



**Charleston Area
Medical Center**

REC'D 10224*15 AM 10:18

NUCLEAR PHARMACY
3200 MacCorkle Ave. SE
Charleston, WV 25304
(304) 388-9295
Pharmacy (304) 388-9701
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2/16/2016

Br. 1

U.S. NRC Region I DNMS
2100 Renaissance Blvd.
King of Prussia, PA 19406

Re: Amendment request License #47-15473-01

03009164

Dear Sirs,

Please amend the above referenced license as follows:

1. Please add Matthew W. Morris, M.D. to the above referenced license as an authorized user for 35.100 and 35.200 material. Please also add Dr. Morris as an authorized user for 35.300 material restricted to the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq and quantities greater than 1.22 GBq as defined under 35.392 and 35.394. Please find enclosed:

- Completed NRC Form 313A (AUD) dated 2/1/2016
- Completed NRC Form 313A (AUT) dated 1/28/2016
- Copy of ABR certificate

If there are any questions regarding this amendment please feel free to contact me at the telephone numbers provided below or you may e-mail your questions to me at kim.lowe@camc.org.

Sincerely,

*Kim Lowe, Pharm.D., BCNP, Assistant RSO
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304
(304) 388-9295 office
(304) 549-0147 mobile*

*Christine Oskin, MBA, RT
Corporate Director
Medical Imaging Services
Charleston Area Medical Center
3200 MacCorkle Avenue, SE
Charleston, WV 25304*



**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: (01/31/2016)

Name of Proposed Authorized User Matthew Morris, M.D.	State or Territory Where Licensed Florida
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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.

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."

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that Matthew Morris, M.D. 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 Matthew Morris, M.D. 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

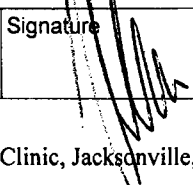
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

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
Jeffrey J. Peterson, M.D.		(904) 953-0143	02/01/2016
License/Permit Number/Facility Name			
State of Florida License No. 1812-3; Mayo Clinic, Jacksonville, FL 32224			



4500 San Pablo Road
Jacksonville, Florida 32224
904-953-2000
mayoclinic.org

RE: Jeffrey J. Peterson, M.D. as preceptor on NRC Form 313A

This letter is to attest that Jeffrey J. Peterson, M.D. is an Authorized User (AU) of radioactive materials in the healing arts under Mayo Clinic's broad scope medical license (State of Florida License No. 1812-3). He is approved for the following uses:

Florida regulation	Equivalent NRC regulation
64E-5.626	10 CFR 35.100
64E-5.627	10 CFR 35.200
64E-5.630 (2)	10 CFR 35.392

Glenn M. Sturchio, PhD, CHP
Radiation Safety Officer





**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: (01/31/2016)

Name of Proposed Authorized User Matthew Morris, M.D.	State or Territory Where Licensed Florida
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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

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
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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)	4 cases	Mayo Clinic Jacksonville, FL	02/23/2011 02/28/2011, 08/22/2011, and 08/31/2011
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3 cases	Mayo Clinic Jacksonville, FL	07/11/2012, 07/24/2012, and 08/23/2012
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; width: 150px; height: 30px; margin: 5px 0;"></div> (List radionuclides)			

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
Manoj K. Jain, M.D.	Florida State License No. 1812-3

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 _____ 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 Matthew Morris, M.D. 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 Matthew Morris, M.D. 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 Matthew Morris, M.D. 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 Matthew Morris, M.D. 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

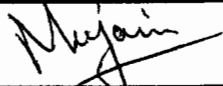
Complete the following for preceptor attestation and signature:

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 Manoj K. Jain, M.D.	Signature 	Telephone Number (904) 953-6693	Date 01/28/2016
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License/Permit Number/Facility Name
Florida State License No. 1812-3, Mayo Clinic



4500 San Pablo Road
Jacksonville, Florida 32224
904-953-2000
mayoclinic.org

RE: Manoj K. Jain, M.D. as preceptor on NRC Form 313A

This letter is to attest that Manoj K. Jain, M.D. is an Authorized User (AU) of radioactive materials in the healing arts under Mayo Clinic's broad scope medical license (State of Florida License No. 1812-3). He is approved for the following uses:

Florida regulation	Equivalent NRC regulation
64E-5.626	10 CFR 35.100
64E-5.627	10 CFR 35.200
64E-5.630 (2)	10 CFR 35.392
64E-5.630 (3)	10 CFR 35.394

Glenn M. Sturchio, PhD, CHP
Radiation Safety Officer



The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of University Radiologists,
the American Association of Physicists in Medicine, and the Society of Interventional Radiology,
the American Board of Radiology hereby certifies that

Matthew W. Morris, MD

Has pursued an accepted course of graduate study and clinical work; has met certain standards
and qualifications, including passing the examinations conducted under the authority of
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification
to practice; and is therefore awarded the Board's certification in

Diagnostic Radiology

All Eligible



Certificate No. 65618

Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification.

This diplomate of the American Board of Radiology
is permitted to use the **ABR** mark to signify this certification.

Milton J. Dubeck, MD
President

[Signature]
Secretary-Treasurer

[Signature]
Executive Director



Effective: October 02, 2015

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

2/16/2016, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-15473-01)
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 590338.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.