U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Termination of U.S. NRC Recognition of the ABR's Certification Processes

Presentation by:
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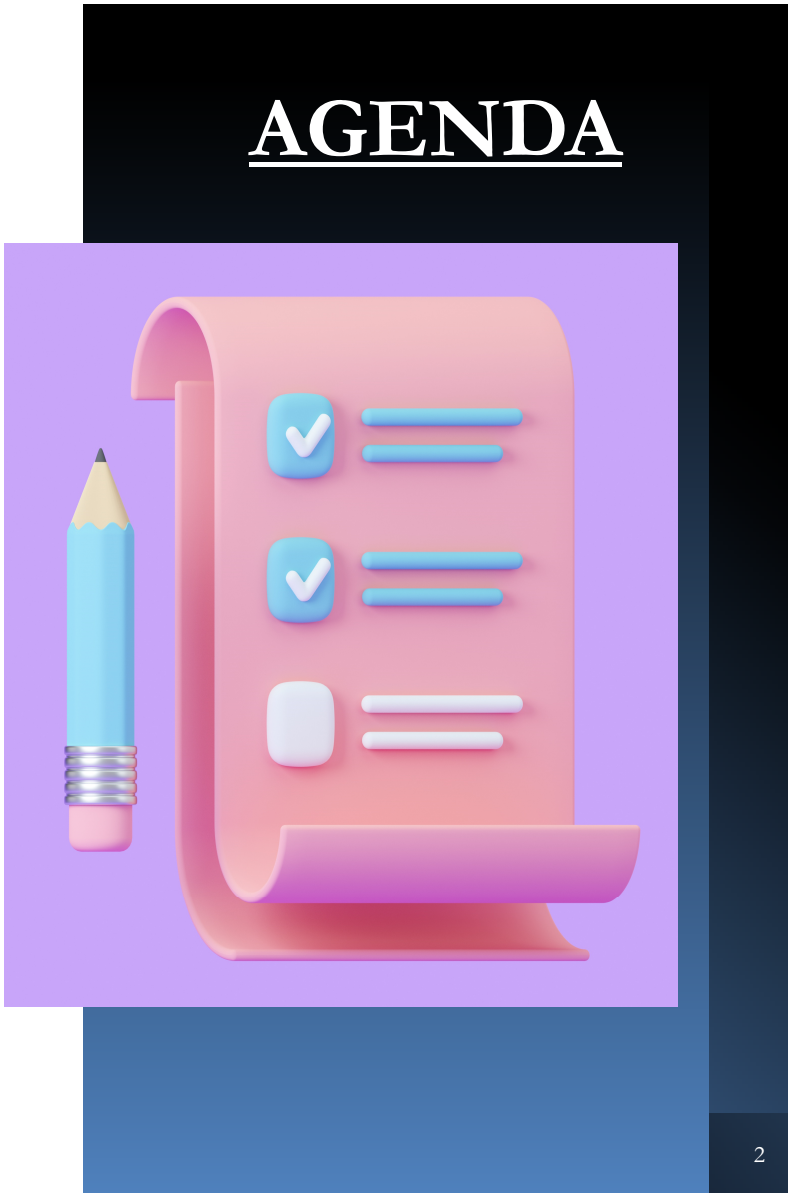
U.S. Nuclear Regulatory Commission
September 12, 2023

Presentation Outline

- Background
  - How to Become an Authorized Individual
  - ABR Recognition Timeline
  - ABR Discontinues NRC Recognition (When? What? Why?)
- What This Means For Individuals and Authorizations
- Where to Find Information
- How to Become an Authorized Individual – Alternate T&E Pathway
- Current Status and Next Steps



How to Become an Authorized Individual

- Individuals must complete T&E criteria in 10 CFR Part 35:
  - To be authorized for the medical use of byproduct material;
  - To independently fulfill the radiation safety-related duties of an authorized individual; and
  - To be listed on a license as an Authorized Individual (e.g., AU, RSO/ARSO, AMP).

How to Become an Authorized Individual

- Three main pathways:

1. Board certification pathway
   - Is the individual certified by an NRC-recognized medical specialty board?
   - Has the necessary additional T&E been completed?
2. Alternate T&E pathway
   - Has all required T&E (classroom & lab; supervised work experience, including case work; and device-specific training) been successfully completed?
   - Was a written attestation submitted?
3. Authorized Individual listed on a license
   - Is the individual already listed on an NRC or Agreement State license for equivalent types of use?
   - Has the necessary additional T&E been completed?

