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NRC Medical Webinar Training

MEDICAL USER AUTHORIZATIONS FOR USE OF MATERIALS UNDER 10 CFR 35.300

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November 5th, 2015

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Outline

- Definition and Overview
- Types of Authorization
- Training Requirements
- Licensing Guidance
- Sample License Actions/Cases
- Questions and Answers

* Note that Agreement States may have regulatory requirements that are similar or more limiting than NRC's regulatory requirements. Please review and reference your State regulations to determine if the NRC regulations referenced in this training are the same and applicable.

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Definition & Overview

- 10 CFR 35.300 – Use of unsealed byproduct material for which a written directive (WD) is required.
- Some common radiopharmaceuticals containing byproduct materials:
  - ***Iodine-131*** for treatment of hyperthyroidism and thyroid cancer.
  - ***Strontium-89 (Metastron)*** for treatment of pain caused by metastatic bone cancer
  - ***Samarium-153 (Quadramet)*** for treatment of pain caused by metastatic bone cancer
  - ***Radium-223 (Xofigo)*** for treatment of metastatic bone cancer.
  - ***Yttrium-90 (Zevalin)*** for treatment of non-Hodgkin's lymphoma.

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Definition – 10 CFR 35.300

- Unsealed byproduct material may be used by a licensee for medical purposes requiring a WD if:
  a. It is obtained from: [1] A manufacturer or preparer for commercial distribution; or [2] A PET radioactive drug producer; OR
  b. It is prepared by (excluding production of PET radionuclides): [1] An authorized nuclear pharmacist (ANP); [2] A physician who is an authorized user (AU) and meets the requirements in 10 CFR 35.290, 35.390; or [3] An individual under the supervision of the ANP or AU; OR
  c. The material is obtained from and prepared by an NRC or AS licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; OR
  d. The material is prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

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Types of Authorization

- An AU may be authorized for one or more of the subcategories below, but not for all unsealed byproduct material. Based on the current regulations, no new user may be authorized for all of 10 CFR 35.300.

10 CFR 35.300 AUTHORIZATION SUBCATEGORIES [from 10 CFR 35.390(b)(1)(ii)(G)]	
Subcategory #1	Oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required
Subcategory #2	Oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131
Subcategory #3	Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required
Subcategory #4	Parenteral administration of any other radionuclide, for which a written directive is required **Note: There are no known clinical uses in this subcategory.

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Training Requirements

- Training Requirements:
  - 10 CFR 35.390 “Training for use of unsealed byproduct material for which a written directive is required”
  - 10 CFR 35.392 “Training for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 33 millicuries (1.22 GBq)”
  - 10 CFR 35.394 “Training for the oral administration of sodium iodide I-131 requiring a WD in quantities greater than 33 millicuries (1.22 GBq)”
  - 10 CFR 35.396 ”Training for the parenteral administration of unsealed byproduct material requiring a written directive”

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Training Requirements

Pathways to AU Approval

1. Is the individual currently an AU on an NRC or Agreement State license for the same use being requested?
2. Is the individual board certified?
3. Is the individual a current AU for 10 CFR 35.300 (unsealed material), 35.400 (manual brachytherapy), or 35.600 (remote afterloader, teletherapy, gamma stereotactic radiosurgery units), seeking additional authorizations?
4. Does the individual have any Training and Experience?

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Training Requirements

10 CFR 35.390 – *Training for use of unsealed byproduct material for which a written directive is required*

Except for experienced AUs under 10 CFR 35.57, an AU has to be a:

1. Board certified physician + AU supervised work experience + written attestation
2. Physician with 700 hrs T&E (including a minimum of 200 hrs of class & lab)

NOTE:

- Board certification process has been recognized by NRC (http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html) or an AS
- AU supervised work experience includes a minimum of 3 cases in administration of dosages in each of the following categories:
  - i. Oral administration of sodium iodide I-131≤ 33mCi (1.22GBq), for which a WD is required;
  - ii. Oral administration of sodium iodide I-131> 33mCi (1.22GBq);
  - iii. Parenteral administration of any beta emitter, or a photon-emitting radionuclide a photon energy less than 150 keV, for which a WD is required; and/or
  - iv. Parenteral administration of any other radionuclide, that requires a WD
- Written attestation signed by a preceptor AU

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Training Requirements

10 CFR 35.392 – *Training for oral administration of sodium iodide I-131 requiring a WD in quantities ≤ 33 mCi (1.22 GBq)*

Except for experienced AUs under 10 CFR 35.57, AU is:

1. Board certified physician + written attestation
2. A physician that is an AU (listed on a license or permit) for administrations ≤ *or > than 33 mCi, or for administration of only > than 33 mCi .*
3. Physician with 80 hrs class & lab training + AU supervised work experience + written attestation

NOTE:

- Board certification process:

  (i) includes 80hrs of applicable class & lab; (ii) includes AU supervised work experience of 3 case minimum in administration of dosages for Oral administration of I-131≤ 33mCi (WD required); and (ii) has been recognized by NRC or an AS;
- Written attestation signed by a preceptor AU

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Training Requirements

10 CFR 35.394 – *Training for oral administration of sodium iodide I-131 requiring a WD in quantities > 33 mCi (1.22 GBq)*

Except for experienced AUs (under 10 CFR 35.57), AU is:

1. Board certified physician + written attestation; OR
2. A physician that is an AU (listed on a license or permit) for oral administrations of sodium iodide I-131 > 33 mCi; OR
3. Physician with 80 hrs of applicable class & lab training + AU supervised work experience + written attestation

NOTE:

- Board certification process:

  (i) includes 80hrs of applicable class & lab; (ii) includes AU supervised work experience; and (iii) has been recognized by NRC (http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html) or an AS.
- AU supervised work experience includes a minimum of 3 cases in oral administration of dosages of I-131 > 33mCi
- Written attestation signed by a preceptor AU

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Training Requirements

10 CFR 35.396 – *Training for parenteral administration of unsealed byproduct material requiring a WD*

Parenteral administration of:

i. Any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV.

ii. Any other radionuclide for which a WD is required.

NOTE:

- Currently no known clinical uses in 10 CFR 35.300 subcategory #4 – parenteral administration of any other radionuclide, for which a WD is required.

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Training Requirements

10 CFR 35.396 – *Training for parenteral administration of unsealed byproduct material requiring a WD*

Except for experienced AUs (under § 35.57), AU is:

1. Physician AU (on a license or permit) under 10 CFR 35.390 for parenteral administration (i) or (ii); OR
2. Physician AU (on a license or permit) under 10 CFR 35.490 or 35.690 or equivalent AS requirements, + 80 hrs of class & lab training + AU supervised work experience + written attestation; OR
3. Board certified physician under 10 CFR 35.490 or 35.690 + has completed 80 hrs of class and lab training + supervised work experience + written attestation.

NOTE:

- AU supervised work experience in the parenteral administration of (i) and/or (ii), for which a WD is required.
- Written attestation signed by a preceptor AU

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Licensing Guidance

NUREG-1556, Volume 9, Rev. 2: Consolidated Guidance About Materials Licensees – Program-Specific Guidance About Medical Use Licenses (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)

- Provides guidance to:
  - NRC and AS licensees and MML permittees – for preparation of applications
  - NRC, AS, and MML staff – for review of applications
- NRC Forms in Appendices to document training and experience
  - ***NRC Form 313A (AUT)***, "AU Training and Experience and Preceptor Attestation (for uses defined under 10 CFR 35.300)
  - *NRC Form 313, "Application for Materials License"*
  - *NRC Form 313A (RSO), "RSO Medical Use Training & Experience & Preceptor Attestation"*
  - *NRC Forms 313A (AMP), (ANP), (AUD), (AUS)*

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Licensing Guidance

NRC FORM 313A (AUT)

- Part I – Training & Experience

NRC FORM 313A (AUT) (10-2015)

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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (12/31/2015)

Name of Proposed Authorized User	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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide 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 clinical 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.

d. Skip to and complete Part II Preceptor Attestation.

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

a. Authorized User on Materials 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. Also provide completed Part II Preceptor Attestation.

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.

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Licensing Guidance

NRC FORM 313A (AUT)

- Part II – Preceptor Attestation

NRC FORM 313A (AUT)
(10-2015)

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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

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

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** 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 attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

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

For 35.390:

Board Certification

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the training and experience requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ (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).

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Licensing Actions – Case Examples

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REMEMBER!!!

Pathways to AU Approval

1. Current AU on an NRC or Agreement State license for the same use being requested
2. Board Certification
3. Current AU for 35.300 (unsealed material), 35.400 (manual brachytherapy), or 35.600 (remote afterloader, teletherapy, gamma stereotactic radiosurgery units) seeking additional authorizations
4. Training and Experience

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Current AU for same uses requested

Case 1:

Dr. Goodfellow has been employed by South Hospital as a nuclear medicine physician since 1989. He is listed on their NRC license for use of unsealed byproduct materials under 10 CFR 35.300. He has been offered a position at North Hospital across town.

- May he be authorized for 10 CFR 35.300 on the new license?

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Current AU for same uses requested

Case 1:

Yes, Dr. Goodfellow may be listed on the new license for uses under 10 CFR 35.300 because he is currently listed on an NRC license for the same uses.

At this point, this is the only way a physician may be authorized for all of 10 CFR 35.300.

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Current AU for same uses requested

Case 2:

A licensee requests that Dr. Kupec be added to their NRC license for Oral administration of sodium iodide I-131 in quantities less than or equal to 33 mCi. As evidence of his experience, the licensee provides a copy of a current Agreement State license listing Dr. Kupec for the identical use.

- May Dr. Kupec be listed for this use on the NRC license?

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Current AU for same uses requested

Case 1:

Yes, Dr. Kupec may be listed for the use of sodium iodide I-131 based on his current listing of the use on the Agreement State license.*

*Note that often, Agreement State licenses reference their State Regulations and you may have to review these to determine if the category of use is the same.

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Board Certification

Three pieces of information are normally necessary to approve a proposed AU by the board certification pathway:

1. Specialty board certification recognized by NRC under 10 CFR 35.300 (The current list and certification dates allowing approval are found on the NRC's website: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)
2. Clinical case experience
3. Preceptor Attestation

Note: NRC Form 313A (AUT) may be used to document Items 2 and 3

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Board Certification

Case:

ABC Hospital has requested that Dr. Smith be added to their license for the use of sodium iodide I-131. Dr. Smith is a board certified Nuclear Medicine physician.

- What do you look for in the supporting information submitted?

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Board Certification

Approved Boards

http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

American Board of Radiology certificate (Diagnostic Radiology) dated from June 2011 forward with “AU eligible” appearing above the ABR seal

OR

Certification Board of Nuclear Endocrinology certification process from 2013 to present for all physicians issued a CBNE Nuclear Endocrinology- High Dose certificate.

