Ohio Administrative Code

Rule 3701:1-46-49 Registration of product information.

Effective: November 8, 2015

(A) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the director for evaluation of radiation safety information about its product and for its registration.

(B) The request for review must be made in duplicate and sent to the director at the following address:

"Ohio Department of Health

Bureau of Environmental Health and Radiation Protection

246 North High Street

Columbus, Ohio 43215"

(C) 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.

(D) The director 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 director formulates reasonable standards and criteria with the help of the manufacturer or distributor. The director 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.

(E) After completion of the evaluation, the director 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.

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

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

(2) The provisions of the registration certificate.

(G) 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:

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

(a) Thirty seven megabecquerels (one millicurie), for beta and/or gamma emitting radionuclides; or

(b) 0.37 megabecquerels (10 microcuries), for alpha emitting radionuclides; or

(2) 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

(a) The intended recipients are licensed under chapter 3701:1-40 of the Administrative Code or

comparable provisions of another agreement state or the United States nuclear regulatory commission; or

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

(c) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than seven hundred forty gigabecquerels (twenty curies) of tritium or 7.4 gigabecquerels (two hundred millicuries) of any other radionuclide.

(H) After the certificate is issued, the director may conduct an additional review as he/she determines is necessary to ensure compliance with current regulatory standards. In conducting the review, the director will complete his/her evaluation in accordance with criteria specified in this rule. The director may request such additional information as he/she considers necessary to conduct his/her review and the certificate holder shall provide the information as requested.

(I) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the director shall request inactivation of the registration certificate. Such a request must be made to the director by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code and must normally be made no later than two years after the initial distribution of all of the source(s) or device(s) 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 ninety days of this determination and briefly describe the circumstances of the delay.

(J) If a distribution license is to be terminated in accordance with rule 3701:1-40-18 of the Administrative Code, the licensee shall request inactivation of its registration certificates associated with that distribution license before the director will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(K) 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.