



May 12, 2011

U.S. Nuclear Regulatory Commission
Region III
2443 Warranville Road, Ste 210
Lisle, IL 60532-4352

Re: NRC License 13-188879-01

Dear Sir/Madam:

We would like to amend our NRC License No. 13-18879-01 to include the following physicians as authorized users:

Michael W. Dye Jr., M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here the preceptor form for Dr. Dye.

Sridevi Sompalli, M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here Dr. Sompalli's ABR Certification in Diagnostic Radiology and record of his training and experience.

Thomas Kang Rhee, M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here Dr. Rhee's ABR Certification in Diagnostic Radiology and record of his training and experience.

Luisito Gonzales, M.D. and Wai Hung Lee, M.D. as authorized users for 10 CFR 35.200. Both physicians are currently authorized for the same under NRC License No. 13-32515-01 (copy attached).

We would also request to remove Janaki Moni, M.D. from our users' list.

If you have any question please contact me at (574) 523-7857.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Steven Leung'.

S. Steven Leung, Ph.D.
Radiation Safety Officer

FORM RM-HU(AUD) Alabama Department of Public Health - Radiation Control																					
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 420-3-26-.07(45), (48) and 70)																					
Name of Proposed Authorized User Michael W. Dye Jr., M.D.	Name of Licensee Where Physician Wishes to be Approved																				
Requested Authorization(s) (check all that apply) <input checked="" type="checkbox"/> 420-3-26-.07(45) Uptake, dilution, and excretion studies <input checked="" type="checkbox"/> 420-3-26-.07(48) Imaging and localization studies <input type="checkbox"/> 420-3-26-.07(70) 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. <input type="checkbox"/> 1. Board Certification a. Provide a copy of the board certification. b. If using only .07(70) materials, stop here. If using .07(45) and/or .07(48) materials, skip to and complete Part II Preceptor Attestation. <input type="checkbox"/> 2. Current .07(56) Authorized User Seeking Additional .07(51) Authorization a. Authorized user on Materials License _____ meeting .07(56) or equivalent NRC or Agreement State requirements seeking authorization for .07(51). b. Supervised Work Experience. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)																					
<table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="width: 35%;">Description of Experience</th><th style="width: 35%;">Location of Experience/License or Permit Number of Facility</th><th style="width: 15%;">Clock Hours</th><th style="width: 15%;">Dates of Experience*</th></tr></thead><tbody><tr><td style="padding: 5px;">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</td><td></td><td></td><td></td></tr><tr><td colspan="4" style="padding: 5px;">Total Hours of Experience:</td></tr><tr><td colspan="2" style="padding: 5px;">Supervising Individual</td><td colspan="2" style="padding: 5px;">License/Permit Number listing supervising individual as an authorized user</td></tr><tr><td colspan="4" style="padding: 10px;">Supervisor meets the requirements below (or equivalent from NRC or Agreement State). [check all that apply] <input type="checkbox"/> .07(51) <input type="checkbox"/> .07(55) + generator experience in .07(51)(c)1.(ii)(VII)</td></tr></tbody></table>		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 from NRC or Agreement State). [check all that apply] <input type="checkbox"/> .07(51) <input type="checkbox"/> .07(55) + generator experience in .07(51)(c)1.(ii)(VII)			
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 from NRC or Agreement State). [check all that apply] <input type="checkbox"/> .07(51) <input type="checkbox"/> .07(55) + generator experience in .07(51)(c)1.(ii)(VII)																					

FORM RM-HU(AUD)

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	University of South Alabama Medical Center & University of South Alabama College of Medicine	66	July 2006 to June 2010
Radiation protection	University of South Alabama Medical Center & University of South Alabama College of Medicine	42	July 2006 to June 2010
Mathematics pertaining to the use and measurement of radioactivity	University of South Alabama Medical Center & University of South Alabama College of Medicine	24	July 2006 to June 2010
Chemistry of byproduct material for medical use (not required for .07(70))	University of South Alabama Medical Center & University of South Alabama College of Medicine	77	July 2006 to June 2010
Radiation biology	University of South Alabama Medical Center & University of South Alabama College of Medicine	62	July 2006 to June 2010
Total Hours of Training:		271	

b. Supervised Work Experience (completion of this table is not required for .07(70)).
 (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*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
Calculating, measuring, and safely preparing patient or human research subject dosages	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010

