How to Become an Authorized User (AU)

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How to Become an Authorized User (AU)…

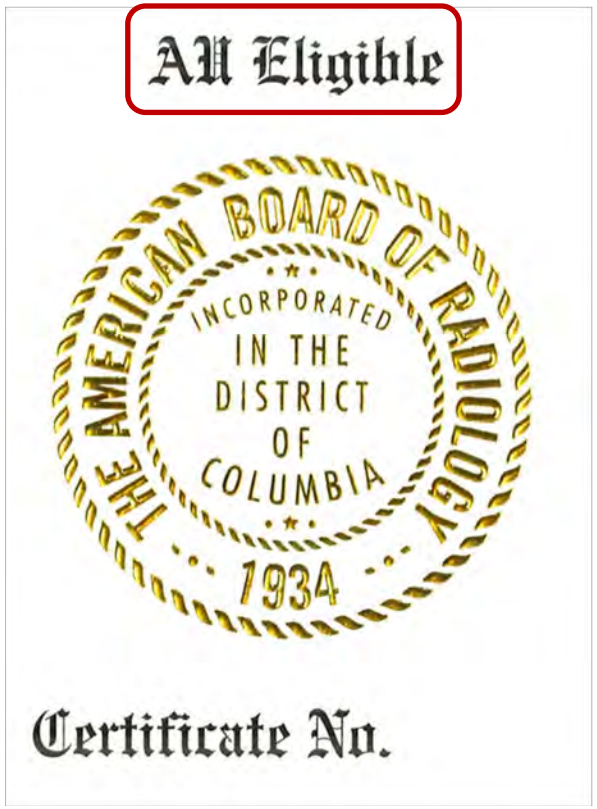
- Getting started
- Pathways to AU status
  - The direct pathway
  - The alternative pathway
  - The highly specific pathway
- NRC Form N313a

Authorized User (AU) – Getting Started

- **First and foremost, sit down and talk with your Radiation Safety Officer (RSO).**
  - They will be the most knowledgeable about the requirements for your state/municipality, and will be the one submitting your paperwork.
  - Plus, once you are an AU utilizing radiopharmaceuticals, open communication and collaboration with the RSO is absolutely critical to a successful program!

Authorized User (AU) Status

- The ABR decided to discontinue maintaining NRC recognition of all currently recognized ABR certification processes after 12/1/2023.
  - Individuals that receive ABR certificates after 12/1/2023, and are seeking to be identified as an Authorized User (AU), Authorized Medical Physicist (AMP), Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) on a license, may seek certification through a different NRC- recognized specialty board **or provide documentation of the applicable training and experience to their employer or licensee.**
  - The licensee may provide the individual's training and experience records to the NRC or Agreement State to verify that the individual meets the NRC training and experience criteria for the uses requested.



AU Status – Training and Experience

- Remember that as a board certified radiation oncologist, the ACGME and the Review Committee would have recommended that your program provide at least 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training.[1]
  - These hours can include basic physics, cancer biology, and general clinical care of oncologic patients who may or may not receive unsealed sources.

- **From 10 CFR 35.59 Recentness of training:[2]**
  - The training and experience … **must have been obtained within the 7 years preceding the date of application <u>or</u>** the individual **must have had related continuing education and experience** since the required training and experience was completed.

1. https://www.acgme.org/specialties/radiation-oncology/program-requirements-and-faqs-and-applications/
2. https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0059.html

