10A NCAC 15 .0328 is amended with changes as published in 31:07 NCR, pp. 549-582, as follows:

10A NCAC 15 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED

An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct material to persons generally licensed under Rule .0309 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

~~(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Rule .0309 of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state shall be approved if:~~

~~(1) the applicant satisfies the general requirements of Rule .0317 of this Section;~~

~~(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:~~

~~(A) the device can be safely operated by persons not having training in radiological protection;~~

~~(B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year a dose in excess of 10 percent of the limits specified in the table of Rule .1604 of this Chapter; and~~

~~(C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:~~

~~(i) whole body, head and trunk, active blood-forming organs, gonads, or lens of eye: 15 rems;~~

~~(ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter: 200 rems; or~~

~~(iii) other organs: 50 rems; and~~

~~(3) each device bears a durable, legible, visible label or labels approved by the agency, which contain in a clearly visible and separate statement:~~

~~(A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);~~

~~(B) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and~~

(C) the information called for in the following statement in the same or substantially similar form: "The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

"CAUTION RADIOACTIVE MATERIAL

(name of manufacturer or distributor)"

The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the applicant desires that the device be tested at intervals longer than six months, either for proper operation of any on-off mechanism and indicator, or for leakage of radioactive material, he or she shall include in his or her application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency shall consider information which includes:

(1) primary containment (source capsule);

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive material;

(6) maximum temperature withstood during prototype test;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

(9) radiotoxicity of contained radioactive material; and

(10) the applicant's operating experience with identical devices or similarly designed and constructed devices.

(c) If the applicant desires that the general licensee under Rule .0309 of this Section, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, be authorized to install the device, collect the sample for analysis by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he or she shall include in his or her application:

(1) Written instructions for each activity to be followed by the general licensee;

~~(2) Estimated calendar year doses associated with the activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license; and~~

~~(3) information to demonstrate that performance of the activity or activities is unlikely to cause that individual to receive a calendar year dose in excess of 10 percent of the limits specified in Rule .1604 of this Chapter.~~

~~(d) Each person licensed under this Rule to distribute devices shall furnish a copy of the general license contained in Section 31.5 of 10 CFR Part 31 to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0309 of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 31.5 of 10 CFR Part 31 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 31.5 of 10 CFR Part 31. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state's equivalent regulations shall be furnished by the licensee.~~

~~(e) Each person licensed under this Rule to distribute devices shall report to the agencies specified in Subparagraphs (e)(1), (2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. The reports shall be submitted to:~~

~~(1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;~~

~~(2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0309 of this Section; and~~

~~(3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 31.5 of 10 CFR Part 31.~~

~~(f) Each person licensed under this Rule to distribute devices shall maintain for agency inspection either copies of all reports required in Paragraph (e) of this Rule or a record containing the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
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