(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:
   (i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;
   (ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and
   (iii) Any other criteria specified in the license issued under §32.53.

(d) No person licensed under §32.53 shall transfer to persons generally licensed under §31.7 of this chapter:
   (1) Any luminous safety device tested and found defective under any condition of a license issued under §32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or
   (2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:
      (i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under §32.53; and
      (ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under §32.53.

§32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under §31.8 of this chapter, will be approved if:
   (a) The applicant satisfies the general requirements of §30.33 of this chapter;
   (b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
§ 32.58 Labeling of devices.

(1) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;
(2) Details of construction and design;
(3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
(5) Details of quality control procedures to be followed in manufacture of the source;
(6) Description of labeling to be affixed to the source or the storage container for the source;
(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and
(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(f) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(g) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.


§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

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 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

(Name of manufacturer or initial transferor)

[72 FR 55929, Oct. 1, 2007]

1 Sources licensed under § 32.57 before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.