



JUN 22 2011

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

Edward E. Wroblewski, M.A.
Radiation Safety Officer
St. Vincent Hospital &
Health Care Center
2001 West 86th Street
Indianapolis, IN 46240-0970

Dear Mr. Wroblewski:

Enclosed is Amendment No. 129 to your NRC Material License No. 13-00133-02 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers. If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

Please note that, at this time, we were unable to approve Brandon Martinez, M.D. as an authorized user (AU) for the use of materials in 10 CFR 35.300, including yttrium-90 Spheres. This is because the information in your letter dated March 21, 2011, was insufficient to complete our review.

If you wish to pursue this request, please submit a written response to the following issues, addressed to my attention as "additional information to control number 574738." Your response should be currently dated and signed by a senior management representative. These steps will help to ensure proper handling takes place in our office and we will then continue our review.

Dr. Martinez was not approved for the use of materials in 10 CFR 35.300 because his classroom and laboratory training had to be at least 200 hours in the topics specified in 10 CFR 35.390(b)(1)(i) and he only presented 170 hours.

In addition, NRC does not accept the specialty board certification in Diagnostic Radiology to demonstrate compliance with 10 CFR 35.390. Please see the attached listing of specialty board certifications that we do accept, from our website.

10 CFR 35.390(b)(1) requires 700 hours of training and experience. Dr. Martinez' forms 313a (AUT) did not specify the number of hours he spent obtaining training and experience because the section on his forms was left blank. Please see the enclosed "marked up" copy of his preceptor forms to see which areas were incomplete.

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E. Wroblewski

Dr. Martinez was not approved as an AU because we were unable to verify the qualifications of his preceptor, Dr. Michael Blend, Ph.D., D.O., because Dr. Blend references the license, under which training of Dr. Martinez took place, as the University of Illinois – Chicago (UIC).

This is an Agreement State license (that we do not have access to) that appears to be a broad scope license, i.e., it does not name AU's on its

license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

Please submit a complete, signed and dated copy of the most recent Agreement State License for UIC.

Please do not submit copies of minutes from the licensee's RSC meetings or other documents from the Agreement State licensee or extraneous documentation that we must protect, per 10 CFR 2.390.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response. Please note that consulting these references, understanding them and applying them to these requests should be very helpful in preparing an appropriate response.

A copy of the guidance for completion of forms NRC 313a is also enclosed, as it appears on our website and in NUREG 1556, Vol. 9, Rev. 2, Appendix D.

If Forms 313a will be used in support of your response, please use the forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

Please do not submit emails, resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"...(a) Information provided to the

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E. Wroblewski

Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

Please note that your letter dated March 21, 2011, did not specify which locations of use listed on the license should be authorized for the use of the SIR-spheres. Therefore I assumed that the locations of use that already had authorization for a therapy modality would be most appropriate. If my assumption is incorrect and any locations of use are authorized for the SIR-spheres that should not be, please contact me immediately at (630) 829-9841. In the future please be sure to include information about locations of use for each modality in amendment and other licensing requests.

In addition, your letter dated March 21, 2011, did not include a training commitment that is present in the 10 CFR 35.1000 guidance for yttrium-90 SIR-spheres on our website that is to be used when applying for this modality. Therefore I added a new Condition No. 19 in order to capture this training commitment and authorize the new modality at this time. If you wish to have this commitment deleted as a separate Condition, you may submit the commitment in a letter, direct us to delete the Condition and add the letter to Condition No. 20 instead.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

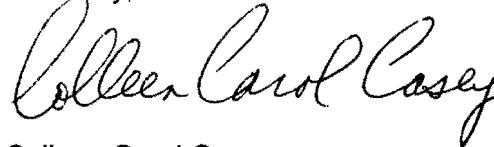
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

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E. Wroblewski

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-01333-02

Docket No. 030-01579

Enclosures:

1. Amendment No. 129
2. Specialty Board Certifications
Acceptable to NRC
3. Dr. Martinez' preceptor forms (marked up)
4. Guidance for completion of 313a forms

*Attachment 2*

Home > Nuclear Materials > Medical, Industrial, and Academic Uses of Nuclear Materials > Medical Uses > Licensee Toolkits > Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

This page includes links to files in non-HTML format. See Plugins, Viewers, and Other Tools for more information.

§35.50 Training for Radiation Safety Officer

American Board of Health Physics from January 1, 2005 to present.

American Board of Science in Nuclear Medicine from June 2006 forward for the Nuclear Medicine Physics and Instrumentation Specialty and the Radiation Protection Specialty .

