

Nuclear Regulatory Commission

§ 32.2

- 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.
- 32.54 Same: Labeling of devices.
- 32.55 Same: Quality assurance; prohibition of transfer.
- 32.56 Same: Material transfer reports.
- 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.
- 32.58 Same: Labeling of devices.
- 32.59 Same: Leak testing of each source.
- 32.60 [Reserved]
- 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.
- 32.62 Same: Quality assurance; prohibition of transfer.
- 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.
- 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.
- 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.
- 32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.
- 32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241.
- 32.103 Schedule D—prototype tests for ice detection devices containing strontium 90.

Subpart C—Quality Control Sampling Procedures

- 32.110 Acceptance sampling procedures under certain specific licenses.

Subpart D—Specifically Licensed Items

- 32.210 Registration of product information.

Subpart E—Violations

- 32.301 Violations.
- 32.303 Criminal penalties.

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 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).

SOURCE: 30 FR 8192, June 26, 1965, unless otherwise noted.

§ 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.

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

§ 32.2 Definitions.

As used in this part:

(a) *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 is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

(b) *Lot Tolerance Percent Defective* means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974]