore.

(3)(a) Any quantity of thorium contained in:

1. An incandescent gas mantle;

2. A vacuum tube;

3. A welding rod;

4. An electric lamp for illuminating purposes, if each lamp contains less than fifty (50) milligrams of thorium;

5. A germicidal lamp, sun lamp, or lamp for outdoor or industrial lighting, if each lamp contains less than two (2) grams of thorium;

6. A rare earth metal, compound, mixture, or product containing not more than 0.25 percent by weight thorium, uranium, or a combination of these; or

7. Personal neutron dosimeters, if each dosimeter contains less than fifty (50) milligrams of thorium.

(b) Source material contained in the following products:

1. Glazed ceramic tableware, if the glaze contains less than twenty (20) percent by weight source material;

2. Glassware containing not more than ten (10) percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass, glass enamel, or ceramic used in construction;

3. Glass enamel or glass enamel frit containing not more than ten (10) percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983;

4. Piezoelectric ceramic containing not more than two (2) percent by weight source material.

(c) Photographic film, negatives, and prints containing uranium or thorium.

(d) A finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, if the thorium content of the alloy does not exceed four (4) percent by weight. The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the product or part.

(e) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of the counterweights, if:

1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission authorizing distribution by the licensee pursuant to 10 CFR Part 40;

2. Each counterweight has been impressed with following legend clearly legible through plating or other covering: "DEPLETED URANIUM;"

3. Each counterweight is labeled or marked, durably and legibly, with the manufacturer's identification, and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED;" and

4. The exemption contained in this subsection shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the counterweights other than repair or restoration of a plating or other covering.

(f) Natural or depleted uranium metal used as shielding constituting part of a shipping container, if:

1. The shipping container is impressed, conspicuously and legibly, with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and

2. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2mm).

(g) Thorium contained in finished optical lenses, if each lens contains less than thirty (30) percent by weight of thorium. The exemption contained in this subsection shall not be deemed to authorize:

1. The shaping, grinding, or polishing of lens or manufacturing processes other than the assembly of lens into optical systems and devices without any alteration of the lens; or

2. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(h) Uranium contained in detector heads for use in fire detection units, if each detector head contains not more than 0.005 microcurie of uranium.

(i) Thorium contained in a finished aircraft engine part containing nickel-thoria alloy, if:

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

2. The thorium content in the nickel-thoria alloy does not exceed four (4) percent by weight.

Section 2. Exemption of Radioactive Material Other than Source Material. (1) Exempt concentrations. A person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of the amounts established in 902 KAR 100:085 except:

(a) This exemption shall not apply to the transfer of radioactive material contained in a food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to a human being; and

(b) A person shall not introduce radioactive material into a product or material knowing or having reason to believe that the product will be transferred to persons exempt under this subsection or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, except in accordance with a license issued as authorized by 902 KAR Chapter 100.

(2) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, a person is exempt from the requirements established in 902 KAR Chapter 100 if he receives, possesses, uses, transfers, owns, or acquires the following products:

(a) Timepieces or hand or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

1. Twenty-five (25) millicuries of tritium per timepiece;

2. Five (5) millicuries of tritium per hand;

3. Fifteen (15) millicuries of tritium per dial including the bezel;

4. 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per other

timepiece;

5. Twenty (20) microcuries of promethium-147 per watch hand or forty (40) microcuries of promethium-147 per other timepiece hand; or

6. Sixty (60) microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial including the bezel;

7. The radiation dose rate from hands and dials containing promethium-147 shall not exceed, when measured through fifty (50) milligrams per square centimeter of absorber:

a. For wrist watches, one-tenth (0.1) millirad per hour at ten (10) centimeters from a surface;

b. For pocket watches, one-tenth (0.1) millirad per hour at one (1) centimeter from a surface;

c. For other timepiece, two-tenths (0.2) millirad per hour at ten (10) centimeters from a surface.

8. One (1) microcurie of radium-226 per timepiece in timepieces acquired prior to January 3, 1986.

(b) A lock illuminator containing not more than fifteen (15) millicuries of tritium or not more than two (2) millicuries of promethium-147 installed in an automobile lock. The radiation dose rate from each lock illuminator containing promethium-147 shall not exceed one (1) millirad per hour at one (1) centimeter from a surface when measured through fifty (50) milligrams per square centimeter of absorber.

(c) A precision balance containing not more than one (1) millicurie of tritium per balance or not more than five-tenths (0.5) millicurie of tritium per balance part.

(d) An automobile shift quadrant containing not more than twenty-five (25) millicuries of tritium.

(e) A marine compass containing not more than 750 millicuries of tritium gas and other marine navigational instrument containing not more than 250 millicuries of tritium gas.

(f) A thermostat dial or pointer containing not more than twenty-five (25) millicuries of tritium per thermostat.