Pathways to Authorized User (AU) Status

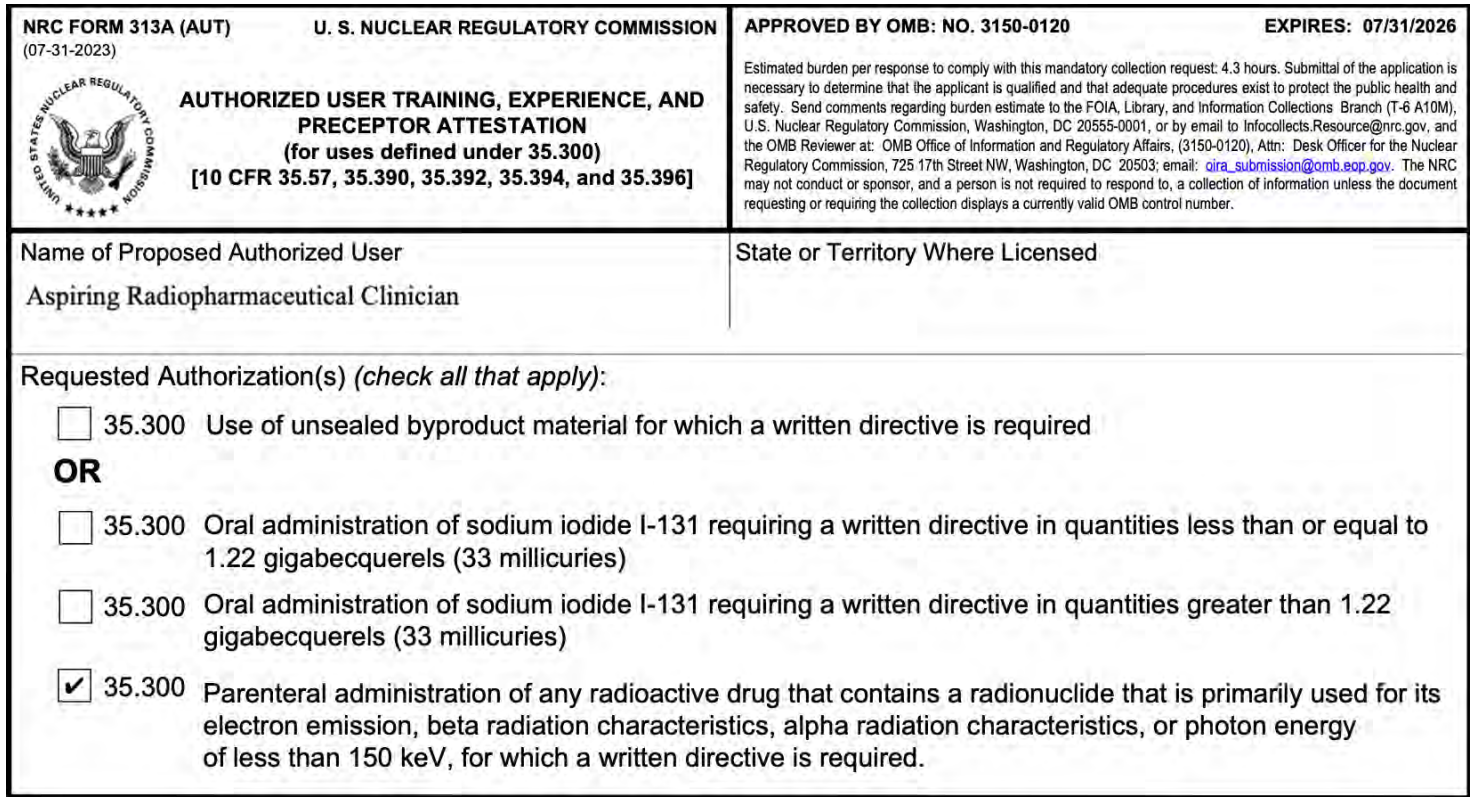
- ***The direct pathway***
- ***The alternative pathway***
- ***The crossover pathway***

Pathways to Authorized User (AU) Status

- ***The direct pathway***
  - No longer an official path (with AU-eligibility from ABR), but even with this pathway documentation needed to be submitted.

  - This and all radiopharmaceutical AU pathways utilize the **NRC Form N313a (AUT)**
    - The NRC Form N313a (AUS) provides access to manual brachytherapy sources, ophthalmic Sr-90, HDR afterloader units, and sealed source teletherapy/gamma knife units, which many of you will have had completed

NRC Form 313A



NRC FORM 313A (AUT) U. S. NUCLEAR REGULATORY COMMISSION
(07-31-2023)

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 07/31/2026

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oira_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

Name of Proposed Authorized User
Aspiring Radiopharmaceutical Clinician

State or Territory Where Licensed

Requested Authorization(s) *(check all that apply)*:

- ☐ 35.300 Use of unsealed byproduct material for which a written directive is required

