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REC R6 1 04 13 16 AM 06 57

March 18, 2016

Licensing Assistance team
Division of Nuclear Materials Safety
USNRC Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Re: #47-05322-02 103012570

To whom it may concern,

We would like to request that James Andrew Epling, M.D. be added as an authorized user of 10 CFR 35.300 materials on our license. He is currently on our license for 10CFR 35.100 and 35.200. His signed attestation from West Virginia University is dated March 10, 2011 however his case experience is beyond the seven year window. Therefore, we repeated his case experience for treatments ≤ 33 mci under preceptor, Dr. Gary Loh. Previous documentation from West Virginia University, the updated signed case log and documentation of Dr. Epling's qualifications are enclosed for your review.

Thank you for your attention in this matter.

Sincerely,

James Murdy
Wheeling Hospital
Chief Financial Officer

590677
NUCLEAR MATERIALS-002



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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 03/31/2016

Name of Proposed Authorized User

James Drew Epling, MD

State or Territory Where Licensed

West Virginia

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

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

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

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

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

1. Board Certification

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

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

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390 35.392 35.394 35.490 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:		<input type="text"/>	

b. Supervised Work Experience 35.390 35.392 35.394 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<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	
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	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience (continued)

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

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

- 35.390 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)	3	Wheeling Hospital 47-05322-02	2/2/2016 2/22/2016 3/11/2016
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 5px;"></div> <p style="text-align: center; font-size: small;">(List radionuclides)</p>			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Gary Loh, MD	47-05322-02

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.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.390:

Board Certification

I attest that James Drew Epling, MD has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
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 James Drew Epling, MD 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 James Drew Epling, MD 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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

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

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

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

OR

Board Certification:

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

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

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

Fifth Section

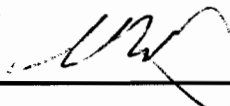
Complete the following for preceptor attestation and signature:

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

- 35.390 35.392 35.394 35.396

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor Gary Loh, MD	Signature 	Telephone Number (304) 243-3270	Date 3/29/16
License/Permit Number/Facility Name 47-05322-02			



American Board of Radiology — Program Director Attestation

COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

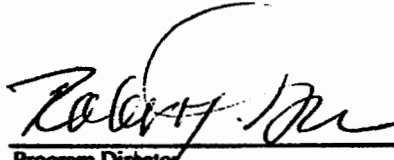
More information can be found at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html>

<u>James A. Epling</u> Resident Name	<u>West Virginia University</u> Program	<u>4205521208</u> Program #
-----------------------------------------	--------------------------------------------	--------------------------------

- | | YES | NO |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| By the time of the ABR oral examination, this applicant will have successfully completed the hours of training and experience as outlined in 10 CFR 35.290, 35.392, and 35.394..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ≤ 33mCi..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy >33 mCi..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The resident's log of these therapy experiences (date, dose, and preceptor attestation) is attached..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The work experience cited above for § 35.290 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The work experience cited above for § 35.392 was obtained under the supervision of an Authorized User (AU) who meets the requirements under § 35.390, 35.392 or 35.394 or equivalent Agreement State requirements..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The work experience cited above for § 35.394 was obtained under the supervision of an Authorized User (AU) who meets the requirements under § 35.390 or 35.394 or equivalent Agreement State requirements..... | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Robert J. Tallaksen
Residency Program Director
(Print Name)


Program Director
(Signature)

3/10/11
Date

Form B

I-131 Therapy Experience Log

James A. Epling
Resident Name

4205521208
Program & Number

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
$\leq 33\text{mCi}$		
1. <u>7/6/07</u>	<u>15.4 mCi</u>	<u>Kenneth Veselicky</u> Print Name <u>[Signature]</u> Sign Name
2. <u>7/9/07</u>	<u>15.0 mCi</u>	<u>Gary Marano</u> Print Name <u>[Signature]</u> Sign Name
3. <u>7/12/07</u>	<u>20.0 mCi</u>	<u>Gary D. Marano</u> Print Name <u>[Signature]</u> Sign Name

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
$>33\text{mCi}$		
1. <u>7/11/07</u>	<u>100.0 mCi</u>	<u>Gary D. Marano</u> Print Name <u>[Signature]</u> Sign Name
2. <u>2/4/09</u>	<u>60.5 mCi</u>	<u>Kenneth Veselicky</u> Print Name <u>[Signature]</u> Sign Name
3. <u>2/4/09</u>	<u>100.0 mCi</u>	<u>Kenneth Veselicky</u> Print Name <u>[Signature]</u> Sign Name



I131 Therapy Experience Log

James A. Epling, M.D.
Radiologist

Gary Loh, M.D.
Preceptor

Date
≤33mci

Dose Administered

Preceptor Print & Sign Name

1. 2/2/16

10 mCi I-131

Gary Loh
Print Name

MRN: 374146

[Signature]
Sign Name

2. 2/22/16

12 mCi I-131

Gary Loh
Print Name

MRN: 392410

[Signature]
Sign Name

3. 3/11/16

15 mCi I-131

Gary Loh
Print Name

MRN: 000447353

[Signature]
Sign Name

This is to acknowledge the receipt of your letter/application dated

03/18/2016, and to inform you that the initial processing which includes an administrative review has been performed.

There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 590677.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader.