

§ 32.1

10 CFR Ch. I (1–11 Edition)

2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of part 30 of this chapter, or

(2) Persons generally licensed under part 31 or 35 of this chapter.

This part also prescribes certain regulations governing holders of these licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part.

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on November 30, 2007 except that the agency or tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing require-

ments of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998; 72 FR 55928, Oct. 1, 2007]

§ 32.2 Definitions.

As used in this part:

Dose commitment means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it