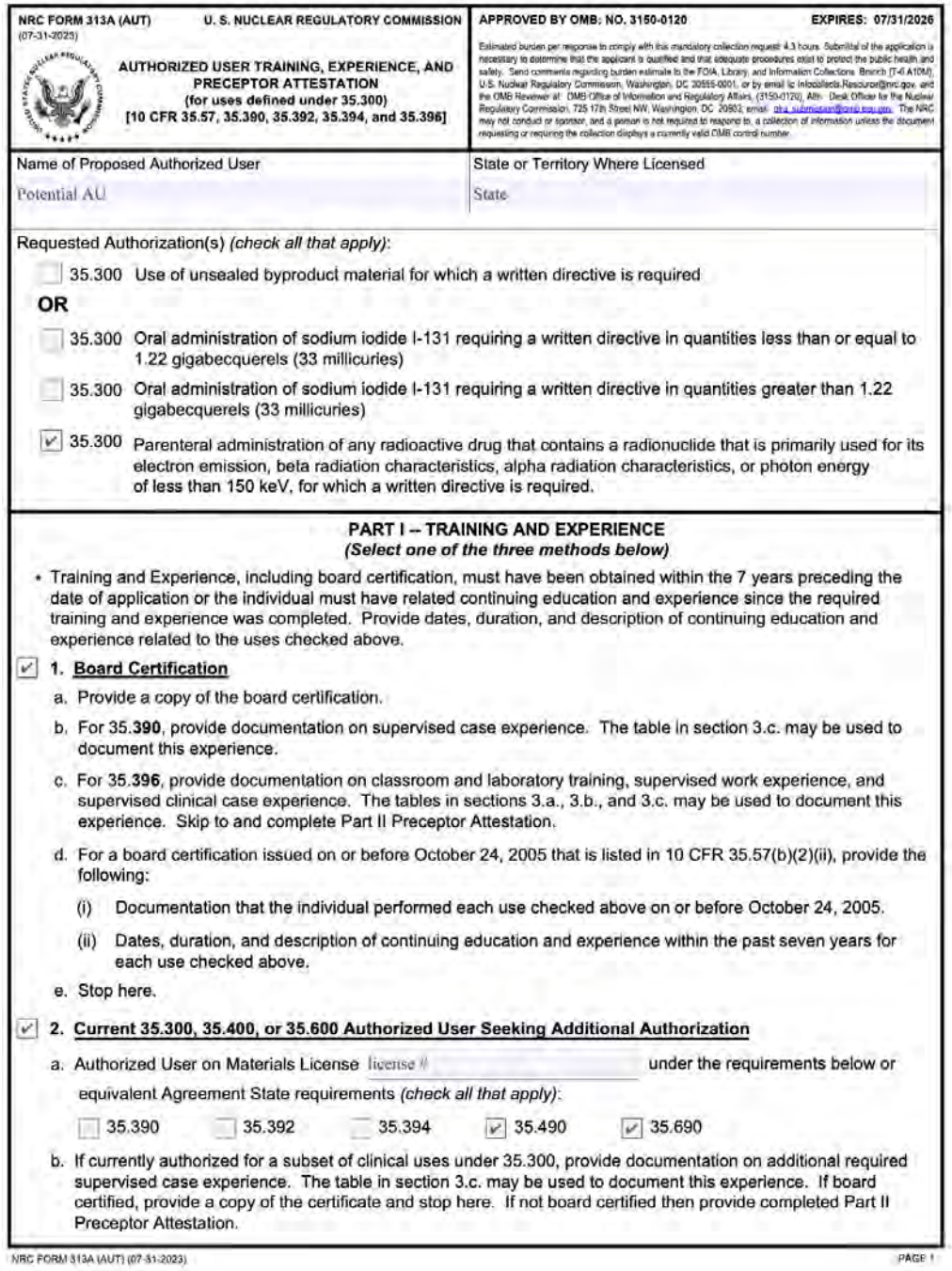
OR

- ☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

- Everything basically comes down to this form, whether you are a newly minted radiation oncologist fresh out of residency, or a very senior radiation oncologist 20 years out who has developed an interest in radiopharmaceutical but has never touched them since the basic 3+3 requirements during original training.

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A



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AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

Name of Proposed Authorized User	State or Territory Where Licensed
Potential AU	State

Requested Authorization(s) *(check all that apply)*:

- ☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

- ☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

- Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☑ **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.**390**, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience.

c. For 35.**396**, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

e. Stop here.

☑ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License license # _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