How to Become an Authorized Individual

Board Certification Pathway	Alternate T&E Pathway
- Complete all required T&E. - Essentially same requirements depending on the type of use. - For certain types of use, T&E must be acquired via a residency training program.	- Complete all required T&E. - Essentially same requirements depending on the type of use.
- Pass examination administered by specialty board that assesses knowledge and competency in areas that include radiation safety.	- Obtain preceptor attestation of satisfactory completion of required T&E, and ability to independently fulfill the radiation safety-related duties for each type of use or device.*

*Note that preceptor attestations are not required for most individuals certified by recognized specialty boards. The attestation in 10 CFR 35.396(b)(3) is required for both board-certified individuals and individuals using the alternate T&E pathway 10 CFR 35.396(b)(1) and (b)(2).

ABR Recognition

ABR becomes an NRC-recognized specialty board

In March 2005 (70 FR 16335), NRC published a final rule, providing, among other things– updated criteria that specialty boards must meet to be recognized by the NRC or the Agreement States.

2005

March/April 2022

ABR notified NRC and submitted letter of intent to discontinue maintaining NRC recognition of certification processes (ML22091A272)

December 31, 2023

ABR will discontinue including AU/AMP/RSO–Eligible designations on issued certificates

BACKGROUND

ABR Discontinues NRC Recognition – WHEN?

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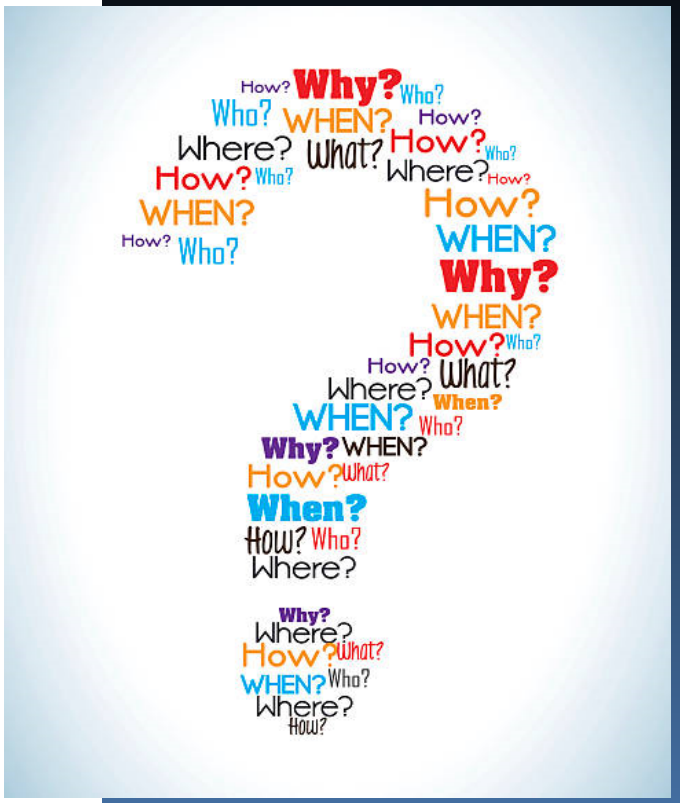
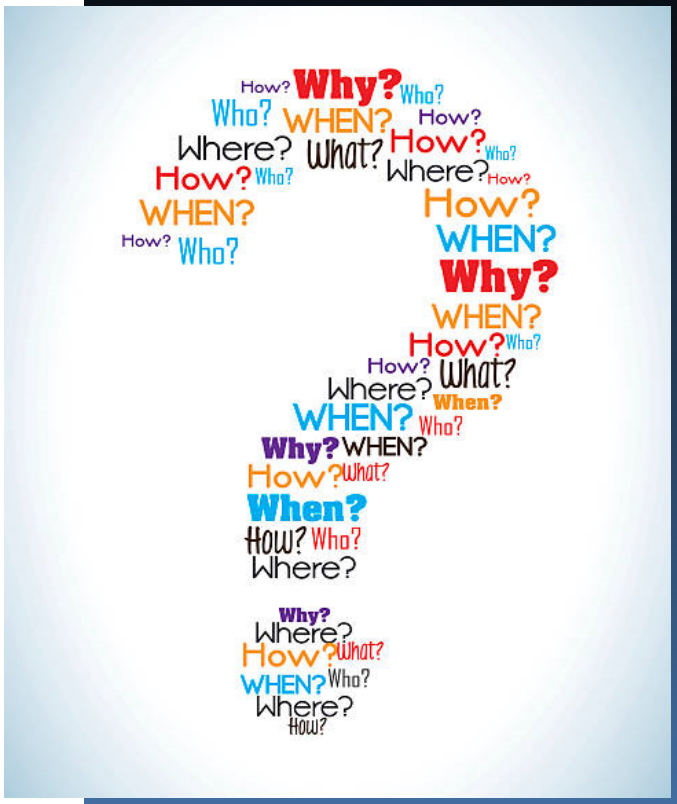


ABR Discontinues NRC Recognition – WHAT?

