

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

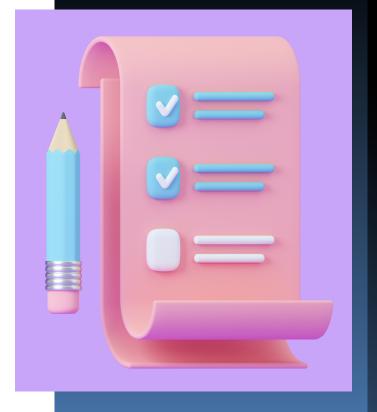
Presentation by:

Maryann Ayoade – Medical Radiation Safety Team Member Office of Nuclear Material Safety and Safeguards 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

AGENDA



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 safetyrelated 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

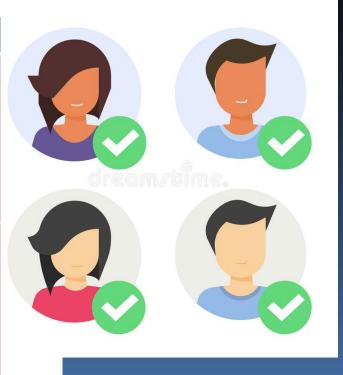
- Complete all required T&E.

- Essentially same requirements depending on the type of use.
- For certain types of use, T&E must be acquired via a residency training program.
- Pass examination administered by specialty board that assesses knowledge and competency in areas that include radiation safety.

Alternate T&E Pathway

- Complete all required T&E.
- Essentially same requirements depending on the type of use.

- 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

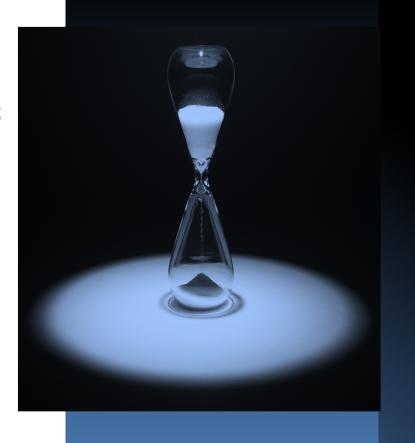
In March 2005 (70 FR 16335), NRC published a final rule, providing, among other things— updated criteria that specialty boards must meet to be recognized by the NRC or the Agreement States.

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

2005 March/April 2022

December 31, 2023

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



ABR Discontinues NRC Recognition – WHEN?

ABR becomes an NRC-recognized specialty board

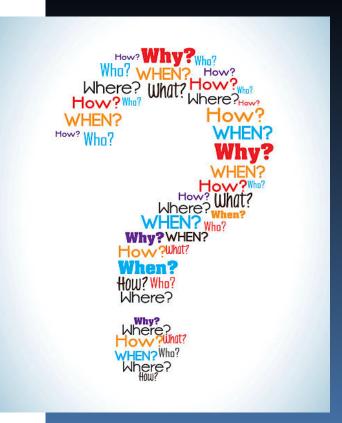
- In March 2005 (70 FR 16335), NRC published a final rule, providing, among other things— updated criteria that specialty boards must meet to be recognized by the NRC or the Agreement States.

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

2005 March/April 2022

December 31, 2023

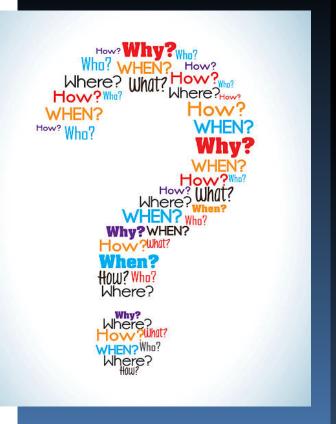
ABR notified NRC and submitted letter of intent to discontinue maintaining NRC recognition of certification processes (ML22091A272)