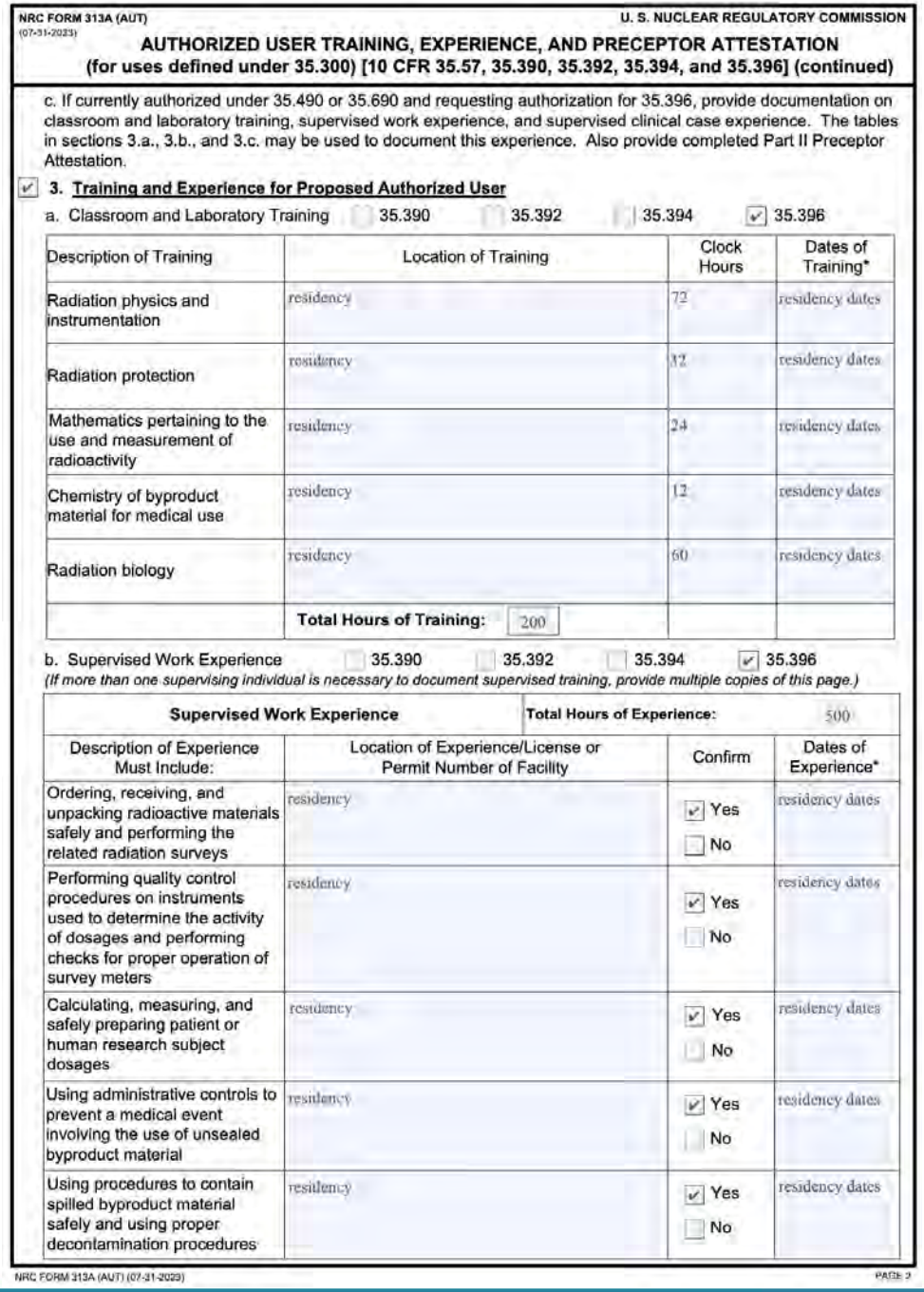
☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.490 ☑ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUT) (07-31-2023) PAGE 1

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A



NRC FORM 313A (AUT) (07-31-2023) — U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

☑ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	residency	72	residency dates
Radiation protection	residency	32	residency dates
Mathematics pertaining to the use and measurement of radioactivity	residency	24	residency dates
Chemistry of byproduct material for medical use	residency	12	residency dates
Radiation biology	residency	60	residency dates
	Total Hours of Training: 200		

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396

(If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

Supervised Work Experience	**Total Hours of Experience:** 500		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	residency	☑ Yes ☐ No	residency dates
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	residency	☑ Yes ☐ No	residency dates
Calculating, measuring, and safely preparing patient or human research subject dosages	residency	☑ Yes ☐ No	residency dates
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	residency	☑ Yes ☐ No	residency dates
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	residency	☑ Yes ☐ No	residency dates