FORM RM-HU(AUD)

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience ^a
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	500	July 2006 to June 2010
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
Administering dosages of radioactive drugs to patients or human research subjects	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
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	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010

Total Hours of Experience: 506

Supervising Individual

Shikha Khullar, MD, MPH

License/Permit Number listing supervising individual as an authorized user

AL Radioactive Materials license #584**University of South Alabama College of Medicine**

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

☒ .07(47)☒ .07(51)☒ .07(56)☒ .07(56) + generator experience in .07(51)(c)1.(B)(VII)**c. For .07(71) only, provide documentation of training on use of the device.**

Device	Type of Training	Location and Dates

c. For .07(70) uses only, stop here. For .07(45) and .07(48) uses, skip to and complete Part II Preceptor Attestation.

FORM RM-HU(AUD)

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 may have been the supervising individual, or may have provided, directed, or verified all 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 .07(71))

First Section

Check one of the following for each use requested:

For .07(47)

Board Certification

☒ I attest that Michael W. Dye Jr., M.D. has satisfactorily completed the requirements in

Name of Proposed Authorized User

420-3-26-.07(47)(a)1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(45).

OR

Training and Experience

☒ I attest that Michael W. Dye Jr., M.D. 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 .07(47)(c)1. and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under .07(45).

For .07(51)

Board Certification

☒ I attest that Michael W. Dye Jr., M.D. has satisfactorily completed the requirements in

Name of Proposed Authorized User

420-3-26-.07(51)(a)1. and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under .07(45) and (48).

OR

Training and Experience

☒ I attest that Michael W. Dye Jr., M.D. 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 .07(51)(c)1., and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under .07(45) and (48).

Second Section

Complete the following for preceptor attestation and signature:

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

☒ .07(47) ☒ .07(51) ☒ .07(56) ☒ .07(56) - generator experience

Name of Preceptor

Shikha Khullar, MD, MPH

Signature



Telephone Number

(251) 471-7128

Date

1-05-2010

License/Permit Number/Facility Name

University of South Alabama Radioactive Materials License No. 584

FORM RM-HU(AUT)

Alabama Department of Public Health - Radiation Control

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 420-3-26-.07(52))
[420-3-26-.07(56), (57), (58) and (59)]

Name of Proposed Authorized User

Michael W. Dye Jr., M.D.

Name of Licensee Where Physician Wishes to be Approved

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

☐ .07(52) Use of unsealed byproduct material for which a written directive is required

OR

☒ .07(52) Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)☒ .07(52) Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)☐ .07(52) 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☐ .07(52) 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**

- Provide a copy of the board certification.
- For .07(56), provide documentation of supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- For .07(59), provide documentation of 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.
- Skip to and complete Part II Preceptor Attestation.

☐ **2. Current .07(52), .07(60), or .07(72) Authorized Users Seeking Additional Authorization**

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

☐ .07(56) ☐ .07(57) ☐ .07(58) ☐ .07(68) ☐ .07(89)

- If currently authorized for a subset of clinical uses under .07(52), 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.
- If currently authorized under .07(68) or .07(89) and requesting authorization for .07(59), 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.

New or first-time Authorized Users must complete sections 3.a., b. and c. and Part II, Preceptor Attestation

FORM RM-HU(AUT)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☒ 3. Training and Experience for Proposed Authorized Usera. Classroom and Laboratory Training ☐ .07(56) ☐ 07(57) ☒ 07(58) ☐ .07(59)

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of South Alabama Medical Center University of South Alabama College of Medicine	66	July 2006 to June 2010
Radiation protection	University of South Alabama Medical Center University of South Alabama College of Medicine	42	July 2006 to June 2010
Mathematics pertaining to the use and measurement of radioactivity	University of South Alabama Medical Center University of South Alabama College of Medicine	24	July 2006 to June 2010
Chemistry of byproduct material for medical use	University of South Alabama Medical Center University of South Alabama College of Medicine	77	July 2006 to June 2010
Radiation biology	University of South Alabama Medical Center University of South Alabama College of Medicine	62	July 2006 to June 2010
Total Hours of Classroom and Laboratory Training:		<u>271</u>	

b. Supervised Work Experience ☐ .07(56) ☐ .07(57) ☒ 07(58) ☐ .07(59)