- All NRC-recognized ABR specialty areas are impacted
  - NRC-Recognized Specialty Boards Webpage: https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Specialty Areas	NRC Regulations	Authorization
Diagnostic Radiology	10 CFR 35.290 10 CFR 35.392, 35.394	Authorized Users
Interventional Radiology / Diagnostic Radiology	10 CFR 35.290 10 CFR 35.394	Authorized Users
Radiation Oncology	10 CFR 35.390, 35.392, 35.394 10 CFR 35.490 10 CFR 35.690	Authorized Users
Diagnostic Medical Physics	10 CFR 35.50	RSOs and Associate RSOs
Nuclear Medical Physics	10 CFR 35.50	RSOs and Associate RSOs
Therapeutic Medical Physics	10 CFR 35.51	Authorized Medical Physicists

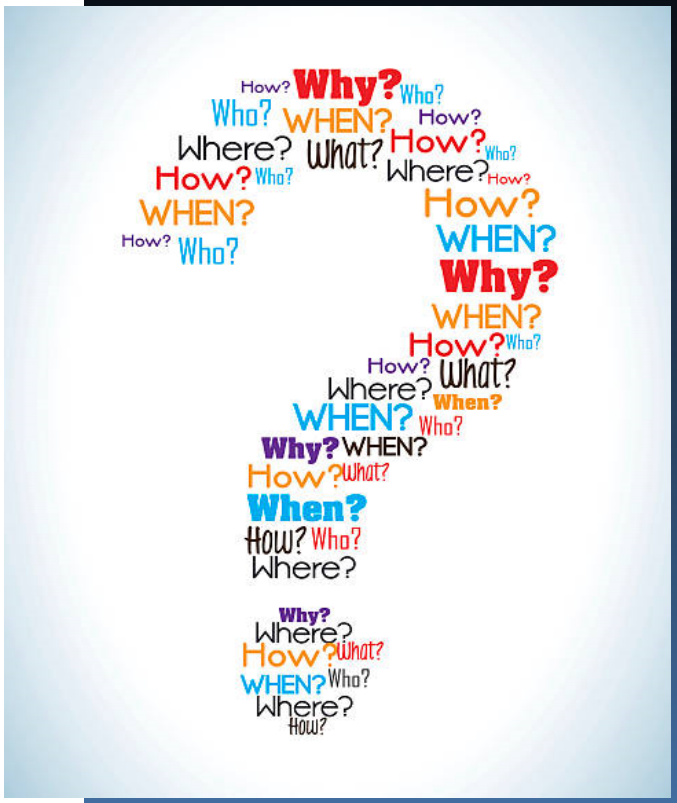
BACKGROUND



ABR Discontinues NRC Recognition – WHY?

- Outside the focus of ABR mission.
- Diverts resources from fundamental objectives (exams & customer service).
- No specific correlation between being board certified & having the AU/AMP/RSO-Eligible status.
- A direct pathway exists with NRC and Agreement States.
- ABR information webinar, direct link, and FAQs:
  https://www.theabr.org/blogs/authorized-user-eligibility-webinar-recording-and-faqs-available
  https://www.youtube.com/watch?v=hkRc9JzP2oA
  https://www.theabr.org/diagnostic-radiology/initial-certification/nrc-compliance#faqs