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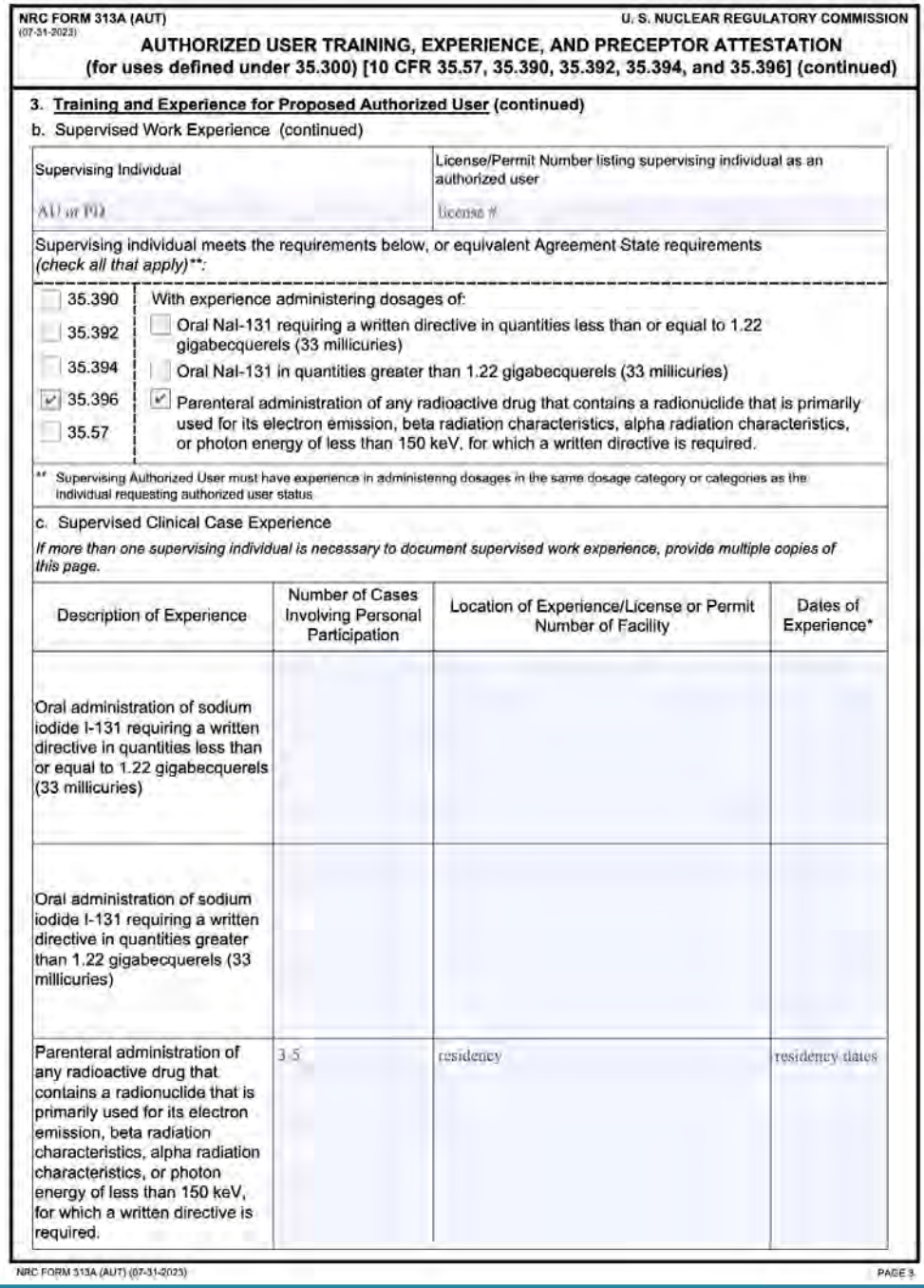
1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A

- May have to submit more than one of this page



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AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

3. **Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
AU or PD	license #

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

☐ 35.390	With experience administering dosages of:
☐ 35.392	☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ 35.394	☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☑ 35.396	☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
☐ 35.57	