OR

American Osteopathic Board of Radiology certificate (Diagnostic Radiology) dated from May 17, 2015 forward with the words “AU Eligible” appearing above the D.O. symbol

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Board Certification

Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed:
  - Part I, Section 1 – indicating the Board Certification pathway
  - Part I, Section 3.c. – documenting at least 3 cases each of oral administration of sodium iodide I-131 in quantities less than or equal to and greater than 33 mCi under the supervision of an AU*
    - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU Status

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Board Certification

Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed (contd.):
  - Part II – Preceptor Attestation
  - First Section – indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework
  - Second Section – confirming that the proposed AU has completed the required clinical casework for Oral NaI-131 in quantities greater than and less than 33 mCi
  - Third Section – confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for oral administration of sodium iodide I-131

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Board Certification

Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed (contd.):
  - Fifth Section – Preceptor signature and confirmation of their training and experience*
  - *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.

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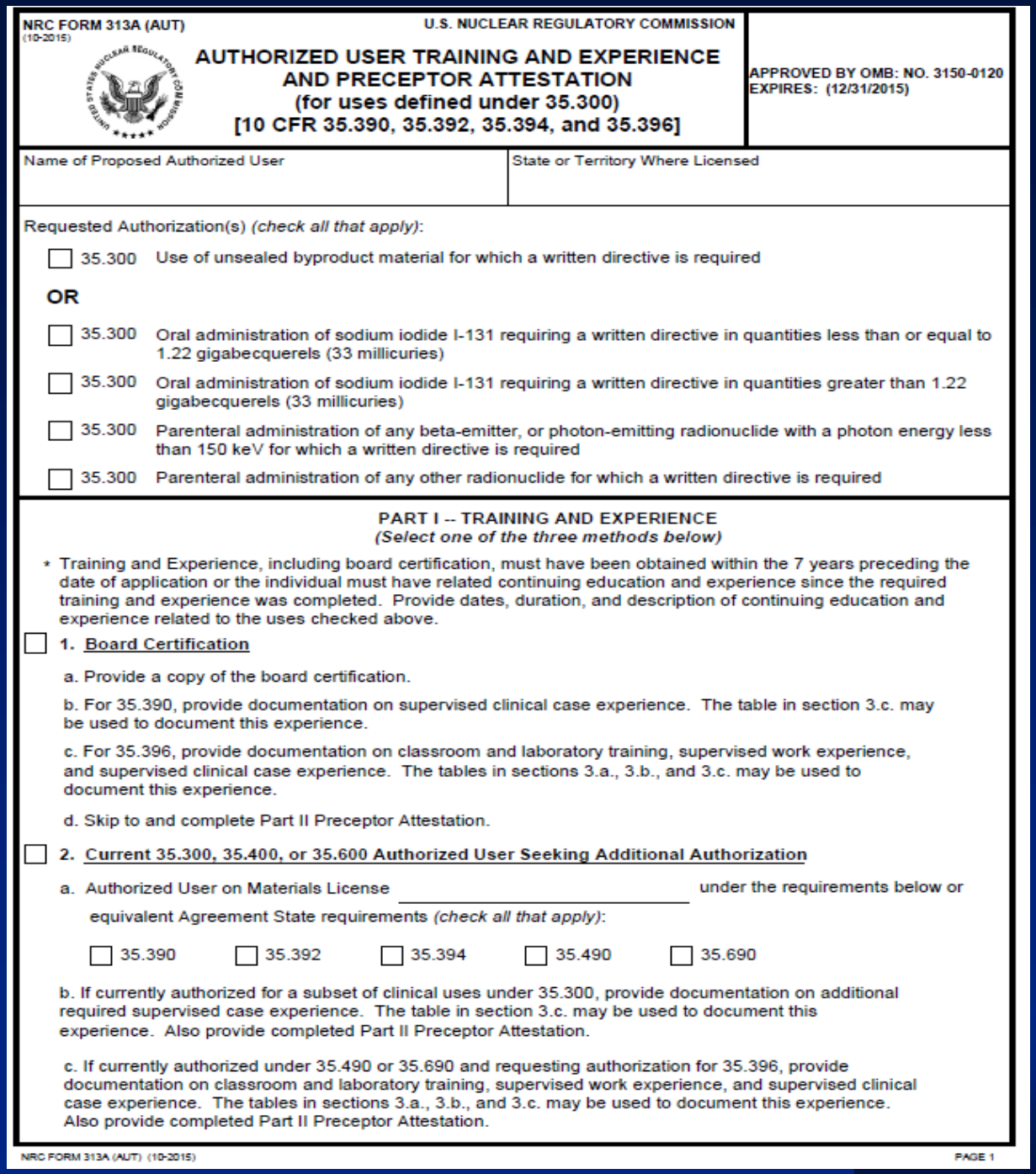
Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 1 indicating the Board Certification pathway



NRC FORM 313A (AUT)
(10-2015)

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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (12/31/2015)

Name of Proposed Authorized User | 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide 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 clinical 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.

d. Skip to and complete Part II Preceptor Attestation.

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

a. Authorized User on Materials 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. Also provide completed Part II Preceptor Attestation.

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.

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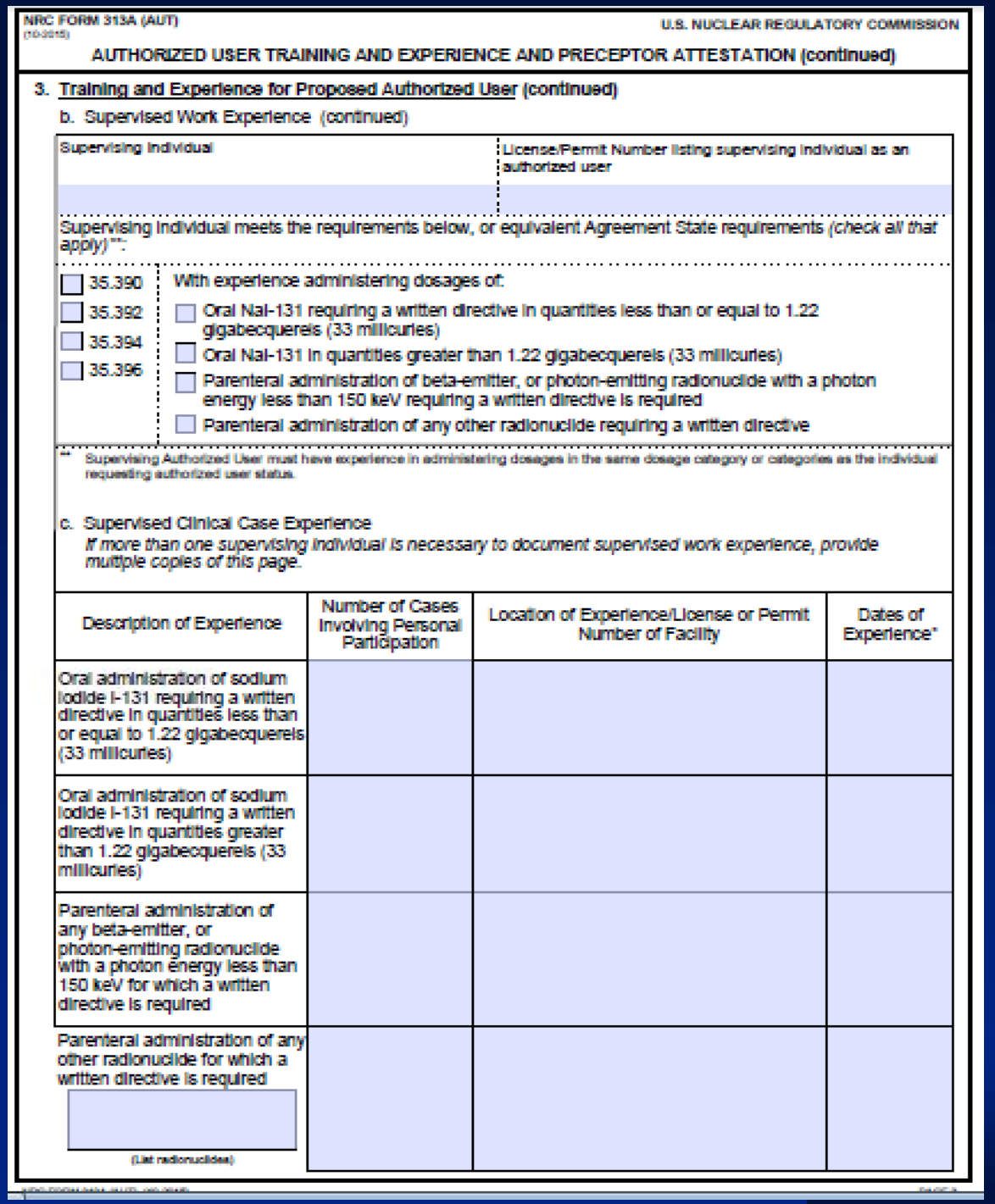
Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3.c. documenting at least 3 cases each of oral administration of sodium iodide I-131 in quantities ≤ and > 33 mCi under the supervision of an AU*
- * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



NRC FORM 313A (AUT) (10-2015) — U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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

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

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

* 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required ☐ (List radionuclides)			

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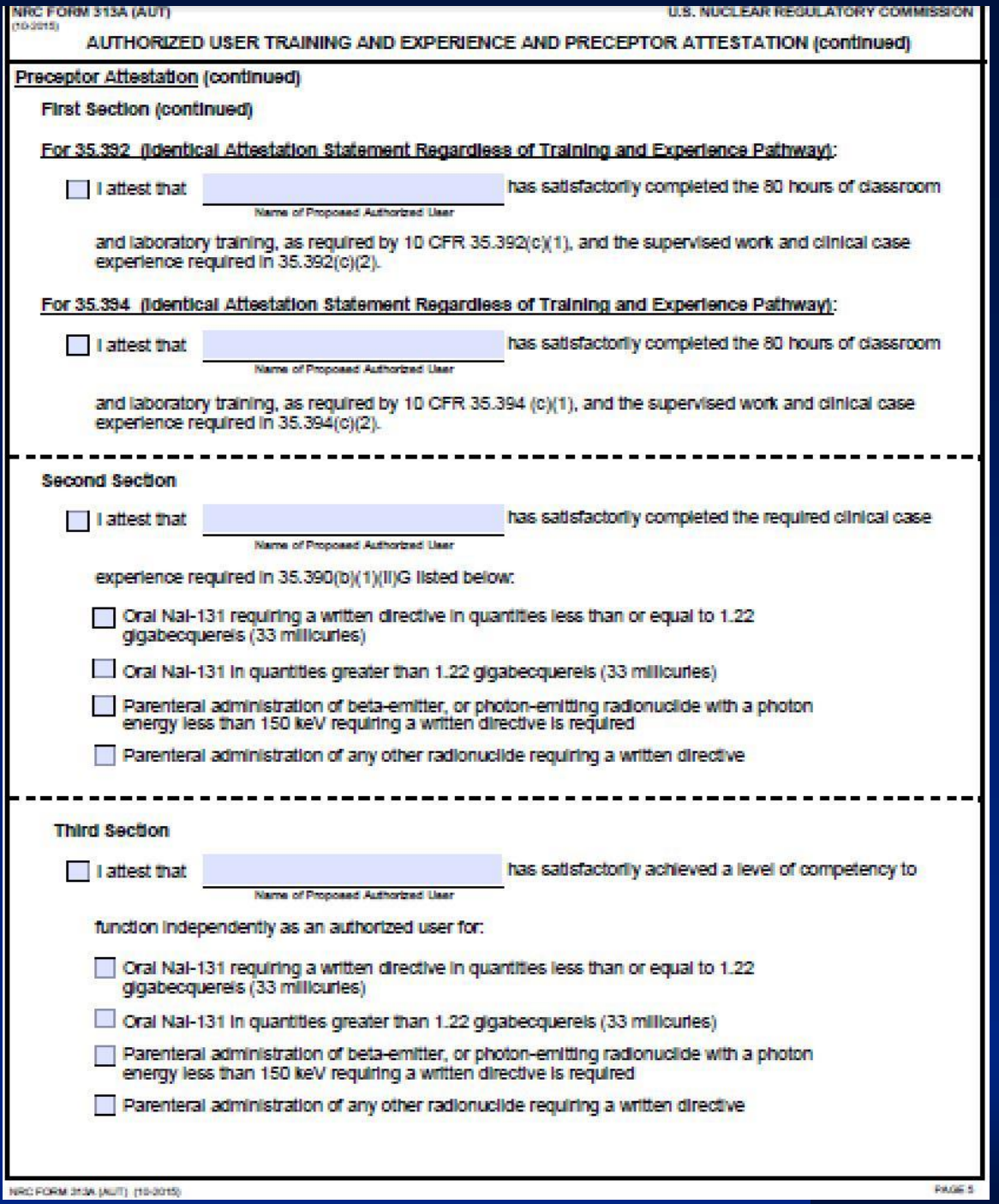
Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- First Section – indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework



NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

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).