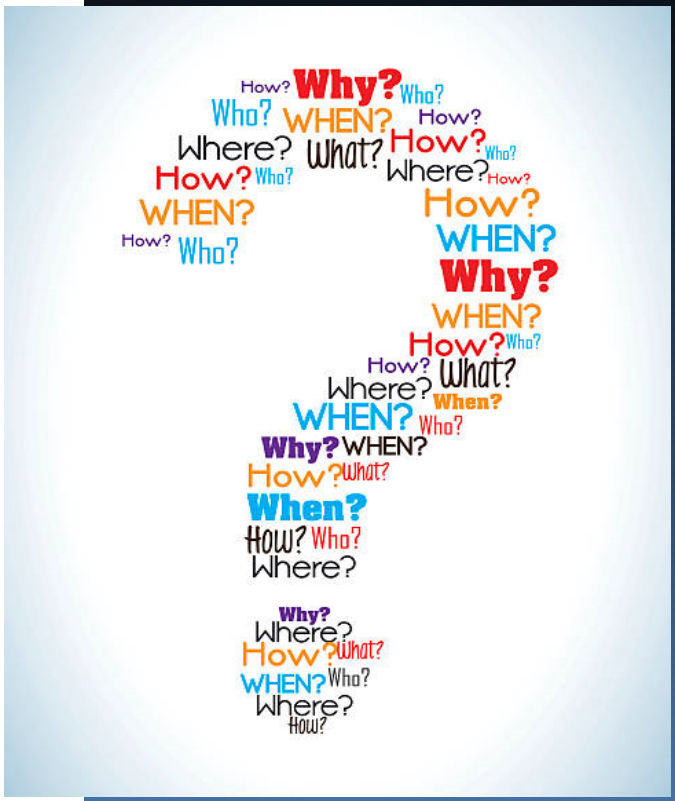
BACKGROUND



Prior to December 31, 2023

- ABR complies with applicable NRC regulations and maintains existing NRC recognition.
- ABR may issue NRC-recognized certificates with AU/AMP/RSO-Eligible designations.
- NRC-recognized certificates (issued prior to December 31st) remain valid for use via the NRC Board Certification Pathway.
- 7-yr. Recentness of Training requirement (10 CFR 35.59) applies.
- Individuals may obtain certification from a different NRC-recognized specialty board.
- Alternate T&E pathway remains an option.
  - Submit documentation of all required T&E and written preceptor attestation directly to NRC or Agreement States via the licensing process.

WHAT THIS MEANS



After December 31, 2023

- ABR will not maintain NRC-recognition and certification processes will not be recognized by the NRC.
- ABR will not issue NRC-recognized certificates with AU/AMP/RSO – designations.
- NRC-recognized certificates (issued prior to December 31st) remain valid for use via the NRC Board Certification Pathway.
- 7-yr. Recentness of Training requirement (10 CFR 35.59) applies.
- Individuals may obtain certification from a different NRC-recognized specialty board.
- Alternate T&E pathway remains an option.
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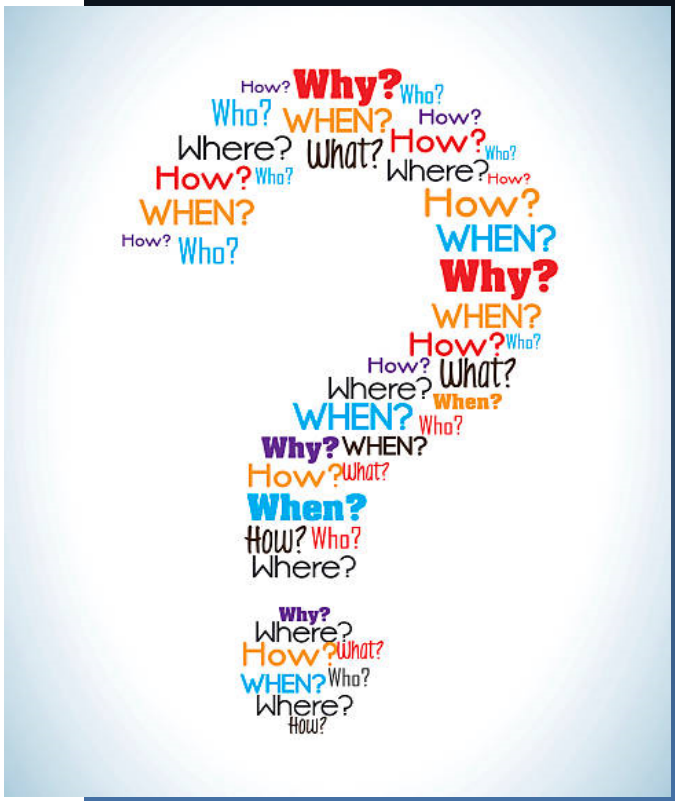


Where to Find Information

NRC's Medical Uses Licensee Toolkit:

- Public Meeting Announcement and ABR 2022 Decision Letter
- Specialty Board Certifications Recognized by NRC Under 10 CFR Part 35
  - How to Become Authorized
  - Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards
  - 2022 Evaluation of NRC Recognized Specialty Boards

Other useful links on the NRC's Medical Uses Licensee Toolkit web page:

