

Instructions for submitting training and experience information for authorized user for uses under 10 CFR 35.300

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 user (AU) for uses under 10 CFR 35.300 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 User for Medical Uses under 35.300:

Provide the following:

- Name of the proposed AU and uses requested;

AND

- Medical license number and issuing entity;

AND

For an individual previously identified as an AU on an NRC or Agreement State license or permit:

- 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 physician was specifically named as an AU for the uses requested;

AND

- For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is

also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 35.396 or 35.390(b)(1)(ii)(G)). A preceptor attestation may also be required. (For example, a preceptor attestation is needed for all individuals to meet the requirements of 10 CFR 35.396 and for individuals seeking authorization through the alternate training and experience pathway for 35.390.)

AND

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

For an individual qualifying under 10 CFR 35.57(b)(3):

- Documentation that the physician used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses performed 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 an earlier date as noticed by the NRC;

AND

- Documentation that the physician used these materials for the same medical uses requested;

AND

- For an AU requesting a medical use for which he or she is not currently authorized on a license or permit, a description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 35.396 or 35.390(b)(1)(ii)(G)). A preceptor attestation may also be required. (For example, a preceptor attestation is needed for all individuals to meet the requirements of 10 CFR 35.396 and for individuals seeking authorization through the alternate training and experience pathway for 35.390).

AND

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

For an individual who was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2):

- Copy of certification issued before October 24, 2005, by a specialty board whose certification is listed in 10 CFR 35.57(b)(2);

AND

- Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

AND

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

For an individual qualifying under 10 CFR Part 35, Subpart E who is board-certified:

- A copy of the certification(s) by a specialty board(s) whose certification process has been recognized¹ by the NRC under 10 CFR Part 35, Subpart E;

AND

- For a physician with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;

AND

- For a physician with a board certification recognized under 10 CFR 35.490 or 10 CFR 35.690 for medical uses described in 10 CFR 35.396, a description of the training and supervised work experience required in 10 CFR 35.396(b)(1) and (2) and a copy of the attestation required in 10 CFR 35.396(b)(3) to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;

AND

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

For an individual qualifying under 10 CFR Part 35, Subpart E who is not board-certified:

- A description of the training and experience identified in 10 CFR Part 35, Subpart E demonstrating that the proposed AU is qualified by training and experience for the use(s) requested;

AND

- A written attestation, signed by a preceptor physician AU² or if applicable the residency program director³, that the above training and experience have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested medical uses;

AND

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

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>.

² Documents that the preceptor physician AU meets the criteria to sign the attestation.

³ Document that the criteria for the residency program director to sign the attestation are met.