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

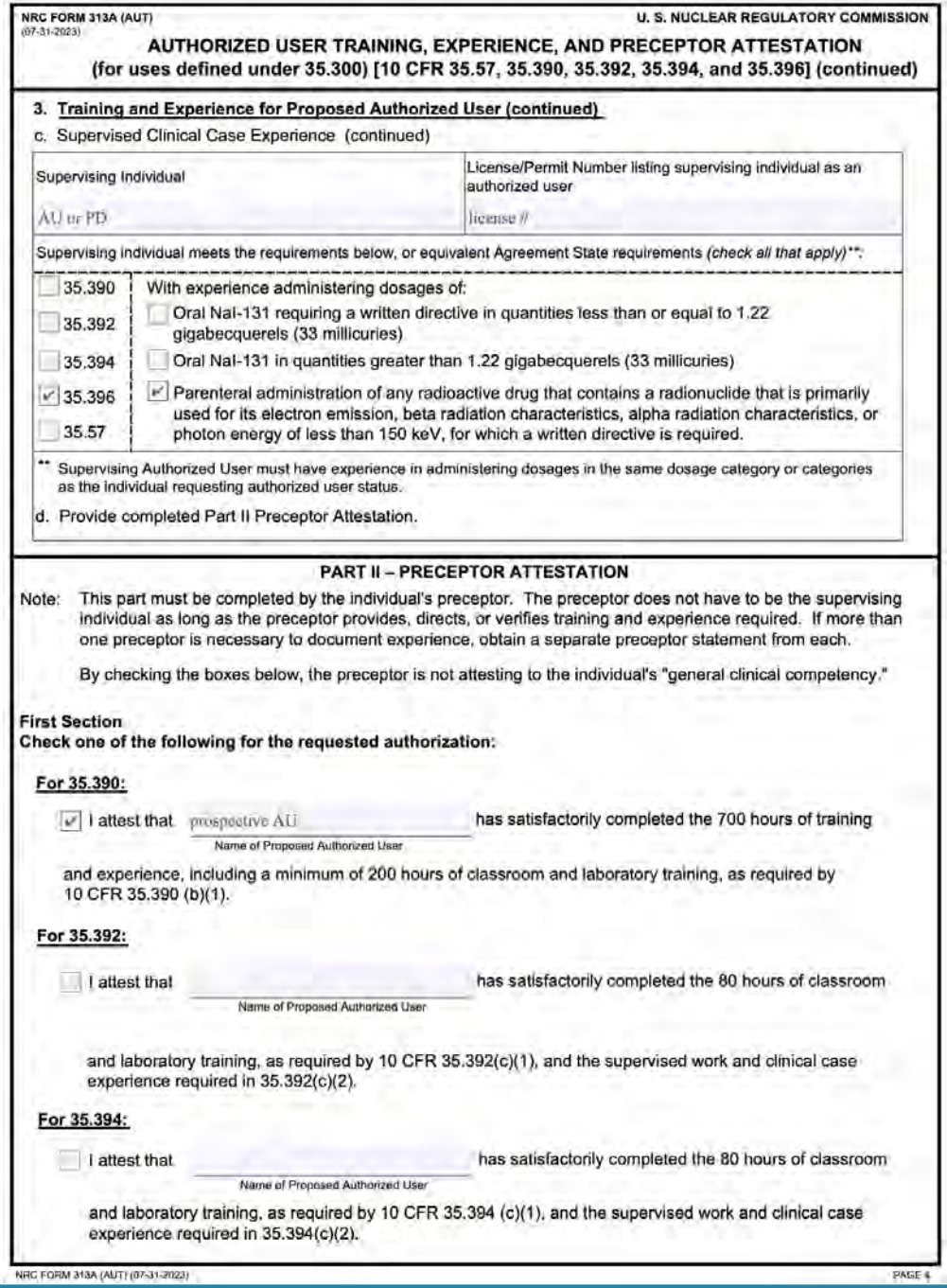
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.	3-5	residency	residency dates

NRC FORM 313A (AUT) (07-31-2023) PAGE 3

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A



NRC FORM 313A (AUT)
(07-31-2023)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
AU or PD	license #

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396 ☐ 35.57	With experience administering dosages of: ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section
Check one of the following for the requested authorization:

For 35.390:

☑ I attest that prospective AU (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

