Nuclear Regulatory Commission

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under §31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by §20.1901(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer
or civil authorities should be notified if
the device is found, that removal of the
labeling is prohibited and that dis-
able and repair of the device may
be performed only by a person holding
a specific license to manufacture or
service such devices;
(c) The Commission determines that:
(1) The method of incorporation and
binding of the strontium-90 in the de-
vice is such that the strontium-90 will
not be released from the device under
the most severe conditions which are
likely to be encountered in normal use
and handling of the device;
(2) The strontium-90 is incorporated
or enclosed so as to preclude direct
physical contact by any individual
with it and is shielded so that no indi-
vidual will receive a radiation exposure
to a major portion of his body in excess
of 0.5 rem in a year under ordinary cir-
cumstances of use;
(3) The device is so designed that it
cannot be easily disassembled;
(4) The device has been subjected to
and has satisfactorily passed the proto-
type tests prescribed by §32.103; and
(5) Quality control procedures have
been established to satisfy the require-
ments of §32.62.
[30 FR 9905, Aug. 10, 1965, as amended at 43
FR 6923, Feb. 17, 1978; 56 FR 23472, May 21,
§ 32.62 Same: Quality assurance; prohi-
bition of transfer.
(a) Each person licensed under §32.61
shall visually inspect each device and
shall reject any which has an observ-
able physical defect that could affect
containment of the strontium-90.
(b) Each person licensed under §32.61
shall test each device for possible loss
of strontium-90 or for contamination
by wiping with filter paper an area of
at least 100 square centimeters on the
outside surface of the device, or by wip-
ing the entire surface area if it is less
than 100 square centimeters. The detec-
tion on the filter paper of more than
2,200 disintegrations per minute of ra-
dioactive material per 100 square centi-
meters of surface wiped shall be cause
for rejection of the tested device.
(c) Each person licensed under §32.61
shall take a random sample of the size
required by the table in §32.110 for Lot
Tolerance Percent Defective of 5.0 per-
cent from each inspection lot, and shall
subject each unit in the sample to the fol-
lowing tests:
(1) Each device shall be immersed in
30 inches of water for 24 hours and shall
show no visible evidence of physical
contact between the water and the
strontium-90. Absolute pressure of the
air above the water shall then be re-
duced to 1 inch of mercury. Lowered
pressure shall be maintained for 1
minute or until air bubbles cease to be
given off by the water, whichever is the
longer. Pressure shall then be in-
creased to normal atmospheric pres-
sure. Any device which leaks, as evi-
denced by physical contact between the
water and the strontium-90, shall be
considered as a defective unit.
(2) The immersion test water from
the preceding test in paragraph (c)(1) of
this section shall be measured for ra-
dioactive material. If the amount of ra-
dioactive material in the immersion
test water is greater than 0.1 percent of
the original amount of strontium-90 in
any device, the device shall be consid-
ered as a defective unit.
(d) An application for a license or for
amendment of a license may include a
description of procedures proposed as
alternatives to those prescribed by
paragraph (c) of this section, and pro-
posed criteria for acceptance under
those procedures. The Commission will
approve the proposed alternative pro-
cedures if the applicant demonstrates
that:
(1) They will consider defective any
sampled device which has a leakage
rate exceeding 0.1 percent of the origi-
nal quantity of strontium-90 in any 24-
hour period; and
(2) The operating characteristic
curve or confidence interval estimate
for the alternative procedures provides
a Lot Tolerance Percent Defective of
5.0 percent at the consumer's risk of
0.10.
(e) No person licensed under §32.61
shall transfer to persons generally li-
censed under §31.10 of this chapter:
(1) Any device which has been tested
and found defective under the criteria
and procedures specified in this §32.62
unless the defective units have been re-
paired or reworked and then met the
tests set out in paragraph (c) of this
section; or