

4731.3330 SPECIFIC LICENSE; CERTAIN DEVICES CONTAINING RADIOACTIVE MATERIALS; MANUFACTURE OR INITIAL TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture or initially transfer devices containing radioactive material to a person generally licensed under part 4731.3215 or equivalent regulations of the NRC or an agreement state shall be approved if:

A. the applicant satisfies the general requirements of part 4731.3070;

B. 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:

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

(2) 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 one year a dose in excess of ten percent of the annual limits under part 4731.2020, subpart 1; and

(3) 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 dose to the appropriate organ as specified in part 4731.3325, Column IV;

C. each device bears a durable, legible, clearly visible label or labels approved by the commissioner, which contain in a clearly identified and separate statement:

(1) instructions and precautions necessary to ensure 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;

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

(3) 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 Minnesota commissioner of health, the Nuclear Regulatory Commission, or a state that has entered into an agreement with the Nuclear Regulatory Commission for the exercise

of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or initial transferor)"

The model, serial number, and name of the manufacturer or initial transferor may be omitted from the label if the information is elsewhere specified in labeling affixed to the device;

D. each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "Caution-Radioactive Material," the radiation symbol described in part 4731.2300, and the name of the manufacturer or initial distributor;

E. each device meeting the criteria of part 4731.3215, subpart 3a, bears a permanent embossed, etched, stamped, or engraved label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "Caution-Radioactive Material" and, if practicable, the radiation symbol described in part 4731.2300; and

F. the device has been registered in the Sealed Source and Device Registry.

Subp. 2. **Additional requirements; alternate testing intervals.** In the event the applicant desires that the device be required to be tested at intervals longer than six months, for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or for both:

A. the applicant must include in the application sufficient information to demonstrate that the longer interval is justified:

(1) by performance characteristics of the device or similar devices; and

(2) by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator; and

B. the commissioner, in determining the acceptable interval for the test for leakage of radioactive material, shall consider information that includes, but is not limited to:

(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 tests;
- (7) maximum pressure withstood during prototype tests;
- (8) maximum quantity of contained radioactive material;
- (9) radiotoxicity of contained radioactive material; and
- (10) operating experience with identical devices or similarly designed and constructed devices.

Subp. 3. **Additional requirements; general licensee authority.** If the applicant desires that a general licensee under part 4731.3215 or under equivalent regulations of the NRC or an agreement state be authorized to install the device, collect the sample to be analyzed 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, the applicant must:

A. include in the application written instructions to be followed by the general licensee, the estimated calendar quarter doses associated with such activity, and the bases for these estimates; and

B. submit information to demonstrate that performance of the activity by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause the individual to receive a dose in excess of ten percent of the annual limits under part 4731.2020, subpart 1.

Subp. 4. **Transfer for use under general license; requirements.** If a device containing radioactive material is to be transferred for use under a general license issued under part 4731.3215, a person that is licensed under this part must provide the information specified in this subpart to each person to whom a device is to be transferred. The information must be provided before the device may be transferred. In case of a transfer through an intermediate person, the information must also be provided to the intended user before the initial transfer to the intermediate person. The required information includes:

A. a copy of the general license issued under part 4731.3215. If part 4731.3215, subpart 3, items B to D, or 3a, do not apply to the particular device, those items may be omitted;

B. a copy of parts 4731.2600, 4731.2610, 4731.3115, and 4731.3205;

C. a list of the services that can only be performed by a specific licensee;

D. information on acceptable disposal options, including estimated costs of disposal; and

E. an indication that the commissioner's policy is to issue high civil penalties for improper disposal.

Subp. 5. **Transfer for use under equivalent regulations; requirements.** If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, a person that is licensed under this part must provide the information specified in this subpart to each person to whom a device is to be transferred. The information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user before initial transfer to the intermediate person. The required information includes:

A. a copy of the NRC or agreement state regulations equivalent to parts 4731.2600; 4731.2610; 4731.3115; 4731.3205; and 4731.3215, or a copy of parts 4731.2600; 4731.2610; 4731.3115; 4731.3205; and 4731.3215. If a copy of the commissioner's rules is provided to a prospective general licensee in lieu of the NRC or agreement state regulations, the copy must be accompanied by a note explaining that use of the device is regulated by the NRC or agreement state. If certain subparts, items, or subitems do not apply to the particular device, those subparts, items, and subitems may be omitted;

B. a list of the services that can only be performed by a specific licensee;

C. information on acceptable disposal options, including estimated costs of disposal; and

D. the name or title, address, and telephone number of the contact at the NRC or agreement state regulatory agency from which additional information may be obtained.