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

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of South Alabama Medical Center Alabama Radioactive Materials License # 584	1	July 2006 to June 2010
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of South Alabama Medical Center Alabama Radioactive Materials License # 584	1	July 2006 to June 2010
Calculating, measuring, and safely preparing patient or human research subject dosages	University of South Alabama Medical Center Alabama Radioactive Materials License # 584	1	July 2006 to June 2010
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of South Alabama Medical Center Alabama Radioactive Materials License # 584	1	July 2006 to June 2010
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of South Alabama Medical Center Alabama Radioactive Materials License # 584	1	July 2006 to June 2010
Total Hours of Supervised Work Experience:		<u>5</u>	

FORM RM-HU(AUT)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

a. Supervised Work Experience (continued)

Supervising Individual

Shikha Khullar, MD, MPH

License/Permit Name and Number listing supervising individual as an authorized user

University of South Alabama / Alabama

Radioactive Materials License No. 584

Supervisor meets the requirements below (or equivalent from NRC or Agreement State). [check all that apply]:

- ☒ .07(56) With experience administering dosages of:
- ☒ .07(57) ☒ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ .07(58) ☒ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☒ .07(59) ☒ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive
- ☒ 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)	10	University of South Alabama Medical Center Alabama Radioactive Materials License No. 584	July 2006 to June 2010
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	7	University of South Alabama Medical Center Alabama Radioactive Materials License No. 584	July 2006 to June 2010
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	NONE		
Parenteral administration of any other radionuclide for which a written directive is required	NONE		
(List radionuclides)			

FORM RM-HU(AUT)

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

Shikha Khullar, MD, MPH

License/Permit Number listing supervising individual as an authorized user

University of South Alabama Radioactive Materials License No. 584

Supervisor meets the requirements below (or equivalent from NRC or Agreement State). [check all that apply]**:

- ☒ .07(56) With experience administering dosages of:
- ☒ .07(57) ☒ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ .07(58) ☒ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☒ .07(59) ☒ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive
- ☒ 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.

First Section

Check one of the following for each requested authorization:

For .07(56):Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience requirements in 420-3-26-.07(56)(a)1.

Name of Proposed Authorized User

ORTraining 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 429-3-26-.07(56)(b)1

Name of Proposed Authorized User

FORM RM-HU(AUT)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For .07(57) (Identical Attestation Statement Regardless of Training and Experience Pathway):

☒ I attest that Michael W. Dye Jr., M.D. has satisfactorily completed the 80 hours of classroom:
Name of Proposed Authorized User

and laboratory training, as required by 420-3-26-.07(57)(c)1., and the supervised work and clinical case experience required in 420-3-26-.07(57)(c)2.

For .07(58) (Identical Attestation Statement Regardless of Training and Experience Pathway):

☒ I attest that Michael W. Dye Jr., M.D. has satisfactorily completed the 80 hours of classroom:
Name of Proposed Authorized User

and laboratory training, as required by 420-3-26-.07(58)(c)1.. and the supervised work and clinical case experience required in 420-3-26-.07(58)(c)2.

Second Section

☒ I attest that Michael W. Dye Jr., M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 420-3-26-.07(57)(b)1.(ii)(VII) 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 Michael W. Dye Jr., 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

FORM RM-HU(AUT)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**Fourth Section**For .07(59):Current .07(68) or .07(89) authorized user:☐ I attest that _____ is an authorized user under 420-3-26-.07(68) or (89) orName of Proposed Authorized User

equivalent NRC or Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 420-3-26-.07(59)(d)1., and the supervised work and clinical case experience required by 420-3-26-.07(59)(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

ORBoard Certification:☐ I attest that _____ has satisfactorily completed the board certificationName of Proposed Authorized User

requirements of 420-3-26-.07(59)(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 420-3-26-.07(59)(d)1., and the supervised work and clinical case experience required by 420-3-26-.07(59)(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:

☒ .07(56) ☒ .07(57) ☒ .07(58) ☒ .07(59)

