

Instructions for submitting training and experience information for authorized nuclear pharmacist

NRC Medical Use Applicants, Licensees, and Master Materials Permittees

This instruction describes the training and experience information that applicants, licensees and Master Material License (MML) permittees should submit for each authorized nuclear pharmacist (ANP) in Item 7, "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience" of NRC Form 313, "Application for a Materials License." These instructions are effective until the Office of Management and Budget (OMB) approves the revisions to the NRC Form 313 A series.

Usually, applicants, licensees, and permittees use the NRC Form 313 A series to provide training and experience information. However, OMB has not yet approved the revisions to the revised NRC Form 313 A series that comports with the final rule, "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," 83 FR 33046 (July 16, 2018). Therefore, these forms should not be used by medical use applicants, licensees, or permittees in submissions to either the NRC or an MML. The current NRC Form 313 A series of forms should also not be used because they do not comport with the final rule.

Applicants, licensees, and permittees should follow the instructions provided below to provide training and experience information to the NRC and MMLs. These instructions are from pages 30 through 49 of "Guidance for the Final Rule 'Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments,'" which is available at <https://www.nrc.gov/docs/ML1817/ML18176A377.pdf>. These instructions comport with the training and experience requirements in 10 CFR Part 35 that went into effect on January 14, 2019.

Authorized Nuclear Pharmacist

Provide the following:

- Provide the following:

- Name of the proposed ANP;

AND

- Pharmacist's license number and issuing entity;

AND

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 35.57(a)(4):

- Documentation that the nuclear pharmacist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC;

AND

- Documentation that the nuclear pharmacist used these materials for the same uses as requested.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification of the specialty board whose certification process has been recognized¹ under 10 CFR 35.55(a);

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 35.55(b):

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience;

AND

- Written attestation, signed by a preceptor ANP², that the above training and experience have been satisfactorily completed and that the individual is able to independently fulfill the radiation safety-related duties as an ANP;

¹ The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

²Document that the preceptor ANP meets the criteria to sign the attestation.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.