American Board of Radiology (ABR) certification process from June 2007 forward for the Radiologic Physics - Medical Nuclear Physics and the Radiologic Physics - Diagnostic Radiologic Physics specialties for diplomates who have been issued certificates before and after that date with the words "RSO Eligible" appearing above the ABR seal."

American Board of Medical Physics certification process for special competence in Medical Health Physics for diplomats that have been issued certificates with the words "RSO Eligible" on the certificate.

§35.51 Training for an authorized medical physicist

American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiologic Physics - Therapeutic Radiologic Physics specialty for diplomates who have been issued certificates before and after that date with the words "AMP Eligible" appearing above the ABR seal."**

Canadian College of Physicists in Medicine (CCPM) certification process from January 2009 forward for the Radiation Oncology Physics specialty**

****Diplomates certified under 10 CFR 35.51 from June 2007 forward for the Therapeutic Radiologic Physics subspecialty of the ABR-Radiologic Physics specialty and from 2009 forward for the Radiation Oncology Physics specialty of the Canadian College of Physicists in Medicine also satisfy the certification portion of the regulatory requirements in 10 CFR 35.50(c) (1) for Radiation Safety Officer authorization.**

§35.55 Training for an authorized nuclear pharmacist

Board of Pharmaceutical Specialties certification process for Board Certified Nuclear Pharmacist (BCNP) from March 6, 1996 to present.

§35.190 Training for uptake, dilution, and excretion studies

American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number.

§35.290 Training for imaging and localization studies

Certification Board of Nuclear Cardiology certification process from October 29, 2000 to present physicians after this dates issued an CBNC certification before 2006 with the wording "for Physicians Residing in the United States" and on or after 2006 with the wording "for Physicians Trained in the United States" appearing in the certificate.

American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians issued an ABNM certification before and after these at dates with the word "United States" appearing under the certification number.

American Osteopathic Board of Radiology (AOBR) certification process from July 1, 2000 forward for the Diagnostic Radiology specialty.

American Osteopathic Board of Nuclear Medicine (AOBNM) certification process from May 18, 2006 forward for the Nuclear Medicine specialty.

American Board of Radiology (ABR) certification process from June 2006 forward for the Diagnostic Radiology certificates issued before and after that date with the words "AU eligible" appearing above the ABR seal.

§35.390 Training for use of unsealed byproduct material for which a written directive is required

American Board of Nuclear Medicine certification process from October 20, 2005 to 2007 and from 2007 to present for all physicians before and after these dates issued an ABNM certification with the word "United States" appearing under the certification number. *

American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal. *

American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty. *

*Diplomates of this specialty board also satisfy the training and experience requirements in 10 CFR 35.392 and 35.394.

§35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

American Osteopathic Board of Radiology (AOBR) certification process from July 1, 2000 forward for the Diagnostic Radiology specialty.

American Board of Radiology (ABR) certification process from June 2006 forward for the Diagnostic Radiology certificates issued before and after that date with the words "AU eligible" appearing above the ABR seal.

§35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

American Board of Radiology (ABR) certification process from June 2011 forward for the Diagnostic Radiology certificates with the words "AU eligible" appearing above the ABR seal.

§35.490 Training for use of manual brachytherapy sources

American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal.

American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty.

§35.590 Training for use of sealed sources for diagnosis

None

§35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiation Oncology specialty with the words "AU eligible" appearing above the ABR seal.

American Osteopathic Board of Radiology (AOBR) certification process from May 1, 2007 forward for the Radiation Oncology specialty.

Page Last Reviewed/Updated Thursday, March 31, 2011

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ATTACHMENT 3
ENCLOSURE "C"

NRC FORM 313A (AUT) (3-2008)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
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]		

Name of Proposed Authorized User <i>Brandon Martinez</i>	State or Territory Where Licensed <i>Indiana</i>
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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 *NRC DOES NOT ACCEPT DIAGNOSTIC RADIOLOGY CERTIFICATION FOR 35.390*

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 35.600

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 35.600 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.

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	University of Illinois Chicago Medical Center	50	07/2006 - 06/2010
Radiation protection	University of Illinois Chicago Medical Center	40	7/06 - 06/10
Mathematics pertaining to the use and measurement of radioactivity	University of Illinois Medical Center	20	07/06 - 06/10
Chemistry of byproduct material for medical use	University of Illinois Chicago	20	07/06 - 06/10
Radiation biology	University of Illinois Chicago	40	07/06 - 06/10
Total Hours of Training:		170	200 HOURS NEEDED

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:	THIS IS NEEDED - WAS LEFT BLANK	
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	IL - 01883-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/06 - 06/10	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	IL - 01883-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/06 - 06/10	
Calculating, measuring, and safely preparing patient or human research subject dosages	IL - 01883-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/06 - 06/10	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	IL - 01883-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/06 - 06/10	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	IL - 01883-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/06 - 06/10	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPT-JR 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

Michael Blend, Ph.D., D.O.

