

## 902 KAR 100:072. Medical use of byproduct material.

RELATES TO: KRS 211.842-211.852, 211.990(4), 10 C.F.R. Part 35, 45 C.F.R. Part 46, 42 U.S.C. 2021

STATUTORY AUTHORITY: KRS 194A.050(1), 211.090(3), 211.844(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844(1) requires the Cabinet for Health and Family Services to promulgate administrative regulations for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation establishes requirements and provisions for the use of byproduct material in the healing arts, for issuance of licenses authorizing the medical use of byproduct material and for specific licensees to possess, use, and transfer byproduct material for medical uses.

Section 1. Definitions. (1) "Agreement state" means a state with which the United States Nuclear Regulatory Commission (NRC) or the United States Atomic Energy Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021(b) et seq.).

(2) "Cabinet" is defined by KRS 194A.005(1).

(3) "Licensee" means a person who holds:

(a) A specific license issued by the cabinet pursuant to 902 KAR 100:040 and this administrative regulation;

(b) A specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement state; or

(c) A general license pursuant to 902 KAR 100:050 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement state.

Section 2. Applicability. This administrative regulation establishes requirements for the medical use of byproduct material and for issuance of specific licensees authorizing the use of this material. Except as established in subsections (1) through (4) of this section, the licensee shall comply with 10 C.F.R. Part 35. (1) The licensee shall not be subject to:

(a) 10 C.F.R. 35.8;

(b) 10 C.F.R. 35.11(c)(1);

(c) 10 C.F.R. 35.13(a)(1);

(d) 10 C.F.R. 35.4001; or

(e) 10 C.F.R. 35.4002.

(2) Application for specific license. Each application for a specific license shall be filed pursuant to 902 KAR 100:040.

(3) Reference to the NRC, the Commission, or an agreement state shall be deemed to reference the Cabinet for Health and Family Services, Department for Public Health, Radiation Health Branch, the NRC, or an agreement state.

(4) Notifications and reports required by 10 C.F.R. 35.14, 35.3045, 35.3047, and 35.3067 shall be directed to the manager, Radiation Health Branch, at:

(a) 275 East Main Street, Mailstop HS1-C-A, Frankfort, Kentucky 40621;

(b) (502) 564-1492: Facsimile;

(c) (502) 564-3700: Telephone, Monday through Friday, 8 a.m. to 4:30 p.m.; or

(d) (800) 255-2587: Telephone, for hours except those established in paragraph (c) of this subsection. (31 Ky.R. 656; 1163; eff. 1-4-2005; 37 Ky.R. 1837; 2627; eff. 6-3-2011; 41 Ky.R. 921; 1612; eff. 2-5-2015; 45 Ky.R. 517, 1255, 1637; eff. 12-12-2018.)