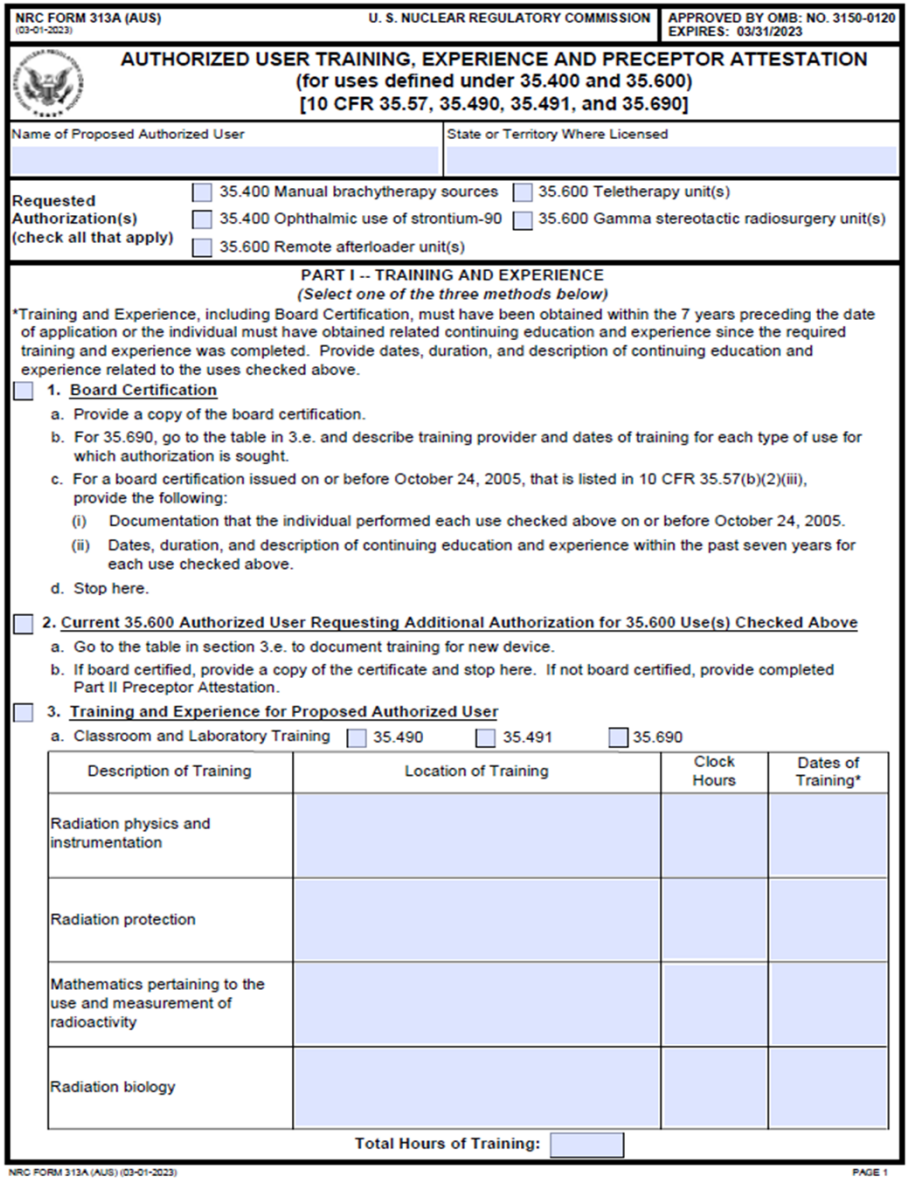
- The NRC's ACMUI Subcommittee Reports
  - Subcommittee on Training and Experience for All Modalities, Final Report
- FAQs About Licensing Medical Uses of Byproduct Material Under 10 CFR Part 35
- NRC Medical List Server

How to become an Authorized Individual – Alternate T&E Pathway

- Licensee submits request to NRC or Agreement State program.
- All applicable T&E documentation should be included.
- May use NRC 313A series forms
  - Detailed instructions in NRC guidance – NUREG-1556, Vol. 9, Rev. 3 (Section 8.7 and Appendix C, D, and E).
- NOTE: NRC does not issue licenses to individuals, but rather to licensees. NRC authorizes individuals to be listed on a license.

Sample
NRC Form 313A (AUS)
Page 1 of 6

- 10 CFR 35.490 – Training for use of manual brachytherapy sources
- 10 CFR 35.491 – Training for ophthalmic use of strontium-90
- 10 CFR 35.690 – Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units



NRC FORM 313A (AUS) (03-01-2023) | U. S. NUCLEAR REGULATORY COMMISSION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 03/31/2023

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690]

Name of Proposed Authorized User | State or Territory Where Licensed

Requested Authorization(s) (check all that apply)
☐ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)
☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)
☐ 35.600 Remote afterloader unit(s)

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 obtained 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 35.690, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
c. For a board certification issued on or before October 24, 2005, that is listed in 10 CFR 35.57(b)(2)(iii), 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.
d. Stop here.

☐ **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**
a. Go to the table in section 3.e. to document training for new device.
b. If board certified, provide a copy of the certificate and stop here. If not board certified, provide completed Part II Preceptor Attestation.