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

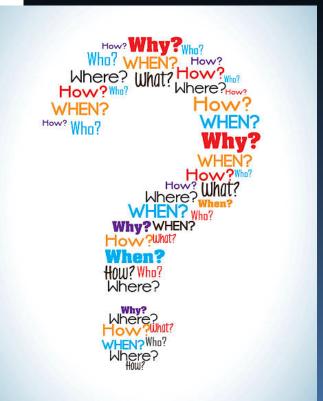
Specialty Areas	NRC Regulations	Authorization
Diagnostic Radiology	10 CFR 35.290 10 CFR 35.392, 35.394	Authorized Users
Interventional Radiology / Diagnostic Radiology	10 CFR 35.290 10 CFR 35.394	Authorized Users
Radiation Oncology	10 CFR 35.390, 35.392, 35.394 10 CFR 35.490 10 CFR 35.690	Authorized 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



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:

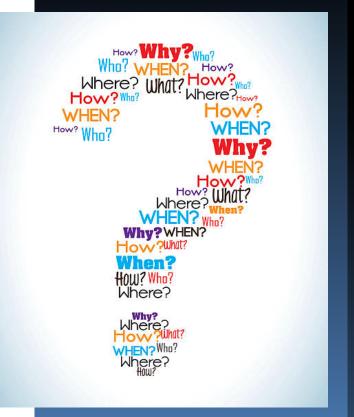
 <a href="https://www.theabr.org/blogs/authorized-user-eligibility-webinar-recording-and-faqs-available-https://www.youtube.com/watch?v=hkRc9JzP2oA-https://www.theabr.org/diagnostic-radiology/initial-certification/nrc-compliance#faqs



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 NRCrecognized 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.

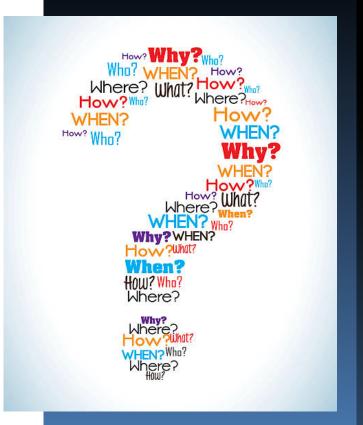
WHAT THIS MEANS



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.
 - ➤ Submit documentation of all required T&E and written preceptor attestation directly to NRC or Agreement States via the licensing process.

WHAT THIS MEANS

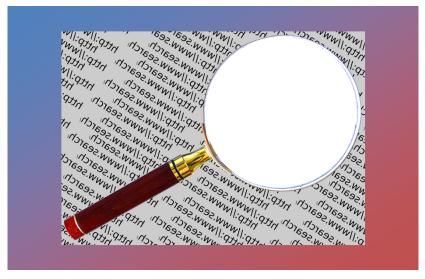




Where to Find Information

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

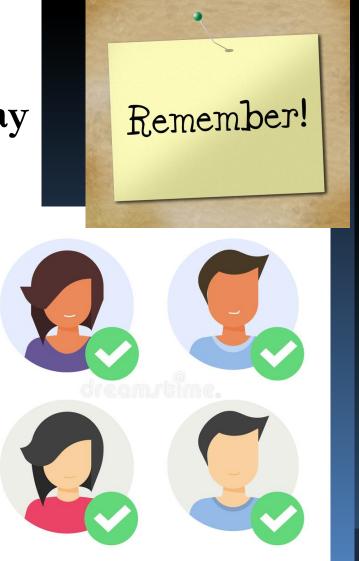


Other useful links on the NRC's Medical Uses Licensee Toolkit web page:

- 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 <u>NUREG-1556</u>, Vol. 9, Rev. 3 (Section 8.7 and Appendix C, D, and E).
- <u>NOTE</u>: NRC does not issue licenses to individuals, but rather to licensees. NRC authorizes individuals to be listed on a license.



