

WAC 246-235-093 Manufacture, assembly or distribution of devices under general license.

(1) An application for a specific license to manufacture or initially transfer or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under WAC 246-233-020 or equivalent regulations of the NRC or an agreement state will be approved if:

(a) The applicant satisfies the general requirements of WAC 246-235-020;

(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:

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

(ii) 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 limits specified in the table in WAC 246-221-010(1); and

(iii) 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:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 centigray (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	200 centigray (200 rem)
Other organs	50 centigray (50 rem)

(c) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:

(i) 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);

(ii) 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 nuclide, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(A) The receipt, possession, use and transfer of this device, Model, Serial No. Note*, are subject to a general license or the equivalent, and the regulations of the NRC or a state with which the NRC has entered into an agreement 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 distributor)*

(B) The receipt, possession, use and transfer of this device, Model , Serial No. Note*, are subject to a general license or the equivalent, and the rules of an agreement state. 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 distributor)*

*Note: The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided 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 nuclide and quantity, the words, "CAUTION - RADIOACTIVE MATERIAL," the radiation symbol described in WAC 246-221-120, and the name of the manufacturer or initial distributor;

(e) Each device meeting the criteria of WAC 246-233-020 (3)(k), bears a permanent (e.g., 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 WAC 246-221-120;

(f) The device has been registered in the sealed source and device registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which 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. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

- (a) Primary containment (source capsule);
- (b) Protection of primary containment;
- (c) Method of sealing containment;
- (d) Containment construction materials;
- (e) Form of contained radioactive material;
- (f) Maximum temperature withstood during prototype tests;
- (g) Maximum pressure withstood during prototype tests;
- (h) Maximum quantity of contained radioactive material;
- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under WAC 246-233-020, 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 include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submit-

ted information must demonstrate that performance of such activity or activities 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 that individual to receive in one year a radiation dose in excess of ten percent of the limits specified in the table in WAC 246-221-010(1).

(4) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to generally licensed persons must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. If transfer is through an intermediate person, the information must also be provided to the intended user before initial transfer to the intermediate person.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in WAC 246-233-020, the required information must include:

(i) A copy of the general license contained in WAC 246-233-020. If WAC 246-233-020 (3)(b), (c), and (d) or (k) do not apply, those subsections may be omitted;

(ii) A copy of WAC 246-232-050, 246-221-230, 246-221-240, and 246-221-250;

(iii) A list of the services that can only be performed by a specific licensee; and

(iv) Information on acceptable disposal options including estimated costs of disposal; and

(v) An indication that the NRC's policy is to issue high civil penalties for improper disposal.

(b) If a device containing radioactive material is to be transferred for use in another jurisdiction under a general license equivalent to WAC 246-233-020, the required information must include:

(i) A copy of the appropriate NRC or an agreement state's regulations, equivalent to WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250. If a copy of WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250 is provided to a prospective general licensee in lieu of the NRC's or the agreement state's regulations, it must be accompanied by a note explaining that the use of the device is regulated by the NRC or the agreement state. If certain subsections do not apply to the particular device, those subsections may be omitted;

(ii) A list of the services that can only be performed by a specific licensee;

(iii) Information on acceptable disposal options including estimated cost of disposal;

(iv) The name or title, address, and phone number of the contact at the appropriate NRC or an agreement state regulatory agency from which additional information may be obtained; and

(v) An indication that NRC policy is to issue high civil penalties for improper disposal;

(c) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under WAC 246-233-020 must report to the department all transfers of devices to persons for use under the general license in WAC 246-233-020 and all receipts of devices from persons licensed under WAC 246-233-020.

(i) Each report must be clear and legible and contain all of the data required. The required information for transfers to general licensees includes:

(A) 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 alternative address for the general licensee must be included with information on the actual location of use;

(B) The name, title, and phone 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 regulations and requirements;

(C) The date of transfer;

(D) The manufacturer or initial transferor, the type, model number and serial number of the device transferred; and

(E) The source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, clearly identify and designate each intermediate person by name, address, contact, and relationship to the intended user.

(iii) For devices received from a general licensee under WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received; and the source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a person generally licensed under WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(v) If no transfers have been made to or from persons generally licensed under WAC 246-233-020 during the reporting period, the report must so indicate.

(vi) The report must cover each calendar quarter, must clearly indicate the period covered by the report, and must be filed within thirty days of the end of the calendar quarter.

(vii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(d) Reports to NRC or an agreement state regulatory agency.

(i) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under the NRC's regulations equivalent to WAC 246-233-020 must report to the NRC all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 246-233-020.

(ii) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under an agreement state's regulations equivalent to WAC 246-233-020 must report to the agreement state's regulatory authority all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 243-233-020.

(iii) Such report must be clear and legible and contain all of the data required. The required information for transfers to general licenses must include:

(A) 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 alternative address for the general licensee must be submitted along with information on the actual location of use;

(B) The name, title, and phone 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 regulations and requirements;

(C) The date of transfer;

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

(E) The quantity and type of radioactive material contained in the device.

(iv) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(v) For devices received from persons generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(vi) If the licensee makes changes to a device possessed by a person generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(vii) The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(viii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(ix) If no transfers have been made to or from NRC licensees during the reporting period, this information must be reported to the NRC.

(x) If no transfers have been made to or from general licensees within an agreement state during the reporting period, this information must be reported to the responsible agreement state agency upon request of the agency.

(e) The person shall maintain all information and keep records concerning transfers and receipts of devices that support the reports required by this section. Records required by this section must be maintained for a period of three years following the date of the recorded event.

(f) If a notification of bankruptcy has been made under WAC 246-233-050 or the license is to be terminated, each person licensed under this section shall provide, upon request, to the department, the

NRC or an agreement state, records of final disposition required under (e) of this subsection.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-235-093, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-093, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-093, filed 11/22/13, effective 12/23/13; WSR 04-04-055, § 246-235-093, filed 1/30/04, effective 3/1/04; WSR 98-13-037, § 246-235-093, filed 6/8/98, effective 7/9/98.]