4731.3065 SPECIFIC LICENSES; APPLICATION.

Subpart 1. **General requirements.**

A. Applications for specific licenses must be filed on an application for radioactive material license form prescribed by the commissioner.

B. An application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee.

C. The commissioner may at any time after the filing of the original application, and before the expiration of the license, require further statements to enable the commissioner to determine whether the application should be granted or denied or whether a license should be modified or revoked.

D. An application must be accompanied by the fee prescribed under Minnesota Statutes, section 144.1205.

E. An application for a license to receive and possess radioactive material that the commissioner has determined will significantly affect the quality of the environment must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any environmental report as required under Code of Federal Regulations, title 10, part 51, subpart A.

Subp. 2. **Sealed source requirements.**

A. Except as provided in items B, C, and D, 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 source must:

(1) identify the source or device by manufacturer and model number as registered with the NRC under Code of Federal Regulations, title 10, section 32.210, with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to Code of Federal Regulations, title 10, section 32.210; or

(2) contain the information identified in Code of Federal Regulations, title 10, section 32.210 (c).

B. For sources or devices manufactured prior to October 23, 2012, that are not registered with the NRC under Code of Federal Regulations, title 10, section 32.210, or with an agreement state, and for which the applicant is unable to provide all categories of information specified in Code of Federal Regulations, title 10, section 32.210 (c), the applicant must provide:

(1) all available information identified in Code of Federal Regulations, title 10, section 32.210 (c) and this chapter concerning the source, and, if applicable, the device; and

(2) 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. This 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.

C. For sealed sources and devices allowed to be distributed without registration of safety information according to Code of Federal Regulations, title 10, section 32.210 (g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

D. 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 source and device.

Subp. 3. **Decommissioning requirements.** As provided under part 4731.3080, certain applications for specific licenses filed under parts 4731.3000 to 4731.3175 and 4731.3300 to 4731.4527 must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

Subp. 4. **Additional requirements.**

A. An application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in part 4731.3150 must contain:

(1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive material would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(2) an emergency plan for responding to a release of radioactive material.

B. One or more of the following factors may be used to support an evaluation submitted under item A, subitem (1):

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

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

(3) the release fraction in the respirable size range would be lower than the release fraction shown in part 4731.3150 due to the chemical or physical form of the material;

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

(5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in part 4731.3150;

(6) operating restrictions or procedures would prevent a release fraction as large as that shown in part 4731.3150; or

(7) other factors appropriate for the specific facility.

Subp. 5. **Emergency plan.** An emergency plan submitted under subpart 4, item A, subitem (2), must include:

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

B. identification of each type of radioactive materials accident for which protective actions may be needed;

C. a classification system for classifying accidents as alert or site area emergencies;

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 on-site, and a description of the program for maintaining the equipment;

F. a brief description of the methods and equipment to assess releases of radioactive materials;

G. a brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the commissioner, and the responsibilities for developing, maintaining, and updating the plan;

H. a commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment does not prevent notification and coordination. The licensee must also commit to notifying the commissioner immediately after the licensee has notified the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release a licensee's responsibility to comply with the Emergency Planning and Community Right-to-Know Act of 1986, title III, Public Law 99-499, 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 off-site response organizations and to the commissioner;

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 must:

(1) familiarize personnel with site-specific emergency procedures;

(2) thoroughly prepare site personnel for their responsibilities in the event of an accident, using accident scenarios postulated as the most probable for the specific site; and

(3) use team training for accident scenarios postulated as the most probable for the specific site;

K. a brief description of the means of restoring the facility to a safe condition after an accident;

L. provisions for conducting quarterly communications checks with off-site response organizations and biennial on site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include checking and updating all necessary telephone numbers. The licensee must invite off-site response organizations to participate in the biennial exercises. Participation of off-site 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 must not be known to most exercise participants. The licensee must critique the exercises 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; and

M. a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

Subp. 6. **Comments.** A licensee must:

A. allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the commissioner; and

B. provide any comments received within the 60 days to the commissioner along with the emergency plan.

Subp. 7. **Application to produce PET radioactive drugs.** An application from a medical facility, educational institution, or federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under NRC, or equivalent agreement state requirements must include:

A. a request for authorization for the production of PET radionuclides or evidence of an existing license issued by the NRC, or an agreement state with requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

B. evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in part 4731.3395, subpart 1;

C. identification of individuals 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 part 4731.3395, subpart 2; and

D. information identified in part 4731.3395, subpart 1, on the PET drugs to be noncommercially transferred to members of its consortium.

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

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