Lutheran
Health Network
Lutheran Hospital

December 10, 2021

U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

IOM Health System, LP d/b/a Lutheran Hospital of Indiana would like to amend its NRC Byproduct Materials License, Number 13-01535-01, to add authorization for Saad M. Ibrahim, M.D. to perform 35.1000 yttrium-90 procedures with the TheraSphere delivery system. Dr. Ibrahim is currently listed on our license as a 35.1000 user of the yttrium-90 SIR-Spheres delivery system. Documentation of case experience and preceptor attestation are enclosed.

Additionally, we would like to add Jonathan M. Lee, M.D. as an authorized user of 35.300 materials (limited to the oral administration of I-131 sodium iodide). Documentation supporting this addition is enclosed.

If there are any questions concerning this license amendment, please contact our nuclear medicine physicist, Mr. Bryce A. Caudle, M.S., DABSNM at 317-443-9035, or by email at bcaudle@mpcphysics.com.

Sincerely,

Brady Dubois C.E.O
Chief Executive Officer

RECEIVED DEC 2 8 2021

LUTHERAN HOSPITAL
7950 W. JEFFERSON BLVD., FT. WAYNE, IN 46804
P: 260 435-7001 | W: LutheranHealth.net

Boston Scientific
Advancing science for life™

TheraSphere™ Y-90 Glass Microspheres Training Record
Saad Ibrahim, MD
Lutheran Hospital

June 4, 2021 - Mock infusion training, 3 in-vitro administrations
June 9, 2021 - Safe Handling Practices Training

This is to confirm that Boston Scientific provided training on the recommended use of TheraSphere in accordance with TheraSphere Package Insert at Lutheran Hospital. Dr. Ibrahim has successfully completed the Authorized User training program. The full scope of training included:

1. Has completed three in-vitro administrations with focus on:
   Safe handling practices
   TheraSphere Administration Set and TheraSphere Administration Accessory Kit overview
   Dose Calibrator verification using Calibration Data Sheet for Y-90
   Preparation of TheraSphere dose vial
   Assembly of the Administration Set
   System priming
   TheraSphere administration
   Disassembly

2. Has training provided by a Y-90 microsphere manufacturer representative involving:
   a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; and
   b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; and
   c. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; and
   d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters4; and

3. Has work experience or training under the supervision of an AU for the type of Y-90 microsphere brachytherapy the applicant is requesting, including (Attestation Attached):
   a. Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and
   b. Using administrative controls to prevent a medical event involving the use of byproduct material5; and
   c. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

Robert M. Erb
Robert M. Erb
Sr. Medical Science Liaison

June 11, 2021

Boston Scientific
Advancing science for life™

THERASPHERE™ Y-90 Glass Microspheres

AU TRAINING FORM

Part 1. Individual

Name [redacted] Saad Ibrahim Specialty Interventional Radiology

Institution Lutheran Hospital City Fort Wayne State IN

Part 2. Training and Experience

The following Therasphere training and experience was conducted under Authorized User supervision:

☒ The individual in Part 1 has satisfied NRC requirements Part A.3.iv.a-c

- ☒ Preparing and administering Therasphere patient dosage
- ☒ Using administrative controls to prevent a medical event involving the use of byproduct material
- ☒ Evaluation of patient or research subjects treatment to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred

Date of Training 6/7/21

☒ Individual in Part 1 has completed clinical patient case per NRC Licensing Guidance Part B

- ☒ Clinical Patient Case: focus on dosimetry, delivery system, safety procedures and TheraSphere administration

Date of Patient Case 6/7/21 6/8/21 10/27/21

Part 3. Attestation

I certify that the individual named in Part 1 has completed the training and experience listed in Part 2.

Name of Supervisor Jonathan Lee

Institution/Address Lutheran Hospital

Signature [signature]

Date 11/17/21.

Supervisor is ☒ TheraSphere Authorized User

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NRC FORM 313A (AUT)
(01-2020)

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 01/31/2023

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

Name of Proposed Authorized User	State or Territory Where Licensed
Jonathan Lee, M.D.	Indiana

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 radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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 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. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

e. Stop here.

☐ **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. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

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.

