have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued pursuant to §32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241 in such sources:

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use and transfer of this source, Model ___, Serial No. ___, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license pursuant to this chapter or from an Agreement State to receive the source.

(4) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium–241 which might otherwise escape during storage.

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241.

[30 FR 8189, June 26, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991]

§31.9 General license to own byproduct material.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

[30 FR 8189, June 26, 1965]

§31.10 General license for strontium 90 in ice detection devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to §32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:

[1] Sources generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

(1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to part 30 or 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of § 20.2001.

(2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

(3) Are exempt from the requirements of parts 19, 20, and 21, of this chapter except that such persons shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202 of this chapter.

(c) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

[30 FR 9905, Aug. 10, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, ''Registration Certificate—In Vitro Testing with Byproduct Material Under General License,'' with the Director of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a), and has received from the Commission a validated copy of NRC Form 483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.

(c) A person who receives, acquires, possesses, or uses byproduct material