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.

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	State or Territory Where Licensed
Dr. Ajay Puri	Michigan

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

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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.

- [x] **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 32.280(c)(1)(ii)(G)

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(03-2016)

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 *(not required for 35.590)*			
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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

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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		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ 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.

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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 (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the 60 hours of training and 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 (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training 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 Eggelston		(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

All Eligible

THE AMERICAN BOARD OF RADIOLOGY INCORPORATED IN THE DISTRICT OF COLUMBIA 1934

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 DABR *mark to signify this certification.*

DABR

AMERICAN BOARD 1933 OF MEDICAL SPECIALTIES EXCELLENCE OPTIMUS

James P. Borgstede, M.D.
President

Secretary-Treasurer

Executive Director

Certificate No. 63590

Effective: October 28, 2013

03590

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

Ajay Puri
Resident Name

Baystate Med. Ctr
Program

4202412088
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.....	☑	☐
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ≤ 33mCi.....	☑	☐
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy >33 mCi.....	☑	☐
The resident's log of these therapy experiences (date, dose, and preceptor attestation) is attached.....	☑	☐
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.....	☑	☐
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.....	☑	☐
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.....	☑	☐

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

Program Director
(Signature)

4/26/13
Date

Form B

I-131 Therapy Experience Log

AJAY PURI
Resident Name

Program & Number

Date	Dose Administered	Preceptor (AU) Print & Sign Name
≤33mCi		
1. 4/24/2012	15mCi	Print Name: I QAMAR Sign Name
2. 4/20/2012	12.1mCi	Print Name: James Polga Sign Name: James Polga MD
3. 4/2/2013	20.6mCi	Print Name: PETER BYRAN Sign Name

Date	Dose Administered	Preceptor (AU) Print & Sign Name
>33 mCi		
1. 4/25/2012	78.4mCi	Print Name: [illegible] Sign Name
2. 6/1/2012	100.3 mCi	Print Name: KAMAL SHAMOO Sign Name
3. 4/11/2011	101.6mCi	Print Name: JAMES POLGA MD Sign Name: James Polga MD

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