Second Section

☐ I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

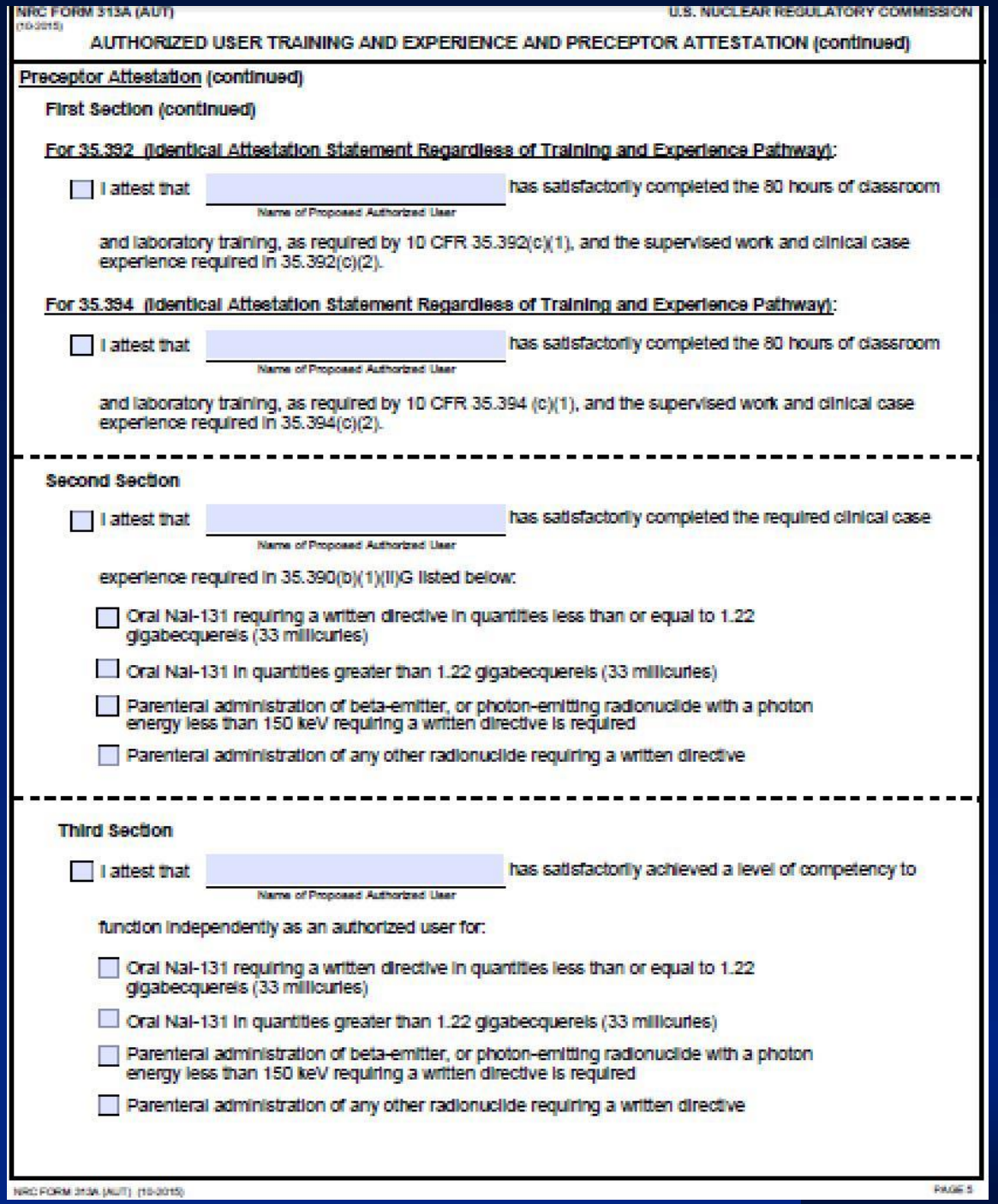
NRC FORM 313A (AUT) (10-2015) PAGE 5

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Second Section – confirming that the proposed AU has completed the required clinical casework for Oral NaI-131 in quantities greater than and less than 33 mCi



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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).

Second Section

☐ I attest that _____ (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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

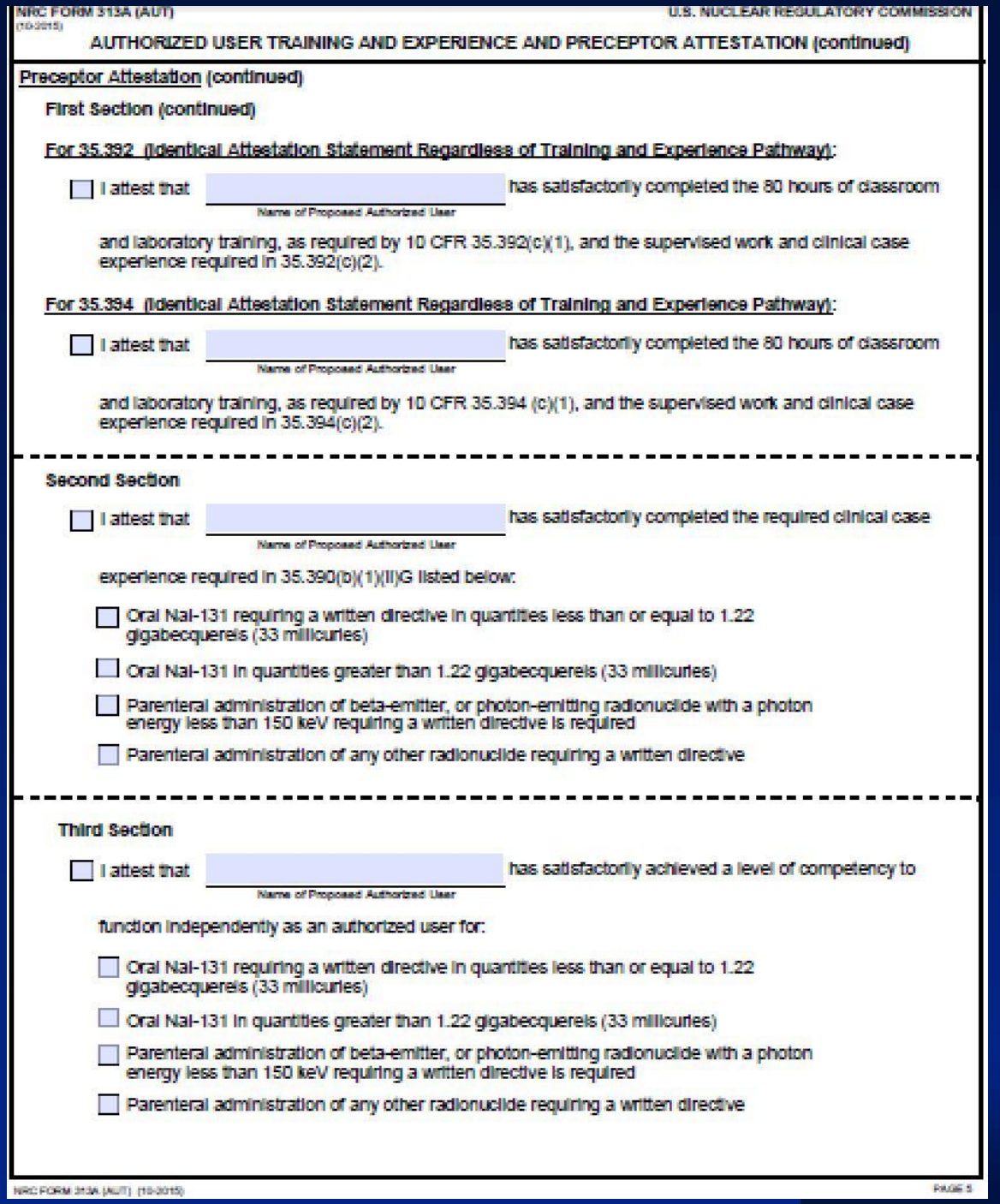
NRC FORM 313A (AUT) (10-2015) PAGE 5

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Third Section – confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for Oral administration of sodium iodide I-131



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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).

Second Section

☐ I attest that _____ (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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