☒ 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)

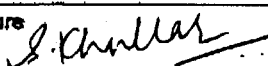
☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor

Shikha Khullar, MD, MPH

Signature



Telephone Number

(251) 471-7128

Date

1-05-2010

License/Permit Number/Facility Name

University of South Alabama / Alabama Radioactive Materials License No. 584

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>

Michael W. Dye Sr., MD U. of South Alabama 420-01-11-008
Resident Name 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 and 35.392.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ($\leq 33\text{mCi}$).....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The work and 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 and 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"/>

Jeffrey C. Brandon, MD
Residency Program Director
(Print Name)

[Signature]
Program Director
(Signature)

1/5/10
Date

Form B

I-131 Therapy Experience

Michael W Dye Sr MD
Resident Name

U. of South Alabama
420-01-11-008
Program & Number

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
1. <u>3/12/09</u>	<u>33.5mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
2. <u>8/11/09</u>	<u>15.1mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
3. <u>9/8/09</u>	<u>98.6mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
4. <u>9/10/09</u>	<u>34.1mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name

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>

Michael W. Dye Sr, MD U. of South Alabama 420-01-11-008
Resident Name 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 and 35.392.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ($\leq 33\text{mCi}$).....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The work and 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 and 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"/>

Jeffrey C. Brandon, MD [Signature]
Residency Program Director Program Director
(Print Name) (Signature)

1/5/10
Date

Form B

I-131 Therapy Experience

Michael W Dye Jr MD
Resident Name

U. of South Alabama
420-01-11-008
Program & Number

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
1. <u>3/12/09</u>	<u>33.5mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
2. <u>8/11/09</u>	<u>15.1mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
3. <u>9/8/09</u>	<u>98.6mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name
4. <u>9/10/09</u>	<u>34.1mCi I-131</u>	<u>Shikha Khullar, MD</u> Print Name <u>S. Khullar</u> Sign Name

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, and the American Association of Physicists in Medicine*
Hereby certifies that


Sridevi Sompalli, 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 that she is qualified to practice,
and is therefore awarded the Board's certification in the specialty of*

All Eligible

Diagnostic Radiology

Effective June 30, 2010


Sam J. Harty
President

Richard L. Morin
Secretary-Treasurer

Harold P. ...
Executive Director

Certificate No. 59048

Valid through 2020

Jan-20-2010 02:03pm From-RADIOLOGY, ADMINISTRATION

T-153 P.002/003 F-219

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>SRIDEVI SAMPALLI
Resident NameStanger Hospital of Cook County 14-01-03-2
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 and 35.392.....

☒ ☐This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ($\leq 33\text{mCi}$).....☒ ☐

The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....

☒ ☐

The work and 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 and 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.....

☒ ☐Patrice Dume
Residency Program Director
(Print Name)Patrice Dume
Program Director
(Signature)1/7/10
Date

Jan-20-2010 02:03pm From-RADIOLOGY, ADMINISTRATION

T-153 P.003/003 F-219

Form B

I-131 Therapy Experience

SRIDEVI SOMPALLI
Resident Name

Stroger Hospital of Cook County

14-01-03-2

Program & Number

	<u>Date</u>	<u>Dose Administered</u>
1.	<u>2/4/09</u>	<u>29.9 mCi</u>
2.	<u>2/11/09</u>	<u>19.8 mCi</u>
3.	<u>6/17/09</u>	<u>27.3 mCi</u>
4.	<u>6/24/09</u>	<u>15.0 mCi</u>

Preceptor (AU) Print & Sign Name

Donald Topaschki
Print Name
[Signature]
Sign Name

Donald Topaschki
Print Name
[Signature]
Sign Name

Donald Topaschki
Print Name
[Signature]
Sign Name

Donald Topaschki
Print Name
[Signature]
Sign Name

Pg: 2/6
05-05-11 07:35a
RADIOLOGY INC.
fax sent by : 5742581101

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, and the American Association of Physicists in Medicine
Hereby certifies that

Thomas Kang Rhee, 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 that he is qualified to practice,
and is therefore awarded the Board's certification in the specialty of

Diagnostic Radiology

Effective June 30, 2010

AM College
JUN 30 2010
JUN 30 2010

Sam J. Harris
President

Richard T. Morin
Secretary-Treasurer

Harvey R. ...
Executive Director

Certification # 60328

Valid through 2020

NRC FORM 313A (AUD) (3-2009)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012	
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]					
Name of Proposed Authorized User THOMAS KINGS RHEE			State or Territory Where Licensed INDIANA		
Requested Authorization(s) (check all that apply)					
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies					
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies					
<input type="checkbox"/> 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.					
<input checked="" type="checkbox"/> 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.					
<input type="checkbox"/> 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).					
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 • generator experience in 32.290(c)(1)(ii)(G)					

NRC FORM 313A (AUD)
(3-2009)

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 Thomas Rhee 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 Thomas Rhee 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

William Spies, MD

[Signature]

312-926-0422

4/28/11

License/Permit Number/Facility Name

Northwestern Memorial Hospital, Chicago, IL.

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>Thomas Rhee
Resident NameNorthwestern 0401062
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 and 35.392.....

☒ ☐This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ($\leq 33\text{mCi}$).....☒ ☐

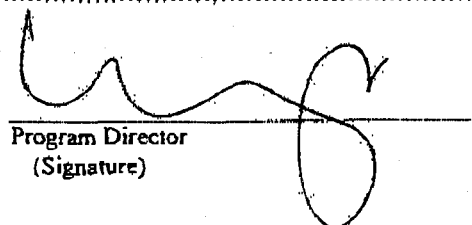
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....

☒ ☐

The work and 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 and 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.....

☒ ☐Robert Ryu, MD
Residency Program Director
(Print Name)
Program Director
(Signature)2/22/10
Date

M Northwestern Memorial® Hospital

May 9, 2011

To whom it may concern,

This letter confirms that under Northwestern Memorial Hospital's Radioactive Material License granted by the State of Illinois (IL-01037-02) that **Dr. William G. Spies, MD** is an authorized user of radioactive material as approved by the Radiation Safety Committee.

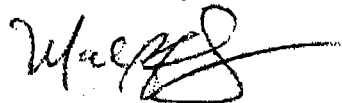
Dr. William G. Spies is authorized for any radiopharmaceutical indentified in 32 Illinois Administrative Codes: 335.3010, 335.4010, 335.5010, and 335. 6010 for diagnostic, therapeutic and research purposes.

Dr. Spies has been an authorized user at Northwestern Memorial Hospital for the past 20 years. Dr. Spies recently received renewal as an authorized user by the RSC for a two-year period extension on April 29th, 2011.

This institution is granted a radioactive material license under the state of Illinois through the agreement compact with the Nuclear Regulatory Commission (NRC). The hospital is not governed directly through the NRC, but through the Illinois Emergency Management Agency (IEMA).

Any questions please feel free to contact me directly.

Respectfully,



Mark D. Pflug, M.S., RRPT, CMLSO, AARST

Radiation Safety Officer / Laser Safety Officer

Radiation Safety Program Manager

Radiation Safety Department

710 North Fairbanks Court, 7th floor, Suite 428 Chicago, IL 60611-3013

(312) 926-8553 • Pager (312) 716-3551 • Fax (312) 926-2294

mpflug@nmh.org

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Elkhart Clinic</p> <p>2. 303 South Nappanee Street Elkhart, IN 46514</p>	<p>In accordance with application dated January 20, 2010,</p> <p>3. License number 13-32515-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date June 30, 2014</p> <p>5. Docket No. 030-36581 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p>
<p>9. Authorized use:</p> <p>A. Any imaging and localization study permitted by 10 CFR 35.200.</p>		

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 303 South Nappanee Street, Elkhart, Indiana.
11. The Radiation Safety Officer for this license is **Luisito Gonzales, M.D.**
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:**
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-------------------------|-------------------------|
| Luisito Gonzales, M.D. | 10 CFR 35.200. |
| Wai Hung Lee, M.D. | 10 CFR 35.200. |
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

S. LEUNG / ROC
Elkhart General Hospital
Elkhart, IN 46514

FIRST-CLASS



US POSTAGE \$01.68⁰



MAY 19 2011
ZIP 46601
0801 1052783

U. S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