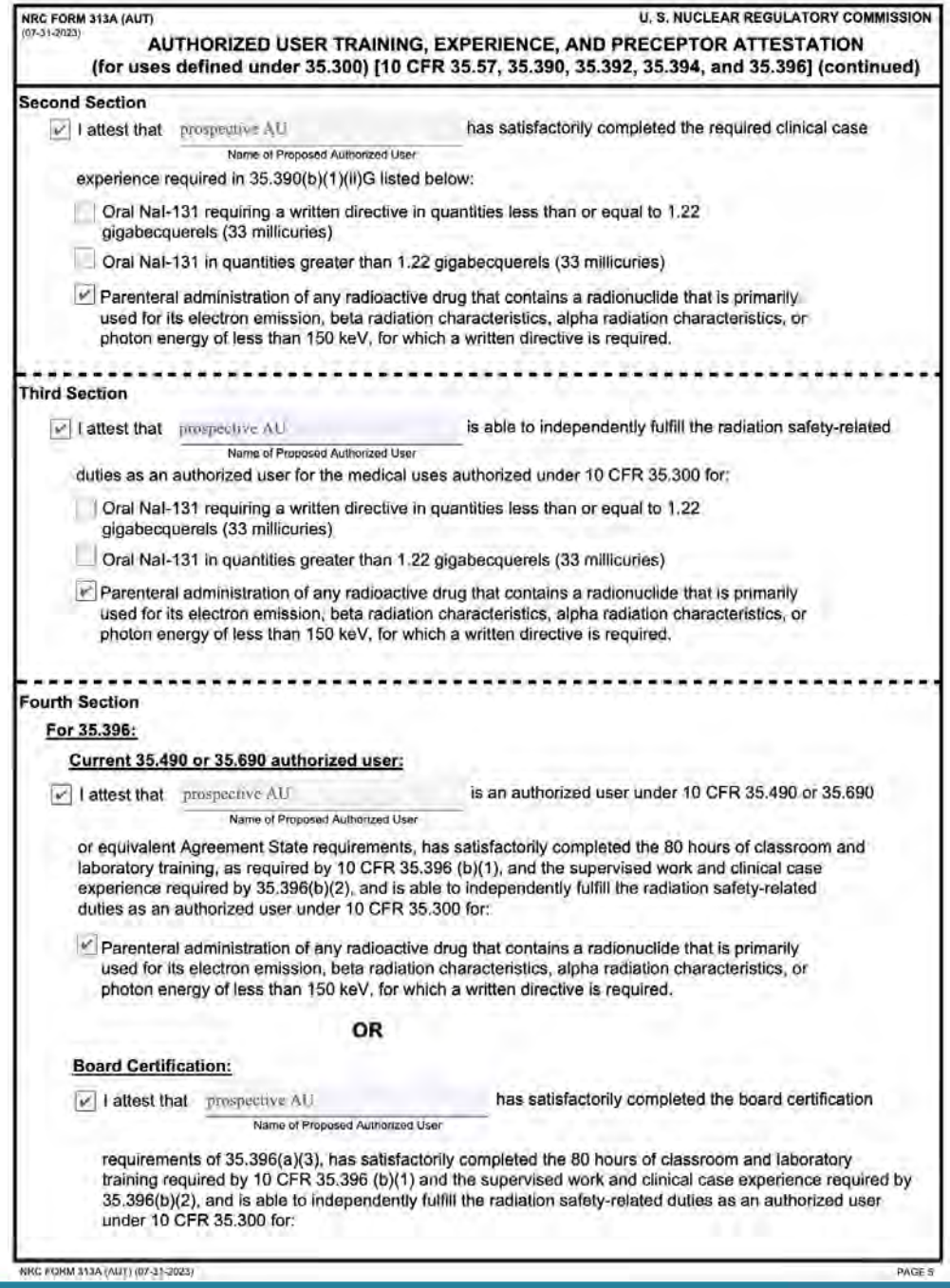
For 35.394:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

NRC FORM 313A (AUT) (07-31-2023) PAGE 4

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A



NRC FORM 313A (AUT) (07-31-2023)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Second Section

☑ I attest that prospective AU (Name of Proposed Authorized User) has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G listed below:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Third Section

☑ I attest that prospective AU (Name of Proposed Authorized User) is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☑ I attest that prospective AU (Name of Proposed Authorized User) is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (b)(1), and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

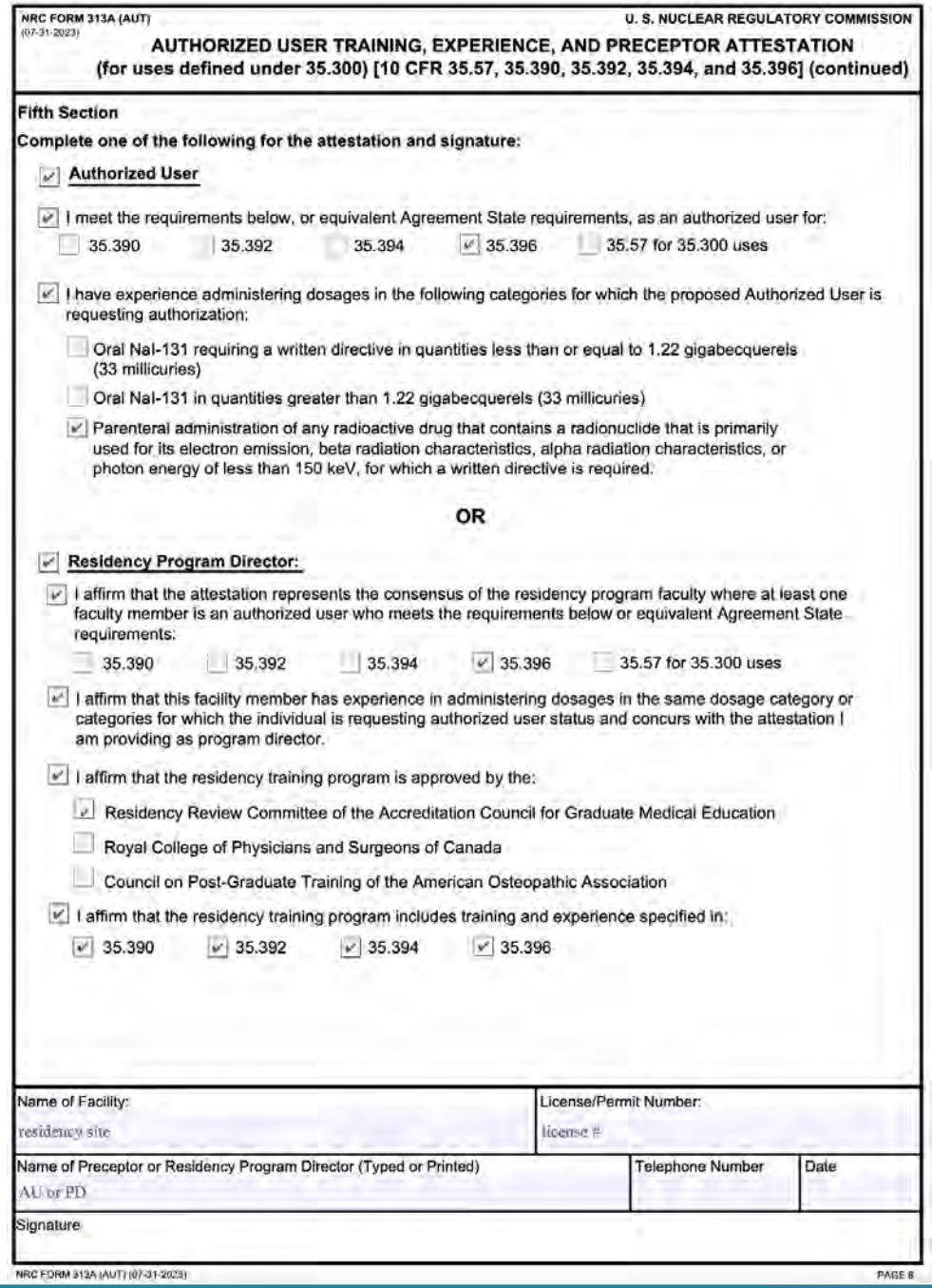
Board Certification:

