

TRANSMISSION VERIFICATION REPORT

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE April 24, 2014

NUMBER OF PAGES 14

SEND TO Jacqueline Katz, RT, MBA - Director of Medical Physics - St. Mary
Medical Center, NRC License 13-03459-03

LOCATION Hobart, Indiana

FAX NUMBER (219) 852-6487

VERIFY BY CALLING

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as
soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.



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soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank You.

The following additional information is needed to review your request to add Dr. Sorin Lazsar, M.D. as an authorized user for the materials in 35.200.

The information submitted with your NRC Form 313A (AUD) was incomplete for the board certification "pathway". We need the following information to complete our review of your request.

1. Fill in name of proposed authorized user (Dr. Sorin Lazar).
2. Specify that State or Territory where the proposed user is licensed to practice medicine.
3. **Provide a copy of the board certification.**
4. Part II- preceptor attestation
 - a. First Section
 - Fill in information under 35.290 - Board Certification - Check box for statement "I attest.....",
 - Fill in Dr. Sorin Lazar 's name.
 - b. Section Section
 - Complete information for Dr. R. Parker Ward.
 - Check box for statement, "I meet the requirements.....".
 - Check Box for 35.290.

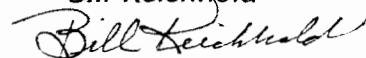
 - Fill in name of Preceptor
 - Have the Preceptor sign Part II
 - Fill in telephone number
 - Fill in date
 - Fill in License/Permit Number/ Facility Name as appropriate.

Please see attached. You may wish to resubmit a "clear" NRC Form 313A (AUD) form. Please see attached. You may also want to review the instructions for completing the NRC Form 313A (AUD). Please see attached. A complete set of instructions for completing the NRC 313 A Series of Forms may be found on the NRC website at: <http://www.nrc.gov/materials/miau/med-use-toolkit/licensing-guidance-form313a.pdf>.

Please send a facsimile (630- 515-1078) of your response to the above within 14 days and state, Response to Control 583609. Please include a cover letter on company letterhead, dated and signed (signed by an individual who is authorized to sign official documents on behalf of the licensee) with your response letter. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents 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).

From the desk of:
Bill Reichhold



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

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

FILL IN NAME

Specify State

NRC FORM 313A (AUD)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User

State or Territory Where Licensed

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device) _____

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

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

1. Board Certification

**SEND COPY OF BOARD
CERTIFICATION**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.

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

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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. (Not required to meet training requirements in 35.590)

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."

*Attachment
R. Parker
ward, MD*

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in _____
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and _____
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that _____ has satisfactorily completed the requirements in _____
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training _____
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature.

CHECK BOX

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

- 35.190
- 35.290
- 35.390
- 35.390 + generator experience

Name of Preceptor

Signature

Telephone Number

Date

License/Permit Number/Facility Name

CHECK BOX

CHECK BOX

FILL IN

Fill in name

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User

State or Territory Where Licensed

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device)

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

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

1. Board Certification

- a. Provide a copy of the board certification.
- b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

- a. Authorized user on Materials License meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			

Total Hours of Training:

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience

Total Hours of Experience:

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual _____ License/Permit Number listing supervising individual as an authorized user _____

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190
 35.290
 35.390
 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