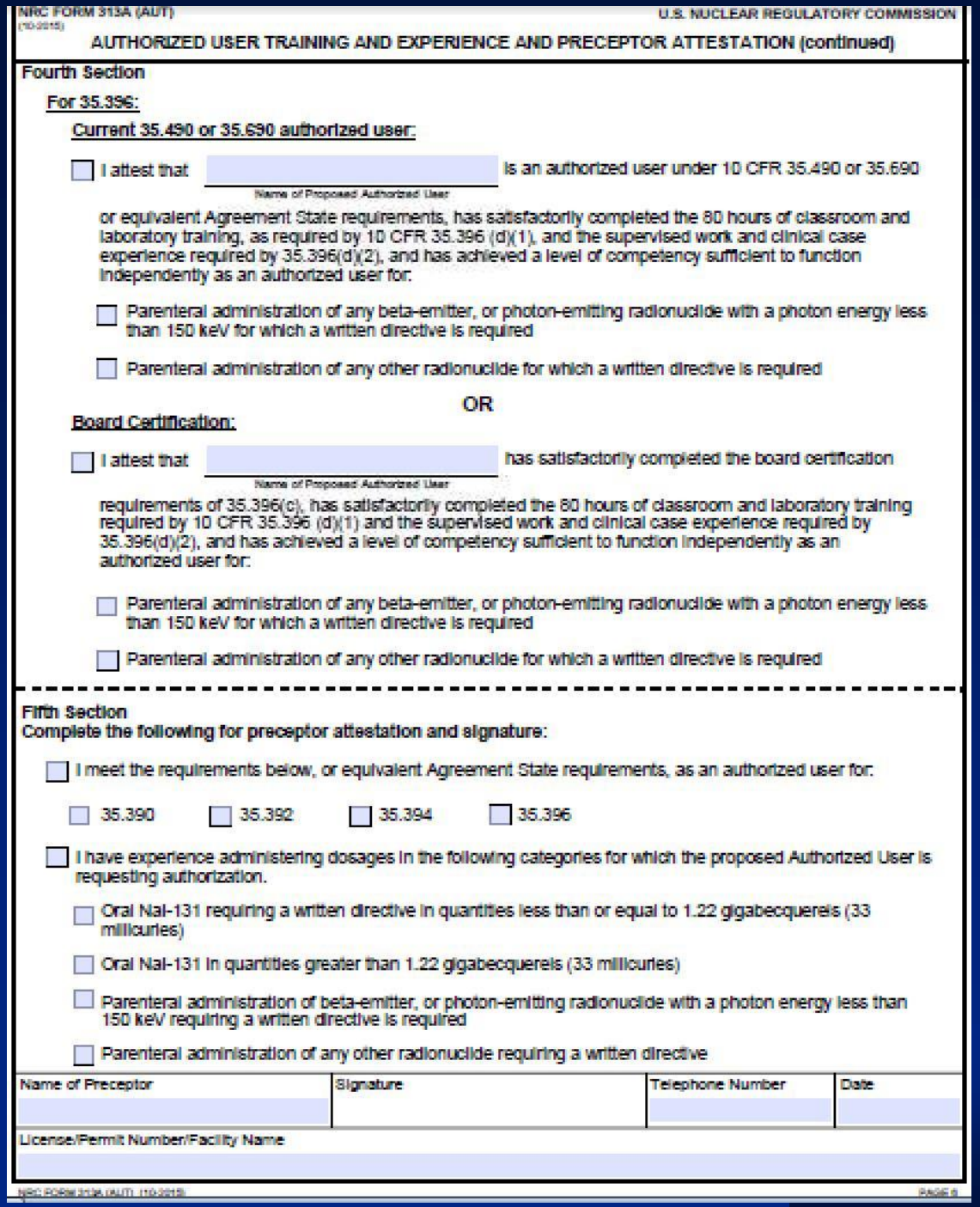
NRC FORM 313A (AUT) (10-2015) PAGE 5

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Board Certification

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Fifth Section – Preceptor signature and confirmation of their training and experience*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☐ 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number/Facility Name

NRC FORM 313A (AUT) (10-2015) Page 6

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UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

REMINDER!

To approve a proposed AU by this pathway:

1. AU under a subset of 10 CFR 35.390 or 35.490 or 35.690, and
2. Successful completion of 80 hours of classroom and lab training applicable to parenteral administrations, for which a written directive is required, and
3. Work experience under an AU who is authorized for 10 CFR 35.390 or 35.396, and

- Documented casework (at least 3), and
- Preceptor attestation

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Protecting People and the Environment

Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

Case 1:

Dr. Stewart is listed as an AU at Main Line Hospital, a medical broad scope licensee, for oral administration of sodium iodide I-131 in quantities less than or equal to 33 mCi. The licensee has requested that Dr. Stewart's authorization be expanded to include all uses of sodium iodide I-131.

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Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

A copy of the broad scope permit authorizing him for the use of sodium iodide I-131 in quantities less than or equal to 33 mCi

- NRC Form 313 (AUT) with the following sections completed:
  - Part I, Section 2 – indicating current status as an AU for 10 CFR35.392
  - Part I, Section 3 – documentation of casework (including the name and authorization of the supervising AU*
    - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

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Protecting People and the Environment

Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

- NRC Form 313 (AUT) with the following sections completed (contd.):
  - Part II – Preceptor Attestation
  - First Section – indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework, as required by 10 CFR 35.394
  - Third Section – confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for oral administration of sodium iodide I-131
  - Fifth Section-Preceptor signature and confirmation of their training and experience*
  - *Confirm that preceptor is an AU by obtaining the NRC or Agreement State license or permit issued by a broad scope licensee that lists the preceptor as an AU.

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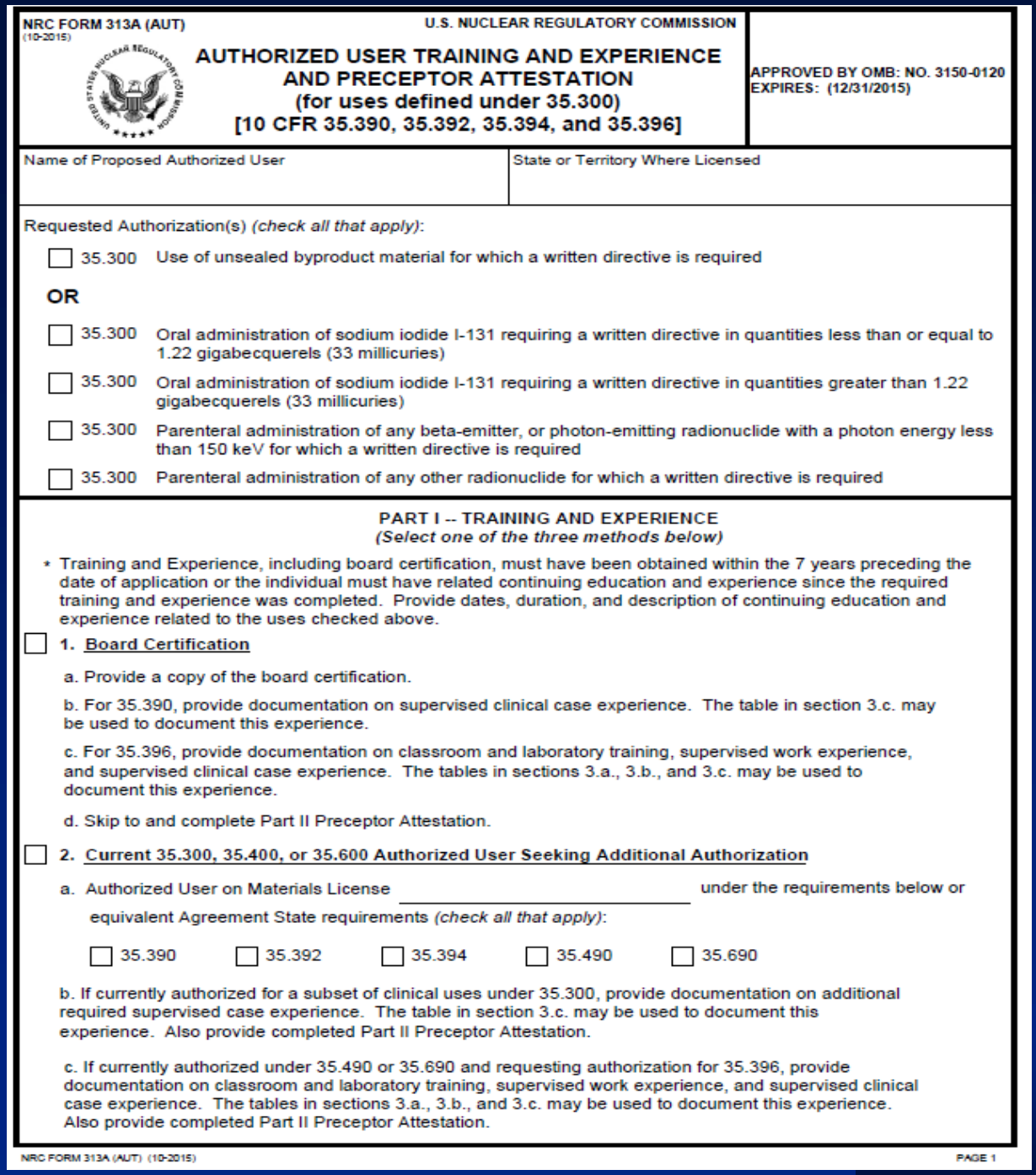
Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 2 – indicating current status as an AU for 10 CFR35.392



NRC FORM 313A (AUT) (10-2015)

U.S. NUCLEAR REGULATORY COMMISSION

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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (12/31/2015)

Name of Proposed Authorized User | 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide 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 clinical 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.

d. Skip to and complete Part II Preceptor Attestation.

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

a. Authorized User on Materials 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. Also provide completed Part II Preceptor Attestation.

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.

NRC FORM 313A (AUT) (10-2015) PAGE 1

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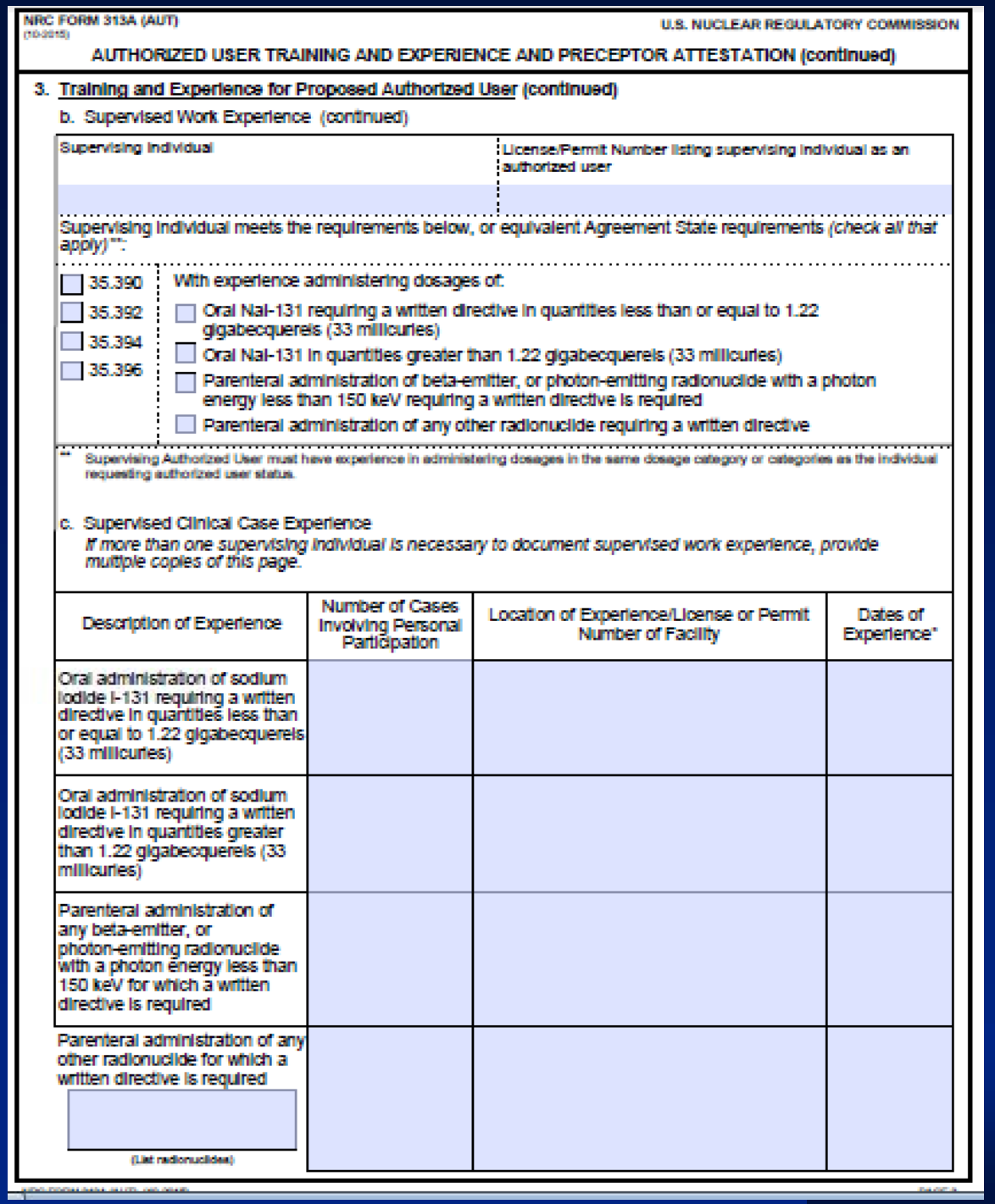
Protecting People and the Environment

Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 – documentation of casework (including the name and authorization of the supervising AU*
  - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU Status



NRC FORM 313A (AUT) (10-2015) — U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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

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

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

* 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required ☐ (List radionuclides)			

U.S.NRC
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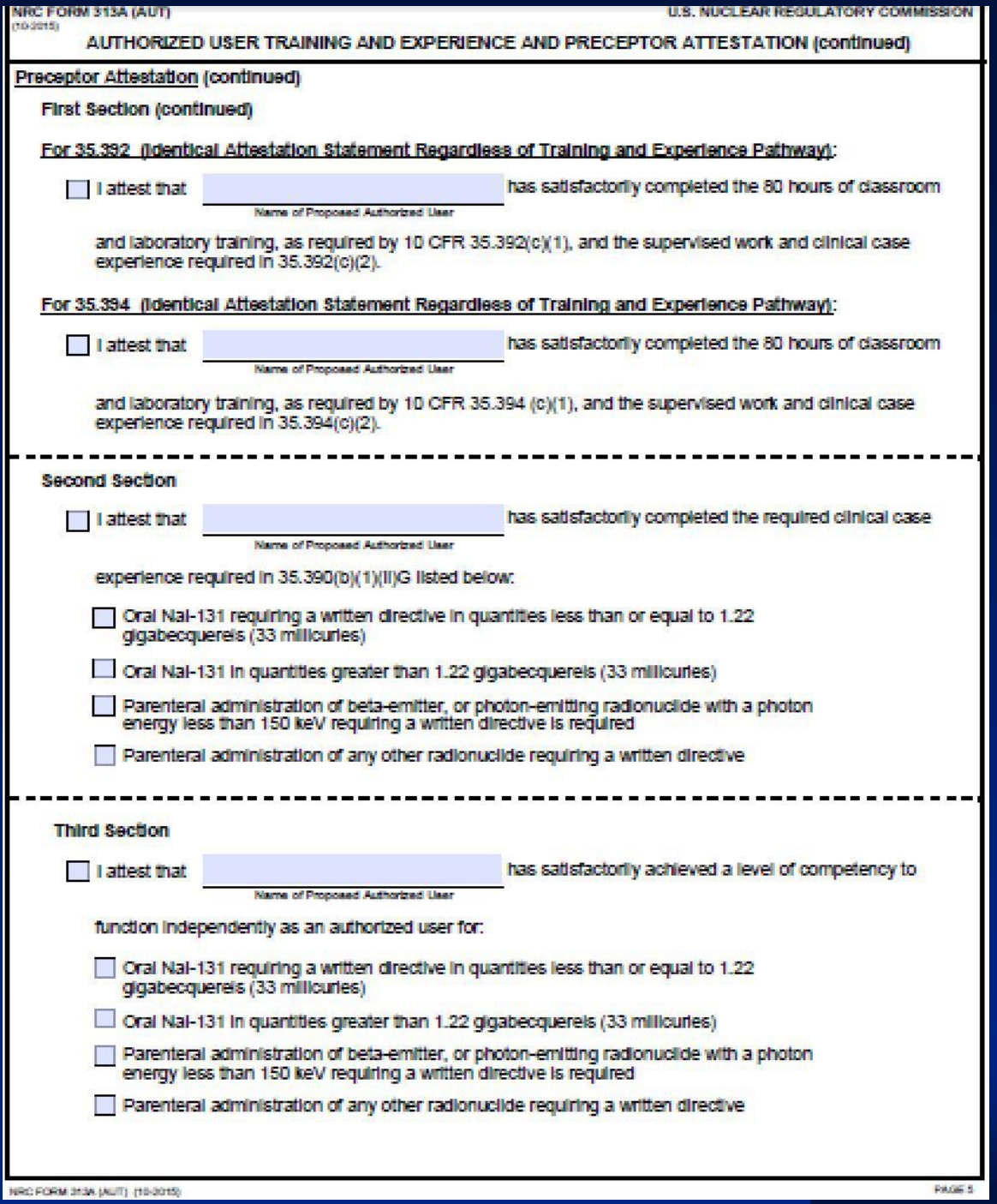
Protecting People and the Environment

Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- First Section – indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework, as required by 10 CFR 35.394



NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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).

Second Section

☐ I attest that _____ (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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

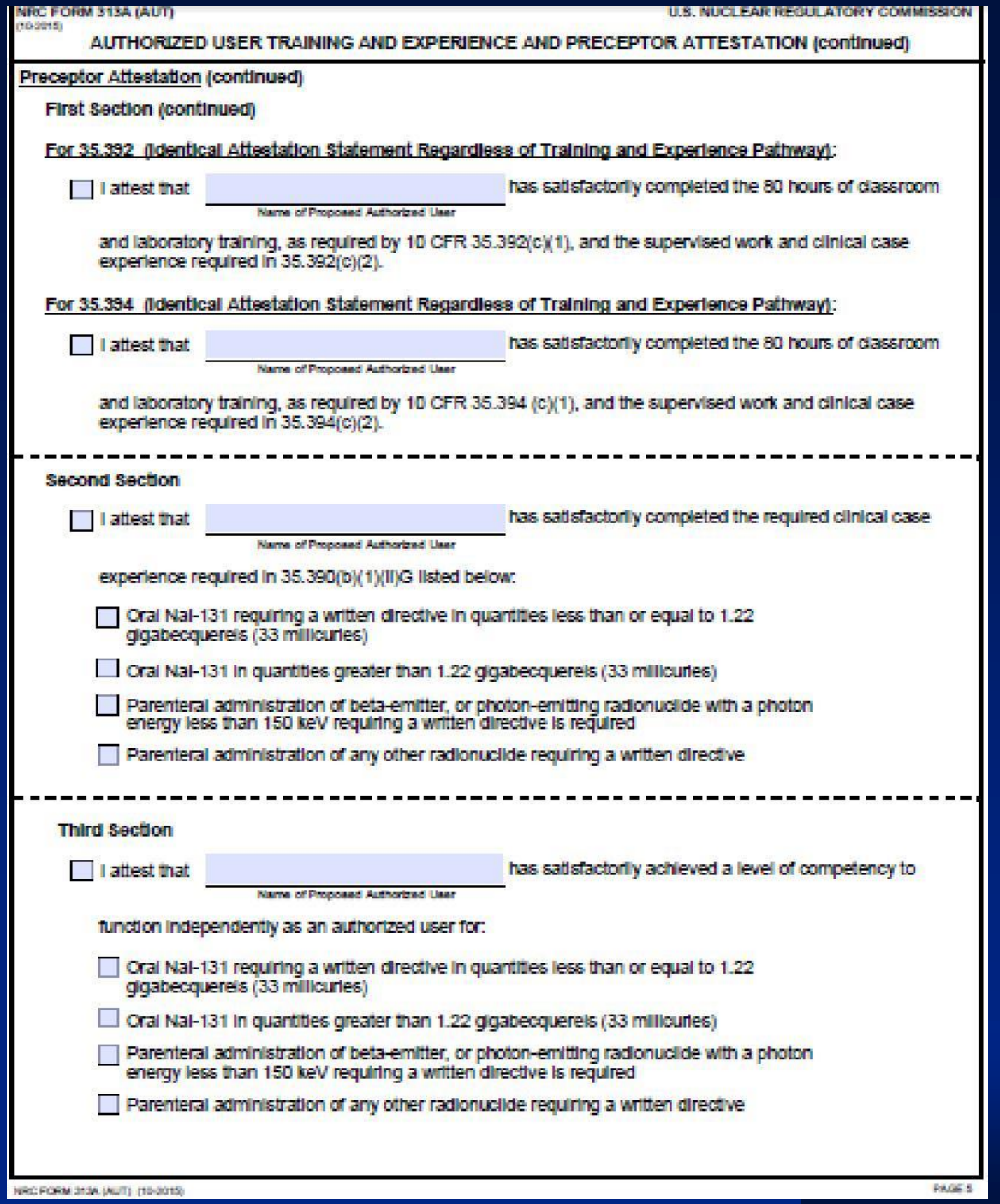
NRC FORM 313A (AUT) (10-2015) PAGE 5

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Third Section – confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for Oral administration of sodium iodide I-131



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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).

Second Section

☐ I attest that _____ (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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

