

This is an amendment to 20.3.7.700 NMAC, Sub-Section E effective XX/XX/XXXX.

20.3.7.700 GENERAL REGULATORY REQUIREMENTS:

A. Provisions for research involving human subjects.

(1) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on the license.

(2) If the research is conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects* (45 CFR Part 46), the licensee shall, before conducting research:

(a) obtain review and approval of the research from an “institutional review board,” as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain “informed consent,” as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(3) If the research will not be conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects*, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license issued by the department. The amendment request must include a written commitment that the licensee will, before conducting research:

(a) obtain review and approval of the research from an “institutional review board,” as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain “informed consent,” as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(4) Nothing in this subsection relieves licensees from complying with the other requirements in this part.

B. FDA, federal and state requirements. Nothing in this part relieves the licensee from complying with applicable FDA, other federal and state requirements governing radioactive drugs or devices.

C. Implementation.

(1) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(2) A licensee shall continue to comply with any license condition that requires it to implement procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC until there is a license amendment or renewal that modifies the license condition.

D. License required.

(1) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer radioactive material for medical use only in accordance with a specific license issued by the department or as allowed in Paragraph (2) of this subsection.

(2) A specific license is not needed for an individual who:

(a) receives, possesses, uses or transfers radioactive material in accordance with the requirements in this chapter under the supervision of an authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition; or

(b) prepares unsealed radioactive material for medical use in accordance with the requirements in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition.

E. Application for license, amendment or renewal.

(1) An application must be signed by the applicant or licensee, or a person duly authorized to act for or on their behalf.

(2) An application for a license for medical use of radioactive material as described in 20.3.7.704 NMAC, 20.3.7.705 NMAC, 20.3.7.708 NMAC, 20.3.7.710 NMAC, 20.3.7.711 NMAC, 20.3.7.712 NMAC and 20.3.7.713 NMAC must be made by:

(a) filing in duplicate of a department form, *application for radioactive material license*, completed according to the instructions in the form; and

(b) submitting written procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

(3) 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:

(a) any reference to the commission or NRC shall be deemed a reference to the department;

(b) 10 CFR 37.5 Definitions of: agreement state, byproduct material, commission and person shall not be applicable,

(c) 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 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable;

(d) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

(4) A request for a license amendment or renewal must be made by:

(a) filing in duplicate of a department form, *application for radioactive material license*, as described in Paragraph (2) of this subsection; and

(b) submitting procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

(5) In addition to the requirements in Paragraphs (2) and (3) of this subsection, an application for a license or amendment for medical use of radioactive material described in 20.3.7.713 NMAC must also include information regarding any radiation safety aspects of the medical use of the material that are not addressed in sections 20.3.7.702 NMAC and 20.3.7.703 NMAC. The applicant shall also provide specific information on:

(a) radiation safety precautions and instructions;

(b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

(6) The applicant or licensee shall also provide any other additional information requested by the department in its review of the application, license renewal or amendment, within 30 days of the request or other time as may be specified in the request.

(7) An applicant that satisfies the requirements specified in Subsection B of 20.3.3.314 NMAC may apply for a type "A" specific license of broad scope.

F. License amendments. A licensee shall apply for and must receive a license amendment:

(1) before it receives, prepares or uses radioactive material for a type of use that is permitted under 20.3.7 NMAC but that is not authorized on the licensee's current license issued under this part;

(2) before it permits anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license, except:

(a) for an authorized user, an individual who meets the definition of an *authorized user* as defined in 20.3.7.7 NMAC;

(b) for an authorized nuclear pharmacist, an individual who meets the definition of an *authorized nuclear pharmacist* as defined in 20.3.7.7 NMAC;

(c) for an authorized medical physicist, an individual who meets the definition of an *authorized medical physicist* as defined in 20.3.7.7 NMAC; or

(d) a physician, podiatrist or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use in non-licensing state (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates;

(3) before it changes radiation safety officers, except as provided in Paragraph (4) of Subsection A of 20.3.7.702 NMAC;

(4) before it receives radioactive material in excess of the amount or in a different form, or receives a different radioactive material than is authorized on the license;

(5) before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change includes the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; other areas of use where radioactive material is used only in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC are exempt;

(6) before it changes the address(es) of use identified in the application or on the license; and

(7) before it revises procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable, where such revision reduces radiation safety.

G. Notifications.

(1) For each individual, no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under Paragraph (2) of Subsection F of this section: *1*) the licensee shall verify the training and experience and provide the department with a copy the documentation demonstrating the training and experience as listed in the definitions of authorized user, authorized nuclear pharmacist or authorized medical physicist in 20.3.7.7 NMAC; or *2*) the licensee shall verify the training and experience and provide the department of a copy of the documentation demonstrating that only accelerator-produced radioactive materials, discrete sources, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use in non-licensing states (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC.

(2) A licensee shall notify the department by letter no later than 30 days after:

(a) an authorized user, an authorized nuclear pharmacist, radiation safety officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) the licensee permits an authorized user or an individual qualified to be a radiation safety officer, under Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50 and Subsection E of 20.3.7.714 NMAC, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with Paragraph (4) of Subsection A of 20.3.7.702 NMAC.

(c) the licensee's mailing address changes;

(d) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Subsection B of 20.3.3.317 NMAC; or

(e) the licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area.

(3) A licensee shall notify the department by letter no later than 30 days after a calibration, transmission or reference source under Subsection E of 20.3.7.703 NMAC is acquired. The notification shall contain a description of the source, manufacturer name, model and serial number of the source, and the license number of the manufacturer of the specific license issued by the department, NRC or an agreement state under Subsection K of 20.3.3.315 NMAC or equivalent NRC or agreement state requirements.

(4) The licensee shall send the documents required in this subsection to the appropriate address identified in 20.3.1.116 NMAC.

H. Exemptions regarding type A specific licenses of broad scope. A licensee possessing a type "A" specific license of broad scope for medical use, issued under 20.3.3.314 NMAC, is exempt from:

(1) the provisions of Paragraph 4 of Subsection E of 20.3.7.700 NMAC regarding the need to file an amendment to the license for medical use of radioactive materials, for use described in 20.3.7.713 NMAC;

(2) the provisions of Paragraph (2) of Subsection F of 20.3.7.700 NMAC;

(3) the provisions of Paragraph (5) of Subsection F of 20.3.7.700 NMAC regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;

(4) the provisions of Paragraph (1) of Subsection G of 20.3.7.700 NMAC;

(5) the provisions of Subparagraph (a) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC for an authorized user, an authorized nuclear pharmacist or an authorized medical physicist;

(6) the provisions of Subparagraph (e) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC;

(7) the provisions in Paragraph (3) of Subsection G of 20.3.7.700 NMAC; and

(8) the provisions of Paragraph (1) of Subsection I of 20.3.7.702 NMAC.

[20.3.7.700 NMAC - Rp, 20 NMAC 3.1.7.700, 04/30/2009; A, XX/XX/XXXX]