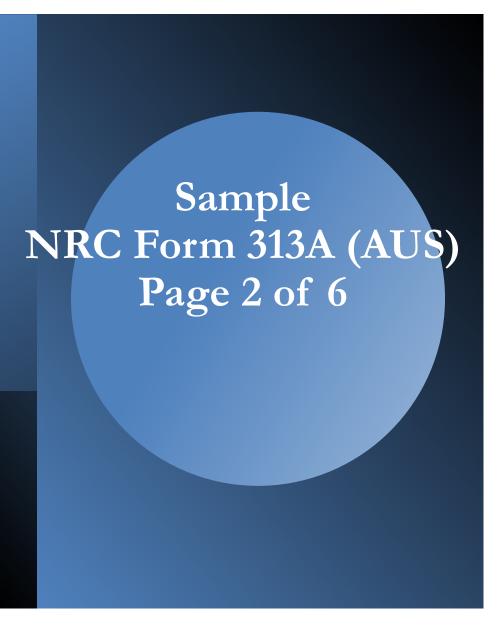
Sample VRC Form 313A (AUS)

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

IRC FORM 313A (AUS) (3-01-2023)	U. S. NUCL	EAR REGULATORY COMM	MISSION	APPROVED BY EXPIRES: 03/31	OMB: NO. 3150-012 /2023
AUTHORIZED US	(for uses define	(PERIENCE AND d under 35.400 ar 35.490, 35.491, an	nd 35.6	300)	ESTATION
ame of Proposed Authorized User		State or Territory Where	e License	d	
equested 35.400 N	lanual brachytherapy	sources 35.600 T	elethera	py unit(s)	
	phthalmic use of stro	ntium-90 35.600 G	Samma	stereotactic rad	iosurgery unit(s)
theck all that apply) 35.600 F	temote afterloader uni	t(s)			
		G AND EXPERIENCE			
Fraining and Experience, including E of application or the individual must training and experience was comple experience related to the uses check 1. Board Certification a. Provide a copy of the board of the provide a copy of the board of the complete in the copy of the stable in the copy of the table in the copy of the copy of the copy of the table in the copy of th	toard Certification, mu have obtained related ted. Provide dates, di ked above.	continuing education a uration, and description	within t and exp n of con	erience since the tinuing education	ne required on and
which authorization is sought	L.				
provide the following:					
(i) Documentation that the					
(ii) Dates, duration, and des each use checked above		education and expene	nce with	iin the past sev	en years for
d. Stop here.					
2. Current 35.600 Authorized U	ser Requesting Addi	tional Authorization	for 35.6	00 Use(s) Che	cked Above
a. Go to the table in section 3.e				, ,	
b. If board certified, provide a co	opy of the certificate a	nd stop here. If not be	oard cert	ified, provide c	ompleted
Part II Preceptor Attestation. 3. Training and Experience for	Proposed Authoriz	ad Hear			
Classroom and Laboratory T		35.491	35.6	390	
Description of Training	Loca	tion of Training		Clock	Dates of
Description of Training	Loca	tion of Training		Hours	Training*
Radiation physics and instrumentation					
Radiation protection					
Mathematics pertaining to the use and measurement of radioactivity					
Radiation biology					
	Total Hours	s of Training:			

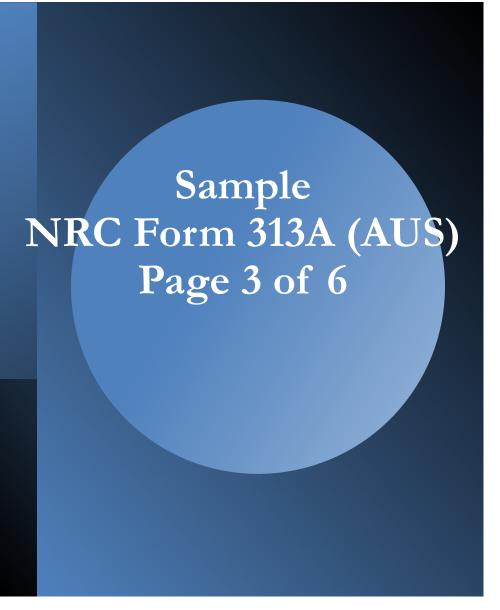
NRC FORM 313A (AUS) (03-01-2023) PAGE 1



NRC FORM 313A (AUS) 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 Location of Experience/License or Confirm Must Include: Permit Number of Facility Experience* Ordering, receiving, and Yes unpacking radioactive materials safely and performing the related No radiation surveys Yes Checking survey meters for proper operation No No Yes Preparing, implanting, and safely removing brachytherapy sources No Maintaining running inventories Yes of material on hand No Using administrative controls to Yes prevent a medical event involving the use of byproduct No No material Yes Using emergency procedures to control byproduct material No Clinical experience in radiation Dates of Location of Experience/License or oncology as part of an approved Permit Number of Facility Experience* formal training program 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