01883-01

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

- 35.390 With experience administering dosages of:
 - 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
 - 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
 - 35.396 Parenteral administration of 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)	7	01883-01	07/06-- 06/10
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	01883-01	07/06-- 06/10
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	380	01883-01	07/06 06/10
Parenteral administration of any other radionuclide for which a written directive is required Yttrium 90 (List radionuclides)	22	01883-01	07/06- 06/10

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 (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual Michael Blend Ph.D. D.O.	License/Permit Number listing supervising individual as an authorized user IL-01883-01
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply):	
<input checked="" type="checkbox"/> 35.300	With experience administering dosages of:
<input checked="" type="checkbox"/> 35.302	<input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1,22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.304	<input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1,22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.308	<input checked="" type="checkbox"/> Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input checked="" type="checkbox"/> 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 35.300:

Board Certification

I attest that Brandon Markins has satisfactorily completed the training and experience requirements in 35.300(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that Brandon Markins 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 35.300 (b)(1).
Name of Proposed Authorized User

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 Brandon Martinez 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 Brandon Martinez 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 312A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.390:

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 35.390 (d)(1), and the supervised work and clinical case experience required by 35.390(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 35.390(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.390 (d)(1) and the supervised work and clinical case experience required by 35.390(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 equivalent user for:

- 35.380 35.382 35.394 35.398

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 <i>Michael J. Blendon</i>	Signature <i>Michael J. Blendon</i>	Telephone Number <i>312-996-3970</i>	Date <i>3-1-0011</i>
License/Form Number/Facility Name <i>University of Illinois at Chicago IL-01883-01</i>			

THIS IS A BROAD SCOPE LICENSE IN AN AGREEMENT STATE.
 WE CANNOT VERIFY THIS PRECEPTOR BECAUSE WE DON'T HAVE
 ACCESS TO THE LICENSE, WHICH DOES NOT LIST A US ON LICENSE ITSELF.

TOTAL P.02



nordion
SCIENCE ADVANCING HEALTH

February 24, 2011

By E-mail

Ester Trinos
UIC Medical Center
1740 West Taylor Street
Chicago, IL 60612

Dear Ms. Trinos:

RE: TheraSphere, Y-90 Glass Microsphere Training

This letter confirms that Brandon Martinez, MD participated in a training program at Northwestern Memorial Hospital on the use of TheraSphere® Yttrium-90 Glass Microspheres for the treatment of hepatocellular carcinoma, which was presented by Nordion representatives on January 26, 2011.

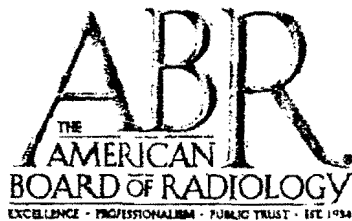
This vendor training program meets the requirements for training and experience specified in paragraph two of the Nuclear Regulatory Commission Guidance "Microsphere Brachytherapy Sources and Devices" revised September 2008.

Yours sincerely,

Jackie M. Groff
Global Brand Manager, TheraSphere
Nordion

JMG/al

cc: Mark Jordan, Clinical Account Manager



5441 E. Williams Boulevard, Suite 200 · Tucson, Arizona 85711-4493
Phone (520) 790-2900 · Fax (520) 790-3200 · www.theabr.org

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- M. Morin, Ph.D.
Florida

November 4, 2010

Brandon Keith Martinez, MD
833 W. 15th Pl Unit 501
Chicago, IL 60608

To whom it may concern:

This letter serves to verify the status of the below-listed individual.

60811 Brandon Keith Martinez, MD

DOB: 06/1976

Certified: Diagnostic Radiology, 2010
Maintenance of Certification: 2010 valid through 12/31/2020

Sincerely,

Gary J. Becker, MD

AS NOTED, THIS CERT. IS NOT
ACCEPTABLE FOR 35.300 USES
10CFR (35.390 TRAINING, ETC)

Gary J. Becker, M.D., Executive Director

Assistant Executive Directors: Primary Certification
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Radiologic Physics: Richard L. Morin, Ph.D.
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SCIENCE ADVANCING HEALTH

February 24, 2011

By E-mail

Ester Trinos
UIC Medical Center
1740 West Taylor Street
Chicago, IL. 60612

Dear Ms. Trinos:

RE: TheraSphere, Y-90 Glass Microsphere Training

This letter confirms that Brandon Martinez, MD participated in a training program at Northwestern Memorial Hospital on the use of TheraSphere®, Yttrium-90 Glass Microspheres for the treatment of hepatocellular carcinoma, which was presented by Nordion representatives on January 26, 2011.

