

This is an amendment to 20.3.3.307 NMAC, Sub-Section E effective XX/XX/2022.

20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES:

A. Except where otherwise determined by the department, applications for specific licenses shall be filed in duplicate on a form prescribed by the department (*application for a radioactive material license*) in accordance with the instructions to the form. Additional copies of the application may be required by the department. Information contained in previous application, statements or reports filed with the department may be incorporated by reference, provided that the reference is clear and specific.

B. The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application shall be granted or denied or whether a license shall be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on their behalf.

D. An application for a license may include a request for a license authorizing more than one activity, provided that the application specifies the additional activities for which licenses are requested and complies with the requirements in this chapter as to applications for such licenses. In such cases, annual fees for all types of activities authorized by the license may be charged as determined by 20.3.16 NMAC.

E. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows:

- (1) any reference to the commission or NRC shall be deemed a reference to the department;
- (2) 10 CFR 37.5 definitions of agreement state, byproduct material, commission and person shall not be applicable;
- (3) 10 CFR 37.7, 10 CFR 37.9, 10 CFR 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.27(c), 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable; and
- (4) the license required report of events or notification in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 71, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469.

F. 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 identify the source and (or) the device by manufacturer name and model number as registered with the *sealed source and device registry*.

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

(a) identify the source or device by manufacturer and model number registered with the NRC pursuant to 10 CFR 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 10 CFR 32.210; or

(b) contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application must include:

(a) all available information identified in 10 CFR 32.210(c) 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 10 CFR 32.210(g)(1), 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 source and device.

G. As provided by 20.3.3.311 NMAC, certain applications for a new or renewal specific license must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

H. An application for a license to receive and possess radioactive material for the conduct of any activity which the department has determined pursuant to Subpart A of 10 CFR 51 will significantly 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 an environmental impact report required pursuant to Subpart A of 10 CFR 51.

I. None of the following applications shall be accepted for review unless it is accompanied by an environmental impact report, submitted by the applicant, that specifically addresses the short-term and long-term environmental, radiological and public health and safety aspects of the applications and alternatives to the proposed action:

- (1) an initial application for a radioactive material license for a commercial radioactive waste disposal site license;
- (2) the first renewal of any such license not previously accompanied by an environmental impact report;
- (3) an application for an amendment to an existing license that may result in additional significant impacts from radiation on the environment or public health or safety beyond those impacts addressed in the existing license and accompanying documents; and
- (4) any other application that the secretary determines may have significant impacts from radiation on the environment or public health or safety.

J. The application for a radioactive material license for a commercial radioactive waste disposal site, or for any renewal thereof, or for an amendment thereto as described in Paragraph (3) of Subsection H of this section, shall demonstrate that the activity for which such license is requested will comply with all laws and regulations enforceable by the department.

K. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 20.3.7 NMAC shall include:

- (1) a request for authorization for the production of PET radionuclides or evidence of an existing license issued under 20.3.3 NMAC or under equivalent NRC or agreement state requirements 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 Subparagraph (b) of Paragraph (1) of Subsection J of 20.3.3.315 NMAC;
- (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 Subparagraph (b) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC; and
- (4) information identified in Subparagraph (c) of Paragraph (1) of Subsection J of 20.3.3.315 NMAC on the PET drugs to be non-commercially transferred to members of its consortium.

L. An application for a specific license to transfer source material under this section.

- (1) An application for a specific license to initially transfer source material for use under 20.3.3.307 NMAC, will be approved if:
 - (a) the applicant satisfies the general requirements specified in this section; and
 - (b) the applicant submits adequate information on, and the department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.
- (2) Each person licensed under this section shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."
- (3) Each person licensed under this section shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
- (4) Each person licensed under this section shall provide the information specified in this paragraph to each person to whom source material is transferred for use under this section. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
 - (a) a copy of Subsection B of 20.3.3.304.B NMAC and 10 CFR 40.51 or equivalent regulations under Subsection L of 20.3.3.307 NMAC; and
 - (b) appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.
- (5) Each person licensed under this section shall report transfers as follows:
 - (a) File a report with the department under 20.3.1.116 NMAC. The report shall include the following information:
 - (i) The name, address, and license number of the person who transferred

the source material; and

(ii) For each general licensee under 10 CFR 40.22 or 20.3.3.304 NMAC to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible agreement state agency that identifies all persons, operating under the provisions equivalent to 10 CFR 40.22, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state:

(i) The name, address, and license number of the person who transferred the source material;

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.

(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 10 CFR 40.22 or equivalent agreement state provisions during the current period, a report shall be submitted to the NRC indicating so. If no transfers have been made to general licensees in a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon request of the agency.

(d) Each person licensed under 20.3.3.304 NMAC shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an agreement state agency.

[20.3.3.307 NMAC - Rp, 20.3.3.307 NMAC, 04/30/2009; A, XX/XX/2022]