NRC FORM 3134 (AUS) (03-01-0023) PAGE 2

15

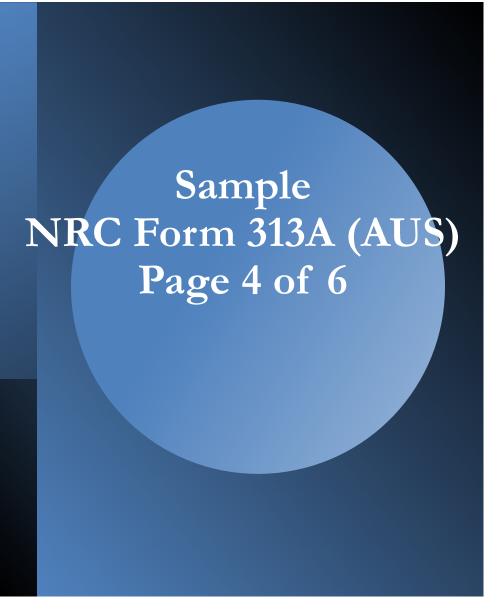


(for uses defined under 35.400 and 35.600) [10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)				
Training and Experience for Proposed Authorized User (continued)				
c. Supervised Clinical Experience	for 10 CFR 35.491			
Description of Experience	Location of Experience/License or Permit Number of 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 Authorized User	supervising indi	vidual as an	
d. Supervised Work and Clinical E	experience for 10 CFR 35.690			
Remote afterloader unit(s)	Teletherapy unit(s) Gamma s	tereotactic radi	osurgery unit(s)	
Supervised Work Experience	Total Hours of Exp	erience:		
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		

U. S. NUCLEAR REGULATORY COMMISSION

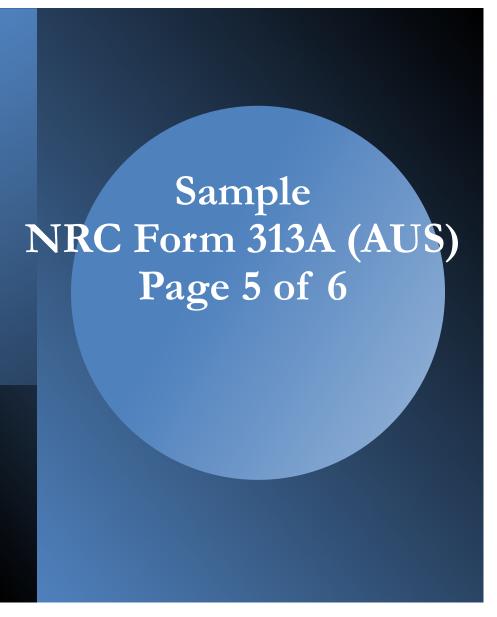
NRC FORM 313A (AUS)

