

WAC 246-235-108 Sealed source and device registration and inactivation. (1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the department for evaluation of radiation safety information about its product and for its registration.

(2) Request for review must be sent to the department by an appropriate method, such as hard copy, properly signed electronic document, or fax.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. 10 C.F.R. 32 Subpart A includes specific criteria that apply to certain exempt products, Subpart B includes specific criteria applicable to certain generally licensed devices, and Subpart C includes specific provisions that apply to certain specifically licensed items.

(5) After completion of the evaluation, the department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

(7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(a) Calibration and reference sources containing no more than:

(i) Thirty-seven megabecquerels (one millicurie) for beta or gamma emitting radionuclides; or

(ii) 0.37 megabecquerels (ten microcuries), for alpha emitting radionuclides; or

(b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and

handle the requested quantity of radioactive material in unshielded form, as specified in their licenses and:

(i) The intended recipients are licensed under WAC 246-235-090 of this chapter, 10 C.F.R. 33, or comparable provisions of an agreement state;

(ii) The recipients are authorized for research and development;
or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 gigabecquerels (20 curies) of tritium (H-3) or 7.4 gigabecquerels (200 millicuries) of any other radionuclide.

(8) After the certificate is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this section. The department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

(9)(a) A certificate holder who no longer manufactures or initially transfers any of the sealed sources or devices covered by a particular certificate issued by the department shall request inactivation of the registration certificate from the department. Such a request must be made to the department by an appropriate method and must normally be made no later than two years after initial distribution of all of the sources or devices covered by the certificate has ceased. However if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(b) If a distribution license is to be terminated in accordance with chapters 246-232, 246-233, and 246-235 WAC, the licensee shall request inactivation of its registration certificates associated with that distribution license before the department will terminate the license. Such a request for inactivation of certificates must indicate that the license is being terminated and include the associated specific license number.

(c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-108, filed 9/20/22, effective 10/21/22. Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-108, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-108, filed 6/10/16, effective 7/11/16.]