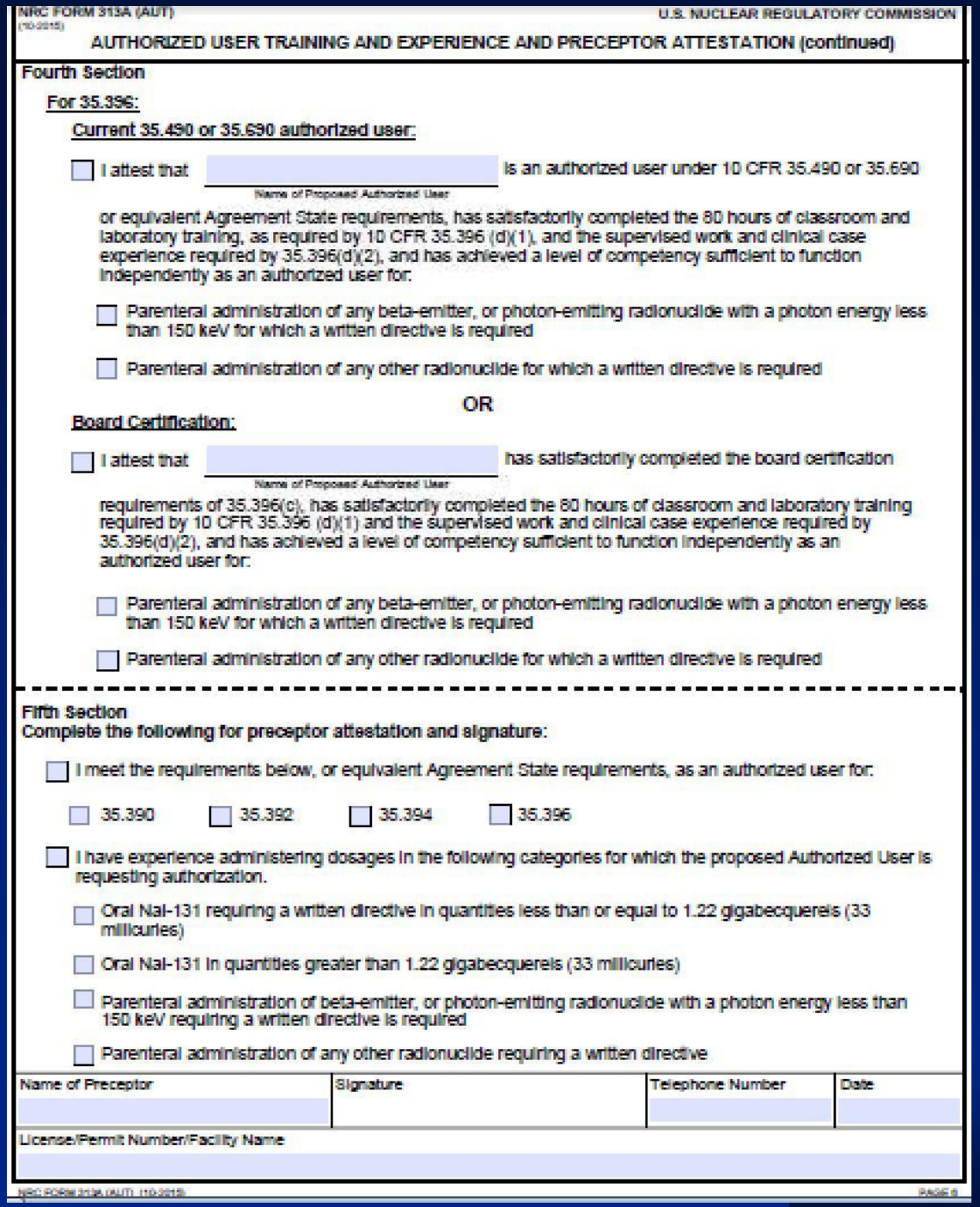
NRC FORM 313A (AUT) (10-2015) PAGE 5

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Fifth Section – Preceptor signature and confirmation of their training and experience*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit issued by a broad scope licensee which lists the preceptor as an AU.



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ (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 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the board certification requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☐ 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number/Facility Name

NRC FORM 313A (AUT) (10-2015) Page 6

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

Case 2:

Dr. Miller is a Radiation Oncologist at Suburban Hospital (AS licensee). She is listed on their license for the use of high dose rate remote afterloader (35.600). The hospital intends to use Xofigo (parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV) in the near future and would like her to be the AU.

- What would Dr. Miller need to provide?

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Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

A copy of the AS license listing her as an AU for 10 CFR 35.600.

- NRC Form 313 (AUT) with the following sections completed:
  - Part I, Section 2 – indicating the current AU pathway
  - Part I, Section 3 – documentation of 80 hrs of classwork and lab training; supervised work experience (including the name and authorization of the supervising AU); and casework*
    - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

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Protecting People and the Environment

Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

- NRC Form 313 (AUT) with the following sections completed (contd.):
  - Part II – Preceptor Attestation
  - Fourth Section – confirming current AU status; 80 hrs of classroom and lab training; supervised work experience; and casework
  - Fifth Section-Preceptor signature and confirmation of their T&E*
  - *Confirm that preceptor is an AU by obtaining the NRC or Agreement State license or permit that lists the preceptor as an AU.

    NOTE: In addition, 10 CFR 35.396 T&E requirements are only for 35.400 and 35.600 users. If an individual is authorized under 35.400 or 35.600, then that individual would only need an additional 80 hours of T&E, specifically in parenteral administrations and three cases of parenteral administration.

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Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 2 – indicating the current AU pathway

NRC FORM 313A (AUT) (10-2015)

U.S. NUCLEAR REGULATORY COMMISSION

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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (12/31/2015)

Name of Proposed Authorized User	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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide 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 clinical 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.

d. Skip to and complete Part II Preceptor Attestation.

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

a. Authorized User on Materials 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. Also provide completed Part II Preceptor Attestation.

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.

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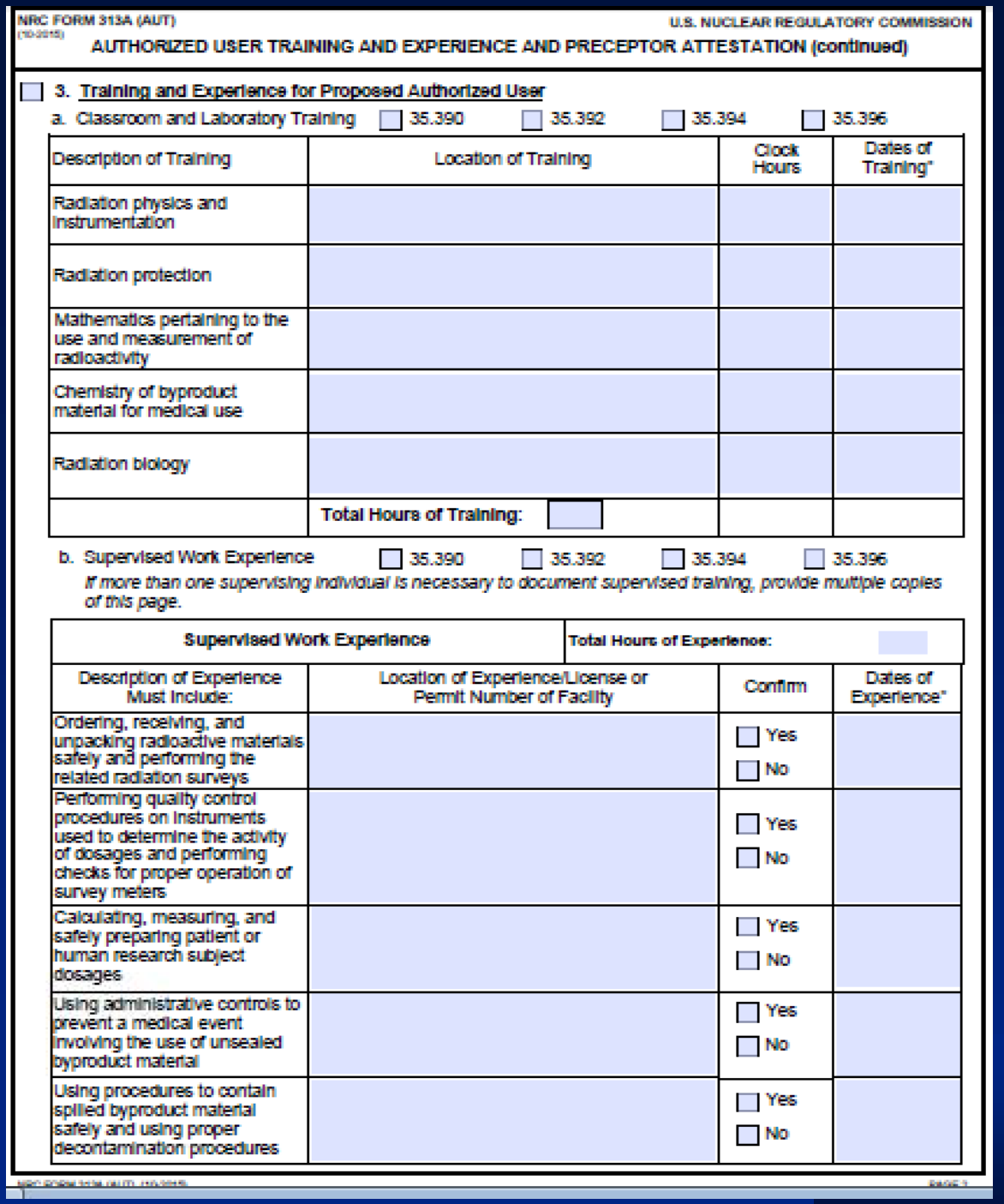
Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 – documentation of 80 hrs of classroom and lab training; supervised work experience (including the name and authorization of the supervising AU); and casework*
  - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training:		

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:	
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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

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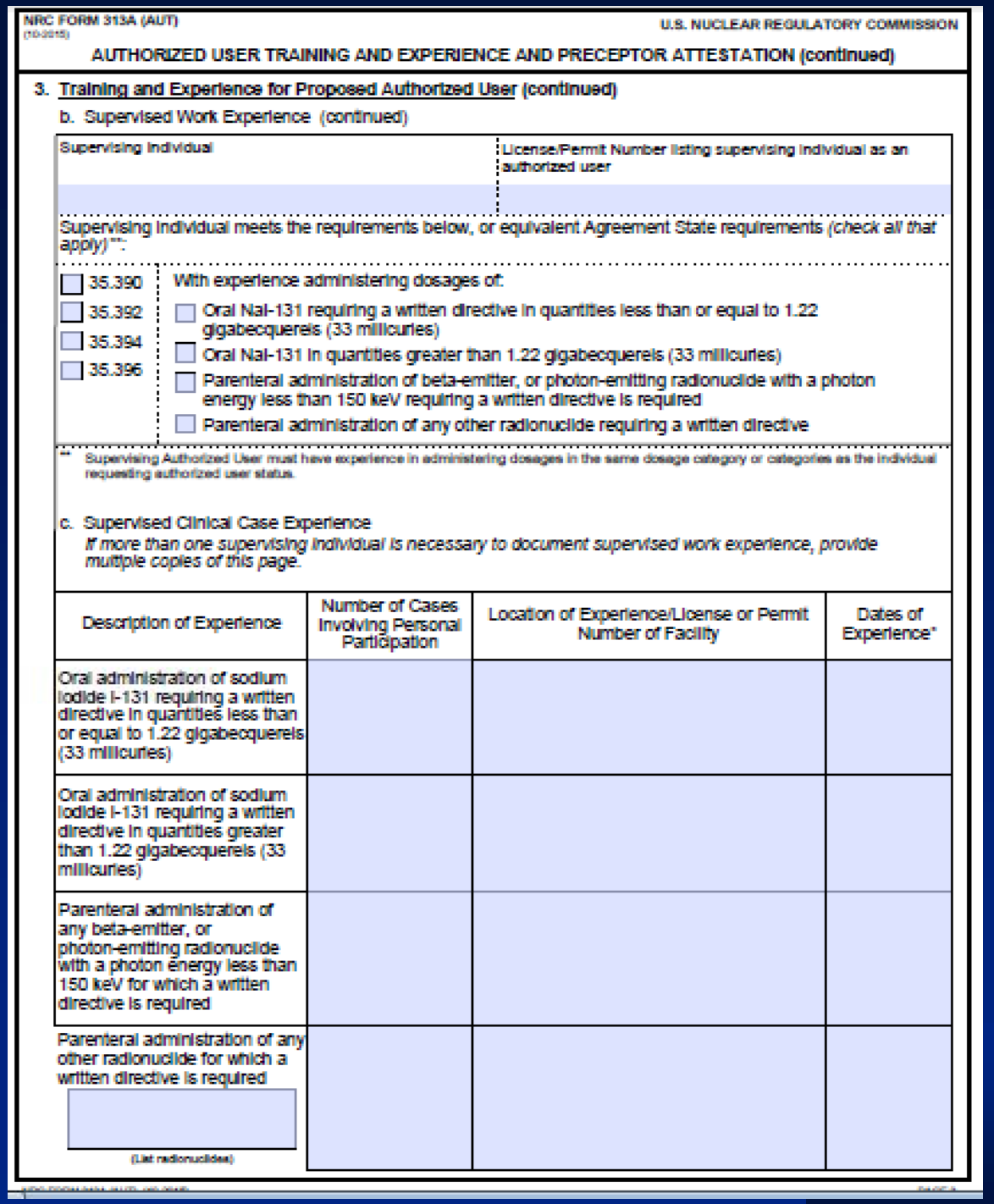
Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 – documentation of 80 hrs of classroom and lab training; supervised work experience (including the name and authorization of the supervising AU); and casework*
  - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



NRC FORM 313A (AUT) (10-2015) — U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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

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

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

* 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

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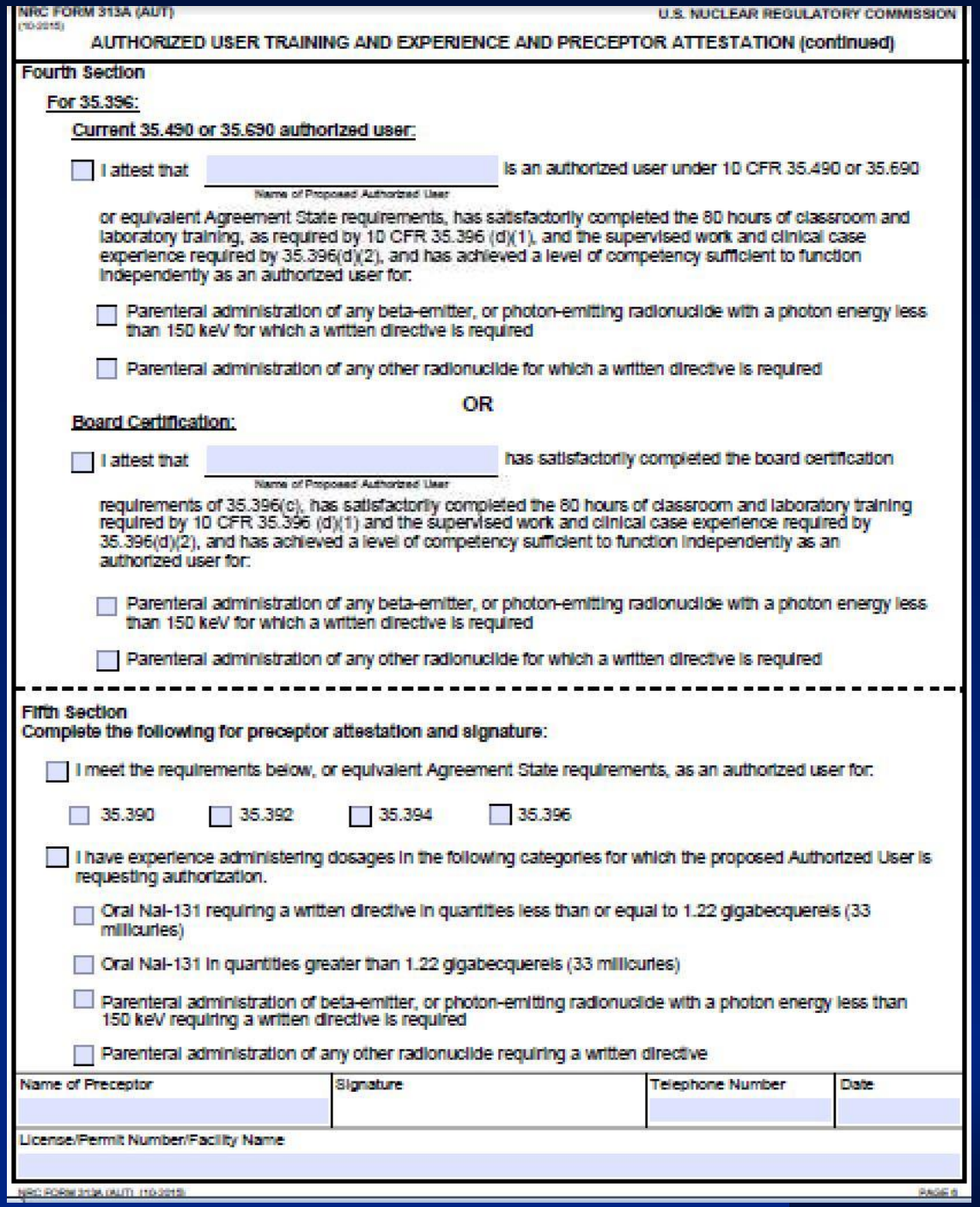
Current AU

NRC Form 313 (AUT) with the following sections completed:

- Part II – Preceptor Attestation
- Fourth Section – confirming current AU status; 80 hrs of classroom and lab training; supervised work experience; and casework
- Fifth Section – Preceptor signature & confirmation of their T&E



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☐ 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number/Facility Name

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Protecting People and the Environment

Training & Experience

Case:

Dr. Jones just completed her residency and has been hired by Metro Hospital. She is a nuclear medicine physician that has not completed her boards. Metro Hospital has requested that Dr. Jones be added to the license as an AU for the use of sodium iodide I-131 in quantities greater than 33 mCi (10 CFR 35.394). She has completed 4 clinical cases.

- What evidence of training and experience would you expect to see?

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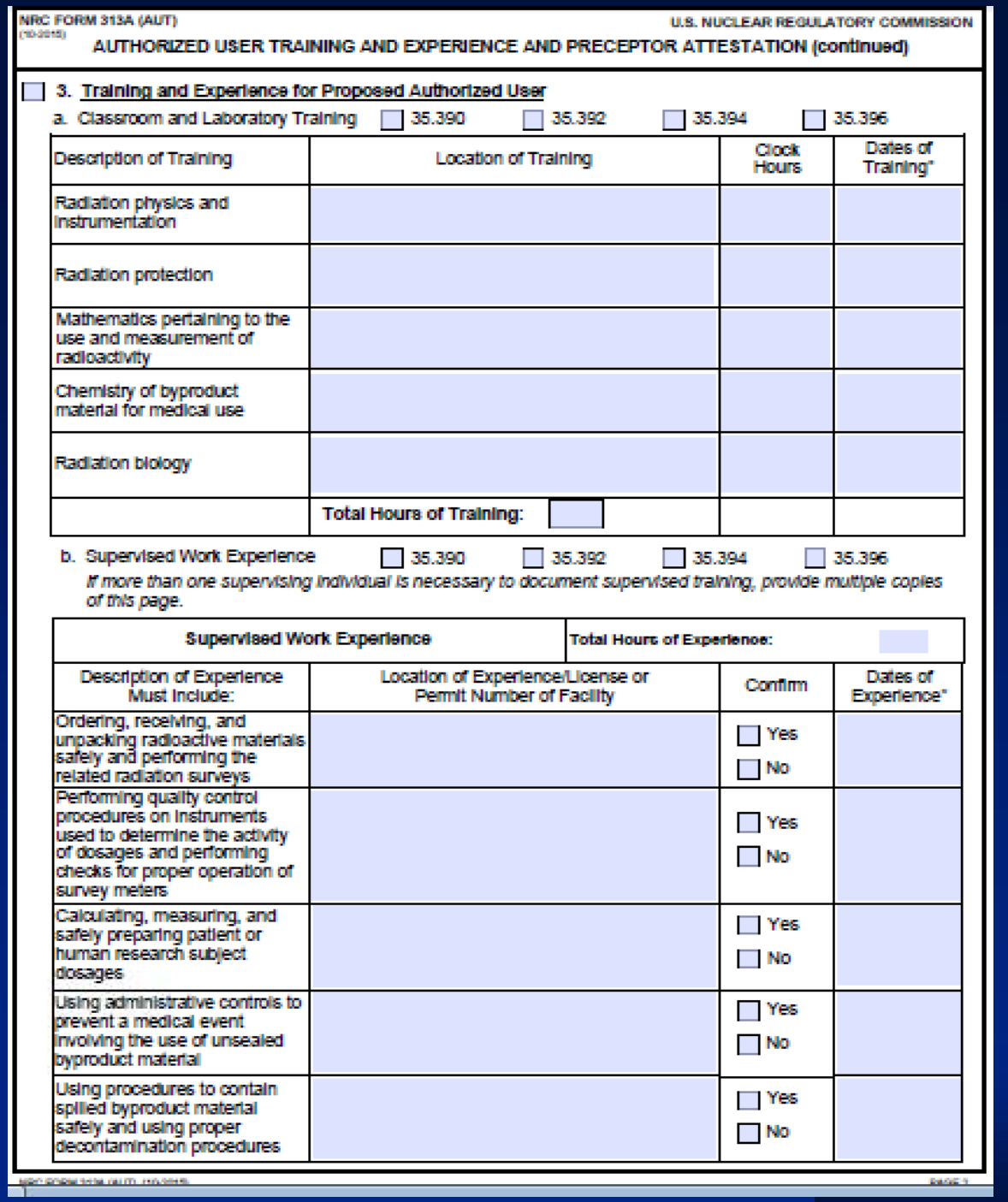
Training & Exp

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3a.,b.,c. – documentation of 80 hrs of class and lab training applicable to administration of I-131; supervised work experience (including the name and authorization of the supervising AU); and casework*

  * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training:		

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:		
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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

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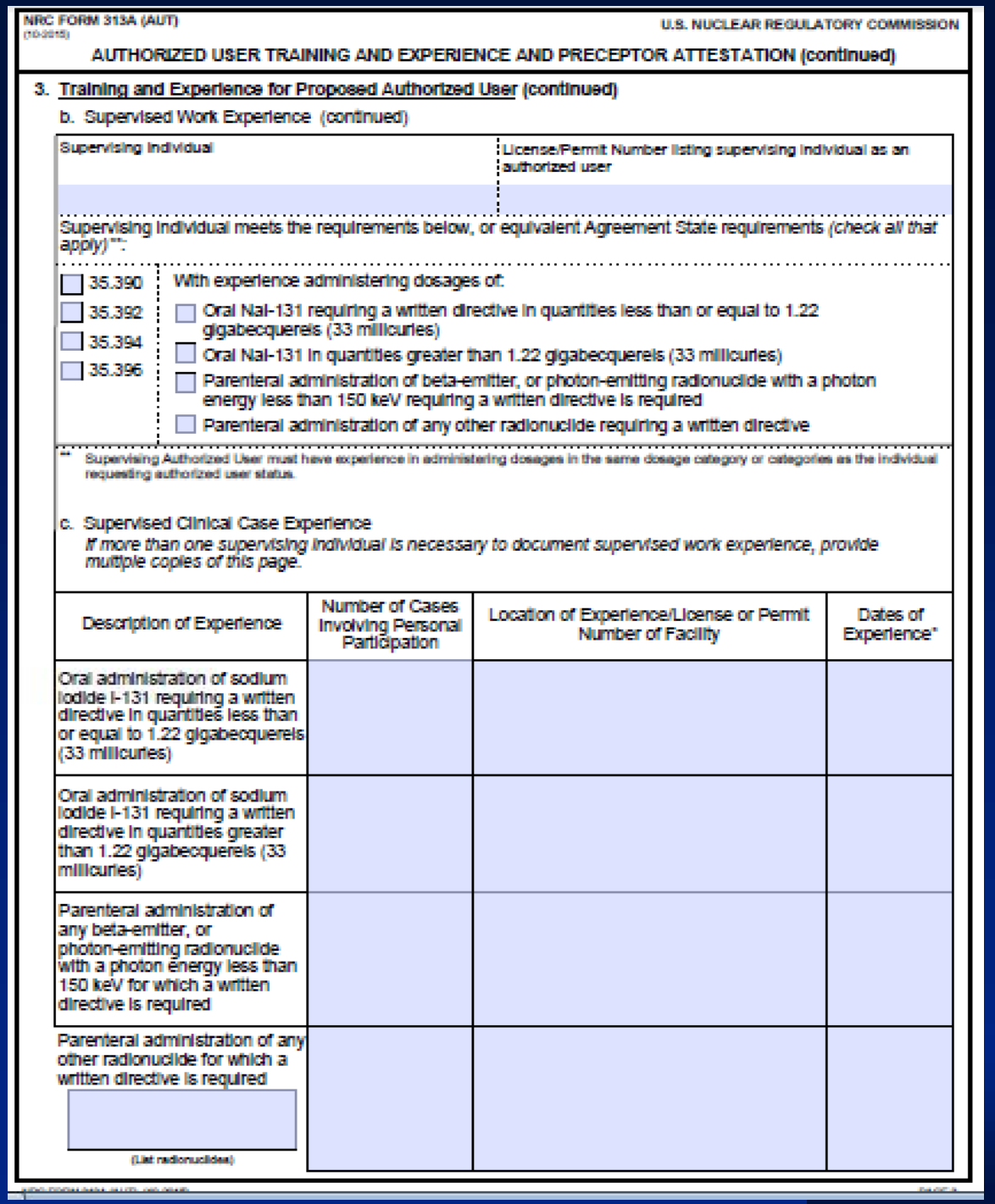
Protecting People and the Environment