☐ **3. Training and Experience for Proposed Authorized User**
a. Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 35.690

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			
Radiation biology			

Total Hours of Training:

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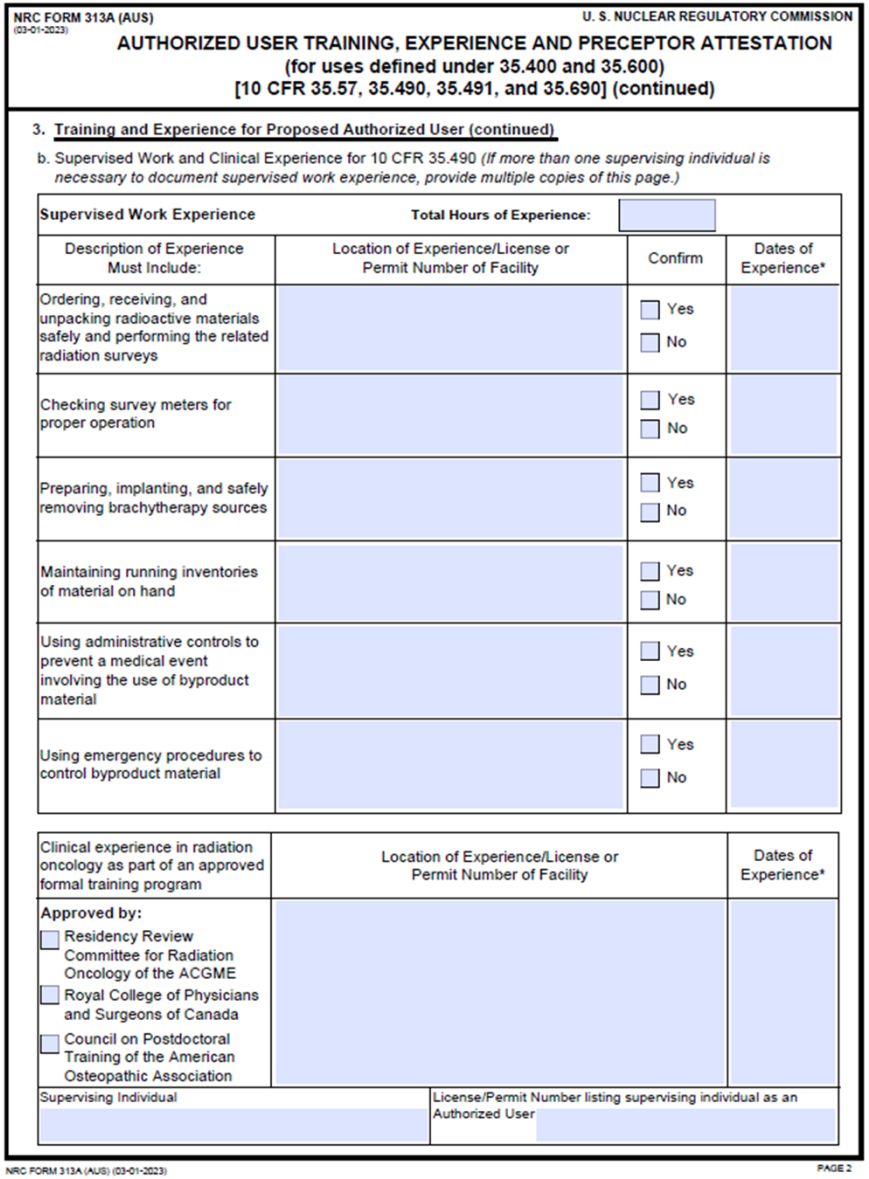

NRC FORM 313A (AUS) (03-01-2023) — U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, 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	
Checking survey meters for proper operation		☐ Yes ☐ No	
Preparing, implanting, and safely removing brachytherapy sources		☐ Yes ☐ No	
Maintaining running inventories of material on hand		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Using emergency procedures to control byproduct material		☐ Yes ☐ No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Council on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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(03-01-2023)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

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*
Reviewing full calibration measurements and periodic spot-checks		☐ Yes ☐ No	
Preparing treatment plans and calculating treatment doses and times		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		☐ Yes ☐ No	
Selecting the proper dose and how it is to be administered		☐ Yes ☐ No	