Subp. 6. **Alternative methods.** A licensee may propose an alternative method of informing customers, other than that specified under subparts 4 and 5, for approval by the commissioner.

Subp. 7. **Labeling requirements.** A device that is transferred after February 19, 2002, must meet the labeling requirements in subpart 1, items D and E.

Subp. 8. **Records upon bankruptcy.** If a notification of bankruptcy is made under part 4731.3075, subpart 4, or the license is to be terminated, a person licensed under this part must provide, upon request, to the commissioner, the NRC, and any appropriate agreement state, records of final disposition required under subpart 11.

Subp. 9. **Report; transfer for use under general license.** A person licensed under this part to initially transfer devices to generally licensed persons must report all transfers of devices to persons for use under the general license in part 4731.3215 and all receipts of devices from persons licensed under part 4731.3215 to the commissioner. The report must be submitted on a quarterly basis on a transfers of industrial devices report form prescribed

by the commissioner or in a clear and legible report containing all the data required by the form. The report must:

A. include:

(1) the identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use;

(2) the name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

(3) the date of transfer;

(4) the type, model number, and serial number of the device transferred; and

(5) the quantity and type of radioactive material in the device;

B. if one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, include the same information for both the intended user and the intermediate person and clearly designate the intermediate person;

C. for devices received from a person generally licensed under part 4731.3215, include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor;

D. if the licensee makes changes to a device possessed by a person generally licensed under part 4731.3215, such that the label must be changed to update the required information, identify the general licensee, the device, and the changes to information on the device label;

E. cover each calendar quarter, be filed within 30 days of the end of the calendar quarter, and clearly indicate the period covered by the report;

F. clearly identify the specific licensee submitting the report and include the license number of the specific licensee; and

G. if no transfers have been made to or from persons generally licensed under part 4731.3215 during the reporting period, so indicate.

Subp. 10. **Report; transfer for use under equivalent regulations.** A person licensed under this part to initially transfer devices to generally licensed persons must report all transfers of devices to persons for use under a general license issued by the NRC or an

agreement state under regulations that are equivalent to part 4731.3215, and all receipts of devices from general licensees in the NRC's or agreement state's jurisdiction to the NRC or the responsible agreement state agency. The report must be submitted on a transfers of industrial devices report form prescribed by the NRC or in a clear and legible report containing all of the data required by the form. The report must:

A. include:

(1) the identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use;

(2) the name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

(3) the date of transfer;

(4) the type, model number, and serial number of the device transferred; and

(5) the quantity and type of radioactive material contained in the device;

B. if one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, include the same information for both the intended user and each intermediate person and clearly designate the intermediate person;

C. for devices received from a general licensee, include the identity of the general licensee by name and address; the type, model number, and serial number of the device received; the date of receipt; and in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor;

D. if the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, identify the general licensee, the device, and the changes to information on the device label;

E. cover each calendar quarter, be filed within 30 days of the end of the calendar quarter, and clearly indicate the period covered by the report;

F. clearly identify the specific licensee submitting the report and include the license number of the specific licensee; and

G. upon request of the NRC or responsible agreement state agency, include a statement that no transfers have been made to or from a general licensee during the reporting period, if applicable.

Subp. 11. **Record retention.** A person licensed under this part to initially transfer devices to generally licensed persons must maintain all information concerning transfers and receipts of devices that supports the reports required under subparts 9 and 10. The records must be maintained for three years following the date of the recorded event.

Statutory Authority: *MS s 144.1201; 144.1202; 144.1203; 144.1204; 144.1205*

History: *29 SR 755; 32 SR 831; 40 SR 145*

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