This vendor training program meets the requirements for training and experience specified in paragraph two of the Nuclear Regulatory Commission Guidance "Microsphere Brachytherapy Sources and Devices" revised September 2008.

Yours sincerely,

Jackie M. Groff
Global Brand Manager, TheraSphere
Nordion

JMG/si

cc: Mark Jordan, Clinical Account Manager

Licensing Guidance for using the NRC FORM 313A Series of Forms
January 2008

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or Radiation Safety Officer (RSO) to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad-scope license, or Master Materials License medical broad-scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses.

In implementing the EPAct, the NRC "grandfathered" physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for medical or nuclear pharmacy uses, before or under the NRC waiver of August 31, 2005, when using these materials for the same uses. These individuals, as well as individuals that performed RSO duties only for uses of accelerator produced radionuclides or discrete sources of Ra-226 at medical or nuclear pharmacy facilities before or during the effective period of the waiver, do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, and G.

The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC FORM 313A (RSO) for the Radiation Safety Officer; NRC FORM 313A (AMP) for the authorized medical physicist; NRC FORM 313A (ANP) for the authorized nuclear pharmacist; NRC FORM 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, and/or 35.500; NRC FORM 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC FORM 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, or RSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a). Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H. Additional training may also need to be documented for RSOs, AMPs, and AUs under 10 CFR 35.600.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. In some cases there may be additional training and experience routes for recognized AUs, ANPs, AMPs, or RSOs to seek additional authorizations.

IV. Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience for physicians include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use,
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization,
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization, and
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). Also, if the applicant requests that a physician be authorized for both high dose-rate remote afterloading and gamma stereotactic radiosurgery under 10 CFR 35.600, only one form, NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following:

" _____ (name of supervising individual or preceptor) is authorized under _____ (name of licensee/permittee) broad-scope license number _____ to use _____ (materials) during _____ (time frame)."

INTRODUCTORY INFORMATION

Name of individual

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name.

Note: Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal telephone number) as part of your qualification documentation.

State or territory where licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of "physician", "dentist", "podiatrist", and "pharmacist" in 10 CFR 35.2).

Requested Authorization(s).

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by NRC (to confirm that NRC recognizes that board's certifications, see NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

Note: An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series.

All applicants under this pathway (except for 10 CFR 35.500 uses) must submit a completed Part II Preceptor Attestation.

Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series. (**Note:** This section does not include individuals who are authorized only on foreign licenses.)

All applicants under this pathway must submit a completed Part II Preceptor Attestation.

Item 3. Alternate Pathway for Training and Experience for Proposed New Authorized Individuals

This pathway is used for those individuals not listed on the license as authorized individuals, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (a) classroom and laboratory training, or (b) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the "classroom and laboratory training," provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed authorized individual may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical

teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the "supervised work experience" sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements to confirm that the listed subject areas were included in the supervised work experience.

The "supervised work experience" for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For nuclear pharmacists, under the "supervised practical experience" section, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

Note: If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Part II. Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. The preceptor language in NRC Forms 313A(AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual has the knowledge to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and a completed preceptor attestation). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in 3.c) and a completed preceptor attestation in Part II). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO. This is documented in Section 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Item 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on the Licensee's License

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's training or identification on the license as an AU, AMP, or ANP is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation for the individual's competency to function independently as an RSO for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed RSO must fill out all four sections.

The preceptor for an RSO seeking authorization to be recognized as an RSO for the additional medical use(s) must fill out the second, third, and fourth sections.

VII. AUTHORIZED MEDICAL PHYSICIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)

See Section V, "General Instructions and Guidance for Filling Out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of device-specific training in the table in 3.c, and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience, which cannot be concurrent. This is documented in Section 3.b by providing the ranges of dates for training and work experience.

If the proposed AMP had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an AMP, the applicant must provide documentation that the supervising individual meets the requirements in 10 CFR 35.51 and 10 CFR 35.59.

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the proposed AMP's training is in the first section.

The attestation for the device-specific training is in the second section.

The attestation of the individual's competency to function independently as an AMP for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new AMP must fill out all four sections of this page. The preceptor for an AMP seeking additional authorizations must complete the last three sections.