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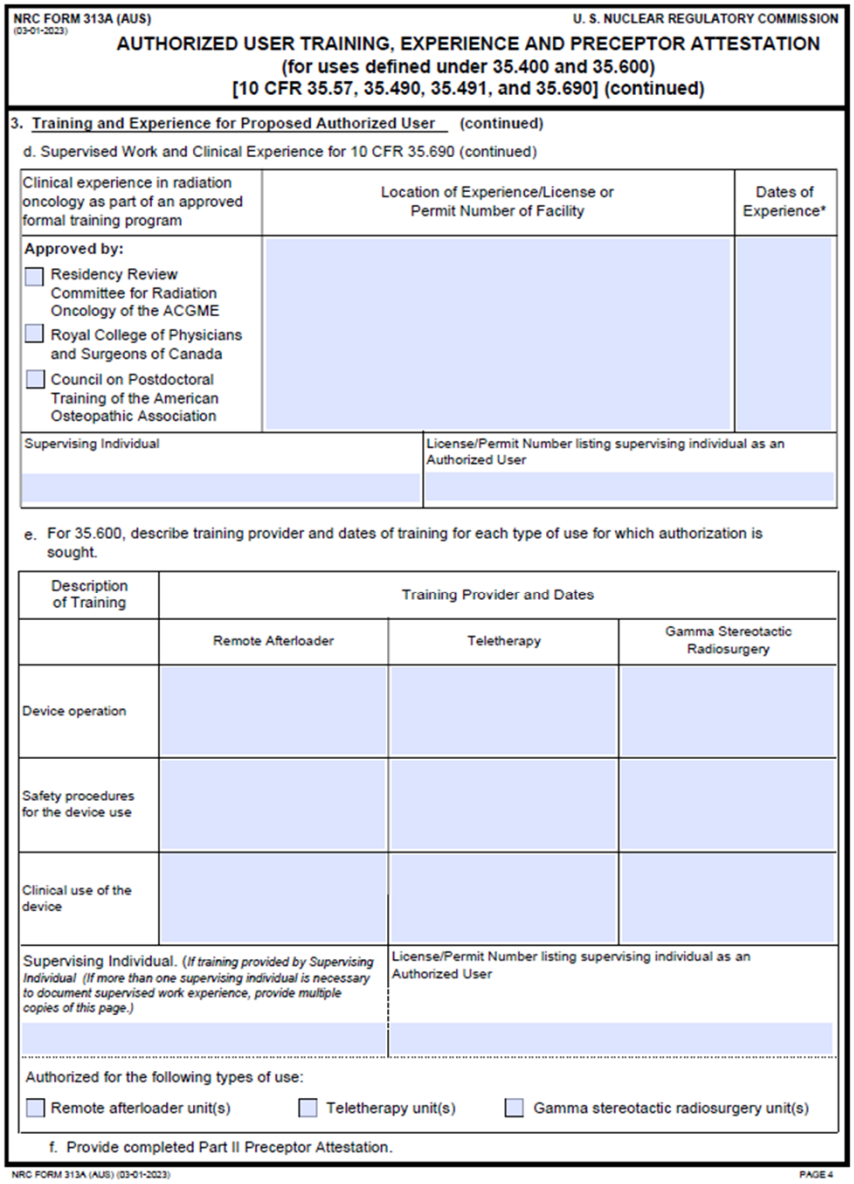

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AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Council on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			

Supervising Individual. (*If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*)	License/Permit Number listing supervising individual as an Authorized User

Authorized for the following types of use:

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

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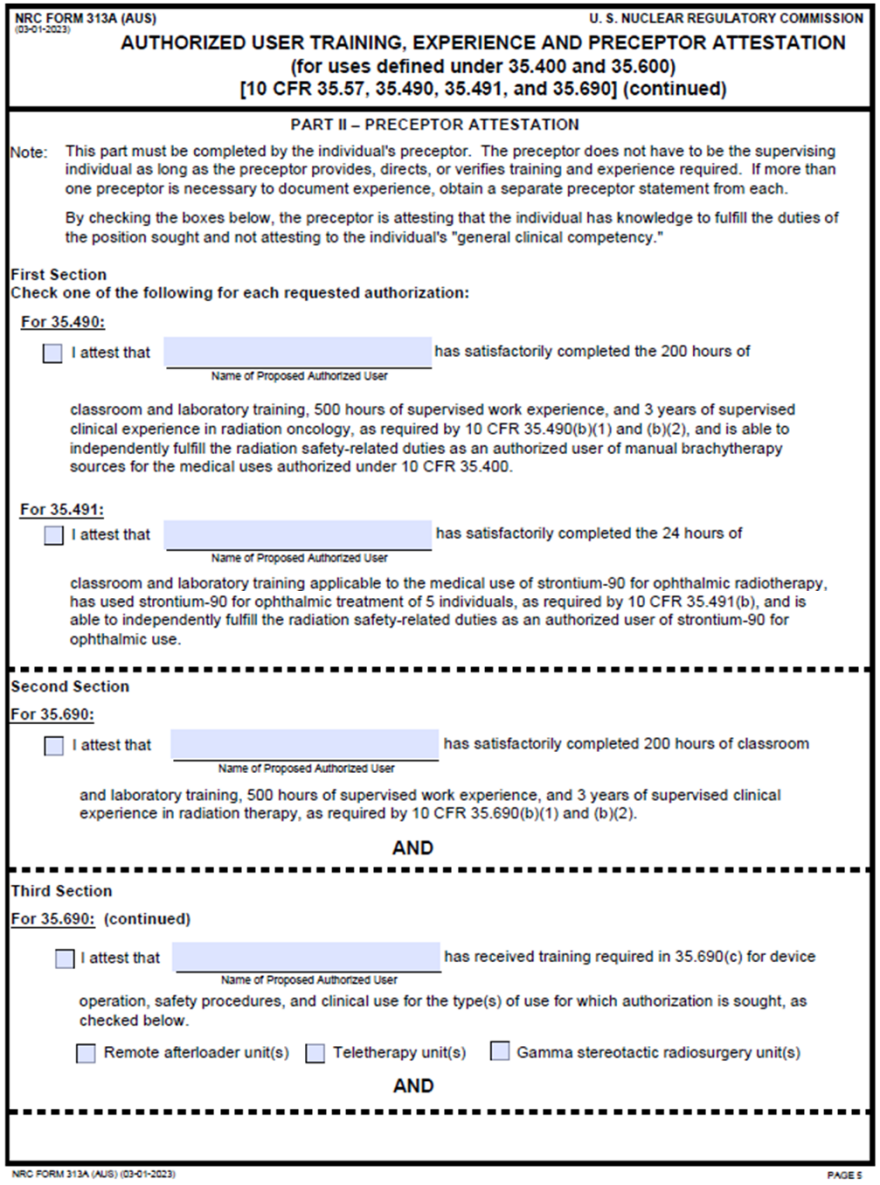

