

March 28, 2016

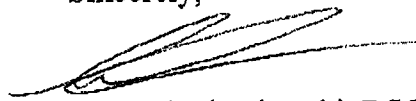
U.S Nuclear Regulatory Commission
Materials Licensing Section
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

Nuclear Regulatory Commission,

Please amend byproducts materials license No. 21-17754-01 by adding Dr. Ajay Puri as an authorized user for 35.100 and 35.200. Included are preceptor attestation and a copy of board certification. I have also included a copy of the ABR form to document his 35.300 training and experience, if this is sufficient I would also like to add Dr. Puri as an authorized user for 35.300 also.

If there are any questions please call our medical physicist: Ray Carlson, M.S. at (734) 455-4730 office/ (734) 395-7361(cell) or I can be reached at (989)356-7758.

Sincerely,



Marty Andrzejewski, RSO.

RECEIVED APR 08 2016

| | | |
|----------------------------------|---|---|
| NRC FORM 313A (AUD) (03-2016) | 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: 03/31/2016 |
|----------------------------------|---|---|

| | |
|---|---|
| Name of Proposed Authorized User Dr. Ajay Puri | State or Territory Where Licensed Michigan |
|---|---|

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)

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(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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 | |

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(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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.

NRC FORM 313A (AUD)
(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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 Dr. Ajay Puri 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 Dr. Ajay Puri 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

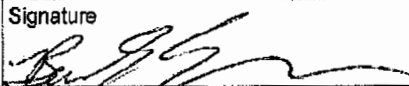
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 |
| Dr. Ben Eggeston |  | (989) 356-7572 | 03/24/2016 |
| License/Permit Number/Facility Name | | | |
| Alpena Regional Medical Center 21-17754-01 | | | |

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*

Ajay Puri, MBBS

*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

AB Eligible

*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.*



James P. Boyette, MD
President

[Signature]
Secretary-Treasurer

[Signature]
Executive Director

ABR

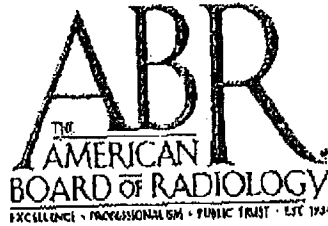


Certificate No. 63590

Effective: October 28, 2013

U3590

Form A



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>

Aray Puri
Resident Name

Baystate Med. Ctr 4202412088
Program 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"/> |

Tara M. Catanzano, MD
Residency Program Director
(Print Name)

Tara M. Catanzano, MD
Program Director
(Signature)

4/26/13
Date

Form B

I-131 Therapy Experience Log

AJAY PURI
Resident Name

Program & Number

Date Dose Administered
≤ 33mCi
1. 4/24/2012 15 mCi

Preceptor (AU) Print & Sign Name
L. O. ARWELL

Print Name
[Signature]

Sign Name

2. 4/20/2012 12.1 mCi

James Polga

Print Name
James Polga MD

Sign Name

3. 4/2/2013 20.6 mCi

PETER BURR

Print Name
[Signature]

Sign Name

Date Dose Administered
> 33 mCi
1. 4/25/2012 78 mCi

Preceptor (AU) Print & Sign Name
L. VAN DER BRUG

Print Name
[Signature]

Sign Name

2. 6/1/2012 100.3 mCi

KAMAL SHARMA

Print Name
[Signature]

Sign Name

3. 4/11/2011 101.6 mCi

JAMES POLGA MD

Print Name
James Polga MD

Sign Name

Fax



ALPENA REGIONAL MEDICAL CENTER

1501 West Chisholm Street, Alpena, MI 49707

To: NRC
 Fax: 6305151078
 Phone:
 Email:

From: Martin Andrzejewski
 Nuclear Medicine/PET
 Fax: 989-356-7551
 Phone: 989-356-7570
 Email: mandrzej@agh.org

RE: License Amendment

Pages: 9 (including cover page)

Date: 03/28/2016 Mon

NOTE:

Att. Material Licensing Branch

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