(g) An electron tube if it does not contain more than one (1) of the following specified quantities of radioactive material:

1. 150 millicuries of tritium per microwave receiver protector tube or ten (10) millicuries of tritium per other electron tube;

2. One (1) microcurie of cobalt-60;

3. Five (5) microcuries of nickel-63;

4. Thirty (30) microcuries of krypton-85;

5. Five (5) microcuries of cesium-137;

6. Thirty (30) microcuries of promethium-147; and, that the radiation dose rate due to radioactive material contained in each electron tube does not exceed one (1) millirad per hour at one (1) centimeter from a surface when measured through seven (7) milligrams per square centimeter of absorber. For purposes of this subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and other completely sealed tubes that are designed to conduct or control electrical currents.

(h) An ionizing radiation measuring instrument containing, for purposes of internal calibration or standardization, one (1) or more sources of radioactive material, if:

1. Each source contains no more than one (1) exempt quantity established in 902 KAR 100:080;

2. Each instrument contains no more than ten (10) exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one (1) or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one (1) or more of the exempt quantities in 902 KAR 100:080, except that the sum of the fractions shall not exceed unity; and

3. For purposes of this paragraph, 0.05 microcuries of americium-241 is considered an exempt quantity under 902 KAR 100:080.

(i) A spark cap irradiator containing not more than one (1) microcurie of cobalt-60 per irradiator,

for use in an electrically-ignited fuel oil burner having a firing rate of at least three (3) gallons per hour.

Section 3. Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. (1) A person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46, which are designed for sand consolidation in oil wells.

(2) A qualifying resin shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the cabinet or an agreement state to the manufacturer of the resin, as authorized by licensing requirements equivalent to those in Section 32.16 and 32.17 of 10 CFR Part 32.

(3) The exemption established in subsection (1) of this section does not authorize the manufacture of resins containing scandium-46.

Section 4. Gas and Aerosol Detectors Containing Radioactive Material. (1) A person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards if:

(a) Detectors containing by-product material have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission as authorized by Section 32.26 of 10 CFR, Part 32, authorizing the transfer of the detectors to persons who are exempt from regulatory requirements; or

(b) Detectors containing other than by-product, source, or special nuclear material have been manufactured or transferred in accordance with a specific license issued by the cabinet or an agreement state under requirements equivalent to those established in 902 KAR 100:058, authorizing the transfer of the detectors to persons who are exempt from regulatory requirements.

(2) The exemption established in subsection (1) of this section does not apply to persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material.

Section 5. Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147. (1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, a person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission as authorized by Section 32.22 of 10 CFR, Part 32, authorizing the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this subsection does not apply to tritium, krypton-85, or promethium-147, used in products for frivolous purposes or in toys or adornments.

(2) Radium-226. A person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, or owns articles containing less than one-tenth (0.1) microcurie of radium-226 which were acquired prior to January 3, 1986.

Section 6. Exempt Quantities. (1) Except as provided in subsections (3) and (4) of this section, a person is exempt from the requirements established in 902 KAR Chapter 100 if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity established in 902 KAR 100:080.

(2) A person who possesses radioactive material received or acquired under the general license

formerly provided in RH-8, Section 3(a)(2) of the Kentucky State Board of Health "RH" Regulations, effective October, 1968, is exempt from the requirements for a license established in 902 KAR Chapter 100 if the person possesses, uses, transfers or owns the radioactive material. The exemption does not apply for radium-226.

(3) Subsections (1) and (2) of this section do not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into a product intended for commercial distribution.

(4) A person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities established in 902 KAR 100:080 knowing or having reason to believe that the quantities of radioactive material will be transferred to persons exempt under this subsection or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission as authorized by Section 32.18 of 10 CFR, Part 32, or by the cabinet, which states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

Section 7. Radioactive Drug: Capsules Containing Carbon-14 Urea for "in vivo" Diagnostic Use for Humans. (1) Except as provided in subsection (2) of this section, a person shall be exempt from the requirements for a license established in 902 KAR 100:040 and 902 KAR 100:073 if that person receives, possesses, uses, transfers, owns, or acquires capsules containing one (1) microcurie (37 kBq) carbon-14 urea each, allowing for nominal variation that may occur during the manufacturing process, for "in vivo" diagnostic use for humans.

(2) A person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance to 902 KAR 100:040.

(3) A person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license issued by the U.S. Nuclear Regulatory Commission in accordance to 10 CFR Part 32, Section 32.21.

(4) Nothing in this section shall relieve a person from complying with applicable federal and state requirements governing receipt, administration, and use of pharmaceutical substances or dangerous materials. (1 Ky.R. 396; eff. 2-5-75; Am. 12 Ky.R. 1020; eff. 1-3-86; 13 Ky.R. 1766; eff. 5-14-87; 18 Ky.R. 1510; eff. 1-10-92; 26 Ky.R. 2392; 27 Ky.R. 967; eff. 10-16-2000.)