Ohio Administrative Code

Rule 3701:1-40-14 Application for specific licenses.

Effective: April 17, 2022

(A) An applicant for a license to receive and possess radioactive material shall apply in accordance with rule 3701:1-38-02 of the Administrative Code and this chapter on a form prescribed by the director. The original application shall be filed with the director. Information contained in previous applications, statements or reports filed with the director may be incorporated by reference, provided that the reference is clear, specific, and has been on file with the department for not more than two licensing periods, and provided that the item being referenced in the document is being referenced without change.

(B) The director may at any time after the filing of the original application require additional information from the applicant in order to determine whether a license should be issued or whether a current license should be modified or revoked.

(C) Each application shall be signed by the applicant or a person duly authorized to act for the applicant.

(D) An application for a license to receive and possess radioactive material for the conduct of any activity which the director has determined pursuant to rule 3701:1-40-36 of the Administrative Code could potentially affect the quality of the environment shall be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any environmental report required pursuant to rule 3701:1-40-36 of the Administrative Code. The applicant is prohibited from the commencement of construction activities in areas covered by the environmental reporting requirements identified in rules 3701:1-40-30 to 3701:1-40-38 of the Administrative Code before the conclusion of these reviews. The terms "construction" and "commencement of construction" shall have the same meaning as identified in rule 3701:1-38-01 of the Administrative Code.

(E)

(1) Except as provided in paragraphs (E)(2), (E)(3), and (E)(4) of this rule, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed sources must either:

(a) Identify the source or device by manufacturer and model number as registered in the sealed source and device registry of the United States nuclear regulatory commission in accordance with sealed source and device registry requirements contained in rule 3701:1-46-49 of the Administrative Code, or with equivalent requirements from an agreement state or the United States nuclear regulatory commission; or

(b) Contain the information specified in sealed source and device registry requirements contained in paragraph (C) of rule 3701:1-46-49 of the Administrative Code so that the director is able to perform the review.

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the director in accordance with rule 3701:1-46-49 of the Administrative Code or equivalent requirements from an agreement state or the United States nuclear regulatory commission, and for which the applicant is unable to provide all categories of information specified in rule 3701:1-46-49 of the Administrative Code, the applicant must provide:

(a) All available information identified in rule 3701:1-46-49 of the Administrative Code concerning the source, and, if applicable, the device; and

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with rule 3701:1-46-49 of the Administrative Code, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed sources and device.

(F) In the case of an application for a license specified in rule 3701:1-40-16 of the Administrative Code, or an application for a specific license specified in Chapter 3701:1-46, 3701:1-48, or 3701:1-58 of the Administrative Code, the applicant shall provide a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

(G) Requirement for an emergency response plan:

(1) Each application to possess radioactive materials in excess of the quantities specified in the appendix to this rule, whether in unsealed form, on foils or plated sources, or sealed in glass, shall contain either:

(a) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 sievert (one rem) TEDE or 0.05 sievert (five rem) to the thyroid; or

(b) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation of the need to submit an emergency plan under this paragraph:

(a) The radioactive material is physically separated so that only a portion of the material could be involved in an accident;

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(c) The release fraction in the respirable size range would be lower than the release fraction specified in the appendix to this rule due to the chemical or physical form of the material;

(d) The solubility of the radioactive material would reduce the dose received;

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than the limit specified in the appendix to this rule;

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in the appendix to this rule; or

(g) Other factors appropriate for the specific facility as determined by the director.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (G)(1)(b) of this rule shall include the following information:

(a) A brief description of the licensee's facility and the area near the site.

(b) An identification of each type of possible radioactive material accident which may require protective action.

(c) A classification system for classifying an accident as either an alert or a site area emergency.

(d) Identification of the means of detecting each type of accident in a timely manner.

(e) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(f) A brief description of the methods and equipment to assess releases of byproduct and accelerator produced materials.

(g) A brief description of the responsibilities of the licensee's personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department, and identification of personnel responsible for developing, maintaining, and updating the plan.

(h) A commitment to, and a brief description of, the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that in the event that some personnel, parts of the facility, or some equipment is not available, that unavailability will not prevent such notification and coordination. The licensee shall also commit to notifying the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements of the "Emergency Planning and Community Right-to-Know Act of 1986, "Title III of Pub. L. 99-499, 100 Stat. 1728, 42 U.S.C. 11001 et seg. or other state or federal reporting requirements.

(i) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the department.

(j) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. The training also shall thoroughly prepare site personnel for their responsibilities in the event of an accident, including training on the emergency scenarios postulated as most probable for the specific site, and the use of team training for such scenarios.

(k) A brief description of the means of restoring the facility to a safe condition after an accident.

(l) Provisions for conducting quarterly communication checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communication checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall

critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(m) A certification that the applicant has met all responsibilities under the "Emergency Planning and Community Right-to-Know Act of 1986, "Title III of Pub. L. 99-499, 100 Stat. 1728, 42 U.S.C. 11001 et seg, if applicable to the applicant's activities at the proposed place of use of the byproduct or accelerator produced material.

(n) The licensee must have and maintain liability coverage for incidents which would activate the plan to cover bodily injury and property damage to third parties caused by incidents which would activate the plan in the amount of at least one million dollars per occurrence with an annual aggregate of at least two million dollars, exclusive of legal defense costs.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident sixty days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the sixty days to the department with the emergency plan.

(H) Information provided by a licensee or applicant for a license or license renewal that constitutes a "trade secret" as defined in section 1333.61 of the Revised Code is not subject to public disclosure in accordance with sections 1333.61 to 1333.69 of the Revised Code.

(I) An application from a medical facility, or educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with rules in Chapter 3701:1-58 of the Administrative Code shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with rule 3701:1-38-02 of the Administrative Code for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in paragraph (A)(2) of rule 3701:1-46-43 of the Administrative Code.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in paragraph (B)(2) of rule 3701:1-46-43 of the Administrative Code.

(4) Information identified in paragraph (A)(3) of rule 3701:1-46-43 of the Administrative Code, on the PET drugs to be non-commercially transferred to members of its consortium.