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AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

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 35.490:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

Third Section

For 35.690: (continued)

☐ I attest that _____ (Name of Proposed Authorized User) has received training required in 35.690(c) for device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

AND

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(for uses defined under 35.400 and 35.600)
[10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)

Fourth Section

☐ I attest that _____ is able to independently fulfill the radiation safety-related duties as an authorized user for:
(Name of Proposed Authorized User)

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete one of the following for attestation and signature:

☐ Authorized User:

☐ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.400 Manual brachytherapy sources
☐ 35.400 Ophthalmic use of strontium-90
☐ 35.600 Remote afterloader unit(s)
☐ 35.600 Teletherapy unit(s)
☐ 35.600 Gamma stereotactic radiosurgery unit(s)
☐ 35.57 for 35.400 and/or 35.600 uses, as applicable

OR

☐ Residency Program Director (for 35.490 and/or 35.690 only):

☐ 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 for:

☐ 35.400 Manual brachytherapy sources
☐ 35.600 Teletherapy unit(s)
☐ 35.600 Remote afterloader unit(s)
☐ 35.600 gamma stereotactic radiosurgery unit(s)
☐ 35.57 for 35.400 uses
☐ 35.57 for teletherapy unit(s)
☐ 35.57 for remote afterloader unit(s)
☐ 35.57 gamma stereotactic radiosurgery unit(s)

☐ I affirm that this faculty member 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 Postdoctoral Training of the American Osteopathic Association

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

☐ 35.490 ☐ 35.690

Name of Facility:	
License/Permit Number:	

Name of Preceptor or Residency Program Director (Typed or printed)	Telephone Number	Date

Signature

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Remember!

Prior to December 31, 2023	After December 31, 2023
ABR complies with applicable NRC regulations and maintains existing NRC recognition.	ABR will not maintain NRC-recognition and certification processes will not be recognized by the NRC.
ABR may issue NRC-recognized certificates with AU/AMP/RSO-Eligible designations.	ABR will not issue NRC-recognized certificates with AU/AMP/RSO – designations..
NRC-recognized certificates (issued prior to December 31st) remain valid for use via the NRC Board Certification Pathway.	
7-yr. "Recentness of Training" requirement (10 CFR 35.59) applies.	
May obtain certification from a different NRC-recognized specialty board.	
Alternate T&E pathway remains an option.	

Current Status / Next Steps

- Discontinuation of ABR's recognition with NRC is to occur on December 31, 2023.
- Licensees and Current/Potential Authorized Individuals:
  - Keep track of T&E documentation.
  - Complete NRC 313A series forms early.
  - Get familiar with NRC Part 35 T&E requirements.
  - Reach out to your friendly regulators. ☺
- NRC will staff will:
  - Conduct a public meeting to share information.
  - Inform/notify stakeholders when discontinuation is finalized via the NRC Medical List Server.

Abbreviations

- ABR – American Board of Radiology
- ACMUI – The Advisory Committee on the Medical Uses of Isotopes
- AU – Authorized User
- AMP – Authorized Medical Physicist
- ARSO – Associate Radiation Safety Officer
- CFR – Code of Federal Regulations
- RSO – Radiation Safety Officer
- T&E – Training and Experience

Questions?

- **Contact Us:**
  - medicalquestions.resource@nrc.gov

- Medical Uses Licensee Toolkit