VIII. AUTHORIZED NUCLEAR PHARMACIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (ANP)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the two methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed Sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in Section 2.b.

Submit a completed Preceptor Attestation.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections. The preceptor must select either the board certification or the structured educational program when filling out the first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material, in addition to the preceptor's signature.

IX. 10 CFR 35.100, 35.200, AND 35.500 AUTHORIZED USERS – Specific Instructions and Guidance for Filling Out NRC Form 313A (AUD)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Current 35.390 Authorized User Seeking Additional 10 CFR 35.290 Authorization

- (a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.
- (b) Provide a description of the proposed user's experience that meets the requirements of 10 CFR 35.290(c)(1)(ii)(G) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

Note: Providing the training and experience information required under 10 CFR 35.290 will allow the individual to be authorized to use materials permitted by both 10 CFR 35.100 and 10 CFR 35.200.

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 10 CFR 35.500 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 10 CFR 35.500 uses.

Submit a completed Preceptor Attestation, except for 10 CFR 35.500 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The attestations for training and experience requirements in 10 CFR 35.190 and 10 CFR 35.290 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

The preceptor must fill out both sections.

Note: The attestation to the proposed user's training and competency to function independently under 10 CFR 35.190 covers the use of material permitted by 10 CFR 35.100 only. The attestation for the proposed user's training and competency to function independently under 10 CFR 35.290 will allow the individual to be authorized to use material permitted by both 10 CFR 35.100 and 10 CFR 35.200.

X. 35.300 AUTHORIZED USER - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUT)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

If the applicant is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.300 on NRC's Web site, provide the requested information

(i.e., a copy of the board certification, documentation of supervised clinical experience (complete the table in section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or supervised clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is a radiation oncologist whose board certification is not listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's Web site, documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 2. Current 10 CFR 35.300, 10 CFR 35.400, or 10 CFR 35.600 Authorized User Seeking Additional Authorization

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the applicant is currently authorized for a subset of clinical uses under 10 CFR 35.300, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meets the requirements in 10 CFR 35.396, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation)). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The attestations for training and experience requirements in 10 CFR 35.390, 10 CFR 35.392, and 10 CFR 35.394 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for competency to function independently as an AU for specific uses is in the third section.

The attestation for training and experience requirements and competency to function independently for a radiation oncologist meeting the requirements in 10 CFR 35.396 is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

There are seven possible categories of individuals seeking AU status under this form. Follow the instructions for the applicable category.

The preceptor for a proposed AU who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on NRC's Web site must complete the first, second, third, and fifth sections.

The preceptor for a proposed AU for all the uses listed in 10 CFR 35.390(b)(1)(ii)(G) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on NRC's Web site must complete the first, second, third, and fifth sections.

The preceptor for a proposed AU for 10 CFR 35.390(b)(1)(ii)(G)(iii) and (iv) uses who is a radiation oncologist with a board certification listed under 10 CFR 35.490 or 10 CFR 35.690 on NRC's Web site must complete the fourth and fifth sections.

The preceptor for an AU who is currently authorized for a subset of clinical uses under 10 CFR 35.300 must complete the second, third, and fifth sections of this part, except for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394.

The preceptor for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394 must complete the first, second, third, and fifth sections.

The preceptor for an AU currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meeting the requirements in 10 CFR 35.396 must complete the fourth, and fifth sections.

The preceptor for a proposed new AU must complete the first, second, third and fifth sections.

XI. 35.400 AND 35.600 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUS)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification) for 10 CFR 35.600 uses, documentation of device-specific training in the table in 3.e, and for all uses, a completed Preceptor Attestation. As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users, or either a supervising AU or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current 10 CFR 35.600 Authorized User Requesting Additional Authorization for 10 CFR 35.600 Use(s) Checked Above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.e)) and a completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience were completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 10 CFR 35.400 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.d for each requested 10 CFR 35.600 use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.e for each specific 10 CFR 35.600 device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The attestation to the training and individual's competency for 10 CFR 35.400 uses or strontium-90 eye applicator use is in the first section.

The attestation to the training for the proposed AU for 10 CFR 35.600 uses is in the second section.

The attestation for the 10 CFR 35.600 device-specific training is in the third section.

The attestation of the individual's competency to function independently as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

The preceptor for a 10 CFR 35.400 proposed AU must fill out the first and fifth sections.

The preceptor for a 10 CFAR 35.600 proposed AU must fill out the second, third, fourth and fifth sections.

The preceptor for an AU seeking additional 10 CFR 35.600 authorizations must complete the third, fourth, and fifth sections.