NRC FORM 313A (AUS) (03-01-2023) PAGE 3



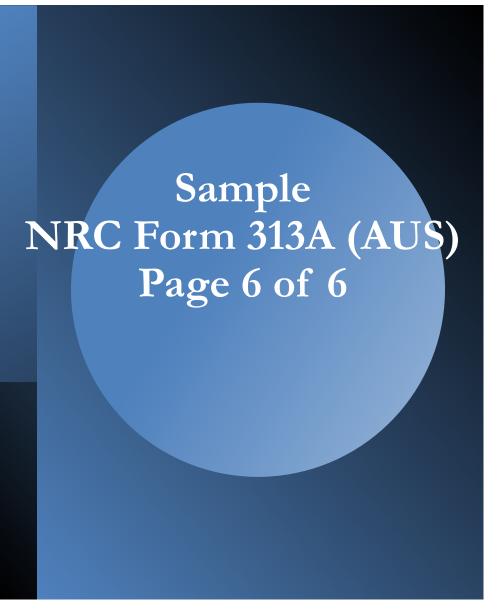
AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.57, 35.490, 35.491, and 35.690] (continued)						
. Training and Experience for Proposed Authorized User (continued)						
d. Supervised Work	and Clinical Ex	perience for 10 CF	FR 35	5.690 (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 Post Training of the A Osteopathic Ass	doctoral American					
Supervising Individual				License/Permit Number listing s Authorized User	supervising individu	ial as an
				Addioized Osei		
For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.				on is		
Description of Training			Tra	aining 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 fo	ollowing types of	of use:				
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)						
f. Provide completed Part II Preceptor Attestation.						

NRC FORM 313A (AUS) (03-01-2023) PAGE 4



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."				
	ection one of the foll	owing for each requested authorization:			
For 3	<u>5.490:</u>				
	I attest that	Name of Proposed Authorized User			
	clinical experi independently	d laboratory training, 500 hours of supervised work experience, and 3 years of supervised ence in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and is able to rufill the radiation safety-related duties as an authorized user of manual brachytherapy e medical uses authorized under 10 CFR 35.400.			
For 3	5.491 <u>:</u>				
	I attest that	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.					
Secon	d Section				
For 35					
	I attest that	has satisfactorily completed 200 hours of classroom			
		Name of Proposed Authorized User			
		ry training, 500 hours of supervised work experience, and 3 years of supervised clinical n radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).			
		AND			
Third 9	Section				
	.690: (continu	ed)			
[I attest that	Name of Proposed Authorized User has received training required in 35.690(c) for device			
	operation, sa	afety procedures, and clinical use for the type(s) of use for which authorization is sought, as			
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)					
		AND			
••••					

RC FORM 313A (AUS) (03-01-2023) PAGE 5



NRC FORM 313A (AUS) 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, 35.4	490, 35.491, and 35	i.690] (continued)		
Fourth Section					
I attest that		is able to independ	dently fulfill the radiation s	afety-	
and a total and a total and	Name of Proposed Authorized User				
	as an authorized user for:		-tttidi		
Remote arte	erloader unit(s) Telethera	py unit(s) Gamma	stereotactic radiosurgery	unit(s)	
Fifth Section					
_	llowing for attestation and sig	jnature:			
Authorized User:					
I meet the requ an authorized u	uirements in 10 CFR 35.490, 35. user for:	.491, 35.690, or equivale	ent Agreement State requ	irements, as	
35.400 Man	nual brachytherapy sources	35.600 Teletherapy	unit(s)		
35.400 Oph	thalmic use of strontium-90	35.600 Gamma ste	reotactic radiosurgery uni	t(s)	
35.600 Rem	note afterloader unit(s)	35.57 for 35.400 ar	nd/or 35.600 uses, as app	licable	
	C	OR			
Residency Program	m Director (for 35.490 and/or	35.690 only):			
I affirm that the	attestation represents the cons	sensus of the residency	program faculty where at	least one	
faculty member requirements for	r is an authorized user who mee or:	ets the requirements bel	ow or equivalent Agreeme	ent State	
35.400 Man	35.400 Manual brachytherapy sources 35.57 for 35.400 uses				
35.600 Tele	35.600 Teletherapy unit(s) 35.57 for teletherapy unit(s)				
35.600 Rem	35.600 Remote afterloader unit(s) 35.57 for remote afterloader unit(s)				
35.600 gam	35.600 gamma stereotactic radiosurgery unit(s) 35.57 gamma stereotactic radiosurgery unit(s)				
I affirm that this	s faculty member concurs with t	he attestation I am provi	iding as program director.		
I affirm that the residency training program is approved by the:					
Residency	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 Resid	dency Program Director (Typed or p	printed)	Telephone Number	Date	
Signature					

RC FORM 313A (AUS) (03-01-2023) PAGE 6

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 <u>NRC 313A series forms</u> 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 <u>Medical List Server</u>.

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