☑ **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	Medical College of Wisconsin Affliated Hospitals - St. Joseph, Milwaukee, WI	16	2014-2018
Radiation protection	Medical College of Wisconsin Affliated Hospitals - St. Joseph, Milwaukee, WI	16	2014-2018
Mathematics pertaining to the use and measurement of radioactivity	Medical College of Wisconsin Affliated Hospitals - St. Joseph, Milwaukee, WI	16	2014-2018
Chemistry of byproduct material for medical use	Medical College of Wisconsin Affliated Hospitals - St. Joseph, Milwaukee, WI	16	2014-2018
Radiation biology	Medical College of Wisconsin Affliated Hospitals - St. Joseph, Milwaukee, WI	16	2014-2018
	Total Hours of Training: 80		

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	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	☑ Yes ☐ No	4/2016-10/2019
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	☑ Yes ☐ No	4/2016-10/2019
Calculating, measuring, and safely preparing patient or human research subject dosages	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	☑ Yes ☐ No	4/2016-10/2019
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	☑ Yes ☐ No	4/2016-10/2019
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	☑ Yes ☐ No	4/2016-10/2019

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (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
Paresh Desai, M.D.	52-02-062

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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
☐ 35.57	

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

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

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	3	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	12/2017- 10/2019
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	Ascension SE Wisconsin Hospital - St. Joseph Campus Wisconsin license # 51-02-062	4/2016- 10/2017
Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.			

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (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
Paresh Desai, M.D.	52-02-062

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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
☐ 35.57	

** 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 not attesting to the individual's "general clinical competency."

First Section
Check one of the following for the requested authorization:

For 35.390:

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

☑ I attest that Jonathan Lee, 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:

☑ I attest that Jonathan Lee, 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).

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Second Section

☑ I attest that Jonathan Lee, 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Third Section

☑ I attest that Jonathan Lee, M.D. is able to independently fulfill the radiation safety-related
Name of Proposed Authorized User

duties as an authorized user for the medical uses authorized under 10 CFR 35.300 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

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 (b)(1), and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Fifth Section

Complete one of the following for the attestation and signature:

☐ **Authorized User**

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

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☐ 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 any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

☑ **Residency Program Director:**

☑ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

☐ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☑ I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

☑ I affirm that the residency training program is approved by the:

☑ Residency Review Committee of the Accreditation Council for Graduate Medical Education

☐ Royal College of Physicians and Surgeons of Canada

☐ Council on Post-Graduate Training of the American Osteopathic Association

☑ I affirm that the residency training program includes training and experience specified in:

☐ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396

Name of Facility:	License/Permit Number:	
Ascension SE Wisconsin Hospital - St. Joseph Campus	52-02-062	
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
Paresh Desai, M.D.		
Signature		

Form A

ABR | AMERICAN BOARD OF RADIOLOGY

American Board of Radiology — Program Director Attestation

COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

Forms A and B must be submitted after completion of your NRC training and experience.

More information can be found at the following link:

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

Jonathan Lee	MCW/St Joseph	51-02-062
Resident Name	Program	Program #

	YES	NO
By the time of the ABR certifying 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.....	☑	☐
I attest that the work experience cited above for § 35.290 was completed under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements.....	☑	☐
I attest that the work experience cited above for § 35.392 was completed 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.....	☑	☐
I attest that the work experience cited above for § 35.394 was completed under the supervision of an Authorized User (AU) who meets the requirements under § 35.390 or 35.394, or equivalent Agreement State requirements.....	☑	☐

PARESH B. DESAI	P B Desai	5/18/18
Residency Program Director (Print Name)	Program Director (Signature)	Date

Rev.05/2017

Form B

I-131 Therapy Experience Log

Jonathan Le
Resident Name

MCW-St. Joseph
Program & Number

Date	Dose Administered	Preceptor (AU) Print & Sign Name
≤ 33mCi		
1. 11/30/2017	30 mCi	Dr. Unna Suriyanarayanan Print Name Sign Name
2. 2/10/2015	13.9 mCi	Dr. Paresh Desai Print Name P.B. Desai Sign Name
3. 10/31/2014	~~8~~ 8.62 mCi	Paresh Desai Print Name P.B. Desai Sign Name

Date	Dose Administered	Preceptor (AU) Print & Sign Name
>33 mCi		
1. 10/19/2017	105 mCi	~~Dr. Paresh Desai~~ Dr. Orlin Hadjiev Print Name Sign Name
2. 10/12/2017	104.1 mCi	Dr. Paresh Desai Print Name P.B. Desai Sign Name
3. 4/1/2014	71.8 mCi	Dr. Paresh Desai Print Name P.B. Desai Sign Name