☑ I attest that prospective AU (Name of Proposed Authorized User) has satisfactorily completed the board certification requirements of 35.396(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

NRC FORM 313A (AUT) (07-31-2023) PAGE 5

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A



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AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Fifth Section

Complete one of the following for the attestation and signature:

☑ **Authorized User**

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396 ☐ 35.57 for 35.300 uses

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

☑ **Residency Program Director:**

☑ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396 ☐ 35.57 for 35.300 uses

☑ I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

☑ I affirm that the residency training program is approved by the:

☑ Residency Review Committee of the Accreditation Council for Graduate Medical Education

☐ Royal College of Physicians and Surgeons of Canada

☐ Council on Post-Graduate Training of the American Osteopathic Association

☑ I affirm that the residency training program includes training and experience specified in:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☑ 35.396

Name of Facility: residency site	License/Permit Number: license #	
Name of Preceptor or Residency Program Director (Typed or Printed) AU or PD	Telephone Number	Date
Signature		

NRC FORM 313A (AUT) (07-31-2023) PAGE 6

1. https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a-aut-info.html

NRC Form 313A – What's with all the #'s?

- **35.300 users** are those already using **radiopharmaceuticals**
- **35.400 users** are those performing **manual brachytherapy** (such as prostate seed implants)
- **35.600 users** are those using a sealed source in a **remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit**

NRC Form 313A – What's with all the #'s?

- 35.300 – this is the **authorization** for administration of an unsealed radioactive byproduct material, either oral or parenteral (not via the digestive system). **Can be authorized for all or part of this.**
- **35.390** – this is the **training** for use of unsealed byproduct material for which a written directive is required.
  - For radiation oncologists, received 700 hours of training and experience (200 of classroom and lab training, and work experience) – *comprehensive*
- **35.396** – this is specifically **training** for the **parenteral administration** of unsealed byproduct material requiring a written directive
  - 80 hours of classroom and laboratory training – *may work for alternative pathway*

NRC Form 313A – What's with all the #'s?

- 35.390 – this is the **training** for use of unsealed byproduct material for which a written directive is required.
  - For radiation oncologists, received 700 hours of training and experience (200 of which is classroom and lab training)
- 35.392 – training for oral administration of <=33 mCi ^{131}I
- 35.394 – training for oral administration of >33 mCi ^{131}I
- 35.490 – training for use of manual brachytherapy
- 35.690 - training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Pathways to Authorized User (AU) Status

- ***The alternative pathway***
  - This is what is recommended for all current residents – prior to graduation, programs may work to add their senior residents to their license to establish AU status.
  - For those who have already graduated, application process is similar to that of a current resident
    - If more than 7 years out, will need to document CME and experience relevant to RPT

- ***The crossover pathway***
  - If you are already an AU for another area (35.300, RPT; 35.400, manual brachy; or 35.600, sealed source afterloader, teletherapy, or GK unit), then can proceed with supervised case experience and a copy of your board certification