Training & Exp

NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3a.,b.,c. – documentation of 80 hrs of class and lab training applicable to administration of I-131; supervised work experience (including the name and authorization of the supervising AU); and casework*

  * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



NRC FORM 313A (AUT) (10-2015) — U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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

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

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

* 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

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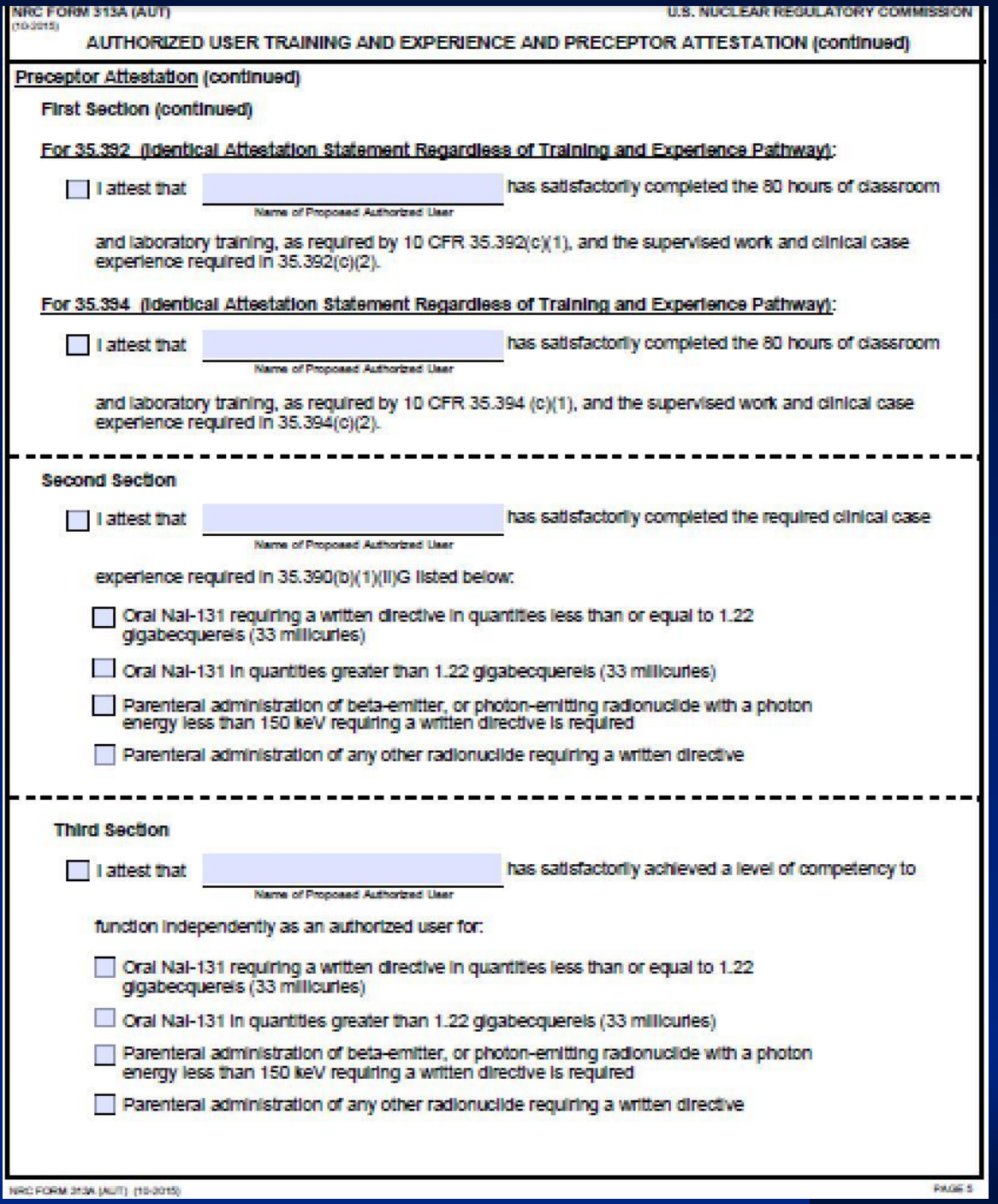
Training & Exp

NRC Form 313 (AUT) with the following sections completed – Part II – Preceptor Attestation:

- First Section – indicating proposed AU for 35.394, has completed 80 hrs of class & lab; supervised work experience; and clinical casework.
- Second Section- confirming that the proposed AU has completed the required clinical casework for administrations > 33 mCi



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ 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).

Second Section

☐ I attest that _____ (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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to function independently as an authorized user 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

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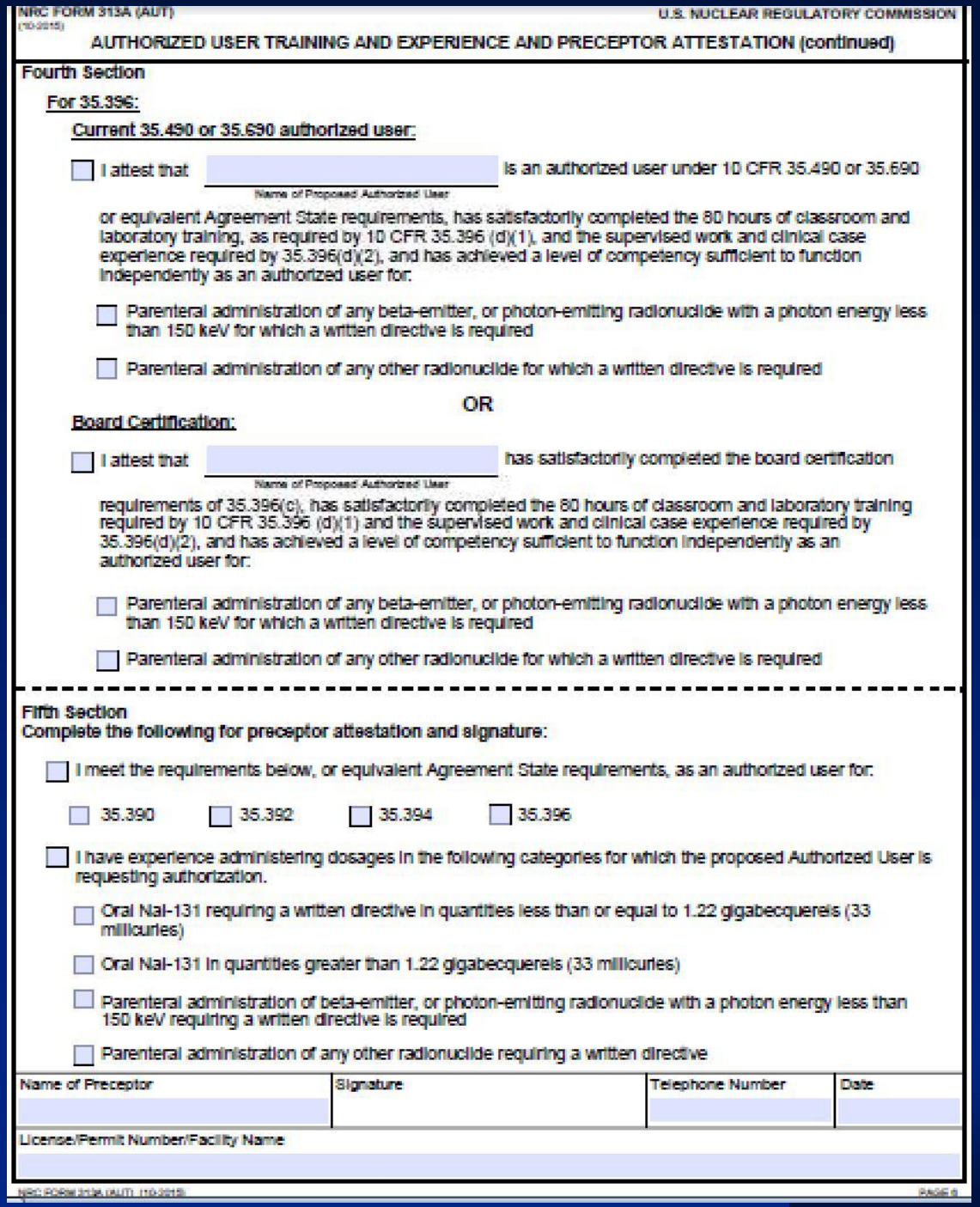
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Training & Exp

NRC Form 313 (AUT) with the following sections completed – Part II – Preceptor Attestation:

- Third Section – confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for administration of I-131
- Fifth Section – Preceptor signature & confirmation of their T&E*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.



NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☐ 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 beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number/Facility Name

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Protecting People and the Environment

Training & Experience

NOTE:

10 CFR 35.392 (b) states that if a physician is authorized for the use of 35.394 materials, they may be authorized for 35.392.

Therefore, Dr. Jones could be approved for the use of sodium iodide I-131 for both less than and greater than 33 mCi.

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Training & Experience

Case (contd.):

What if Dr. Jones had documented 5 cases of sodium iodide I-131 less than or equal to 33 mCi and 2 cases of sodium iodide I-131 greater than 33 mCi?

- 35.394(c)(2)(vi) requires that the proposed AU have experience administering dosages in at least 3 cases involving the oral administration of greater than 33 mCi of sodium iodide I-131.

Therefore, Dr. Jones would be authorized for sodium iodide I-131 less than or equal to 33 mCi only.

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QUESTIONS ?