Lutheran Health Network
Lutheran Hospital

February 10, 2022

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 Andrew Ceranske, M.D. as an authorized user of 35.100, 35.200, and 35.1000 materials (limited to the yttrium-90 TheraSphere delivery system). 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

Chief Executive Officer

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

Authorized User T&E (Andrew Ceranske, M.D.) 10 CFR 35.1000

Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 10.2

5.1.A.

3.i.a.

Experience in diagnostic radiology demonstrated by:
Board Certification in Diagnostic Radiology by the ABR (enclosed)

b. Experience in interventional radiology demonstrated by:
Board Certification in Interventional Radiology by the ABR (enclosed)

ii. Classroom and laboratory training satisfied by board certification in diagnostic radiology by the ABR (as noted in footnote 3 of Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 10.2)

iii. Work experience under an AU or manufacturer representative for Y-90:
Documentation enclosed

iv. Work experience under an AU for the type of Y-90 microsphere requested:
Documentation enclosed

B. Documentation of hands-on clinical case experience:
Pending completion of cases. Requesting conditional approval with a commitment to provide the NRC with case logs documenting the first 3 clinical cases once completed. Documentation of 3 mock cases completed is enclosed.

C. Written attestation of completion of Parts A and B above from an AU approved for Y-90 TheraSphere is enclosed.

The American Board of Radiology

hereby certifies that

Andrew Ceranske, MD

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

Interventional Radiology/Diagnostic Radiology

AU 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 Continuous Certification.

DABR

AMERICAN BOARD 1933 OF MEDICAL SPECIALTIES EXCELLENCE ETHICS HONOR SKILL OPIBUSQUE

Vincent P. Mathews, MD
President

Secretary-Treasurer

Executive Director

Certificate No. 76545

Effective: October 20, 2021

Boston Scientific
Advancing science for life™

THERASPHERE® Y-90 Glass Microspheres

AU TRAINING FORM

Part 1. Individual

Name **Andrew Ceranske, MD** Specialty **Interventional Radiologist**

Institution **Lutheran Hospital of Indiana** 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 **12/8/21**

☐ 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

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 **Jeff Ramkaransingh, MD**

Institution/Address **Roodebush VAMC/IU School of Medicine, Indianapolis, IN**

Signature  Date **12/08/21**

Supervisor is ☑ TheraSphere Authorized User

Boston Scientific
Advancing science for life™

TheraSphere® Training Record – Andrew Ceranske, MD

Lutheran Hospital of Indiana

Fort Wayne, IN 17821

December 13, 2021	- Mock infusion training, 3 in-vitro administrations
December 8, 2021	- Completed NRC required 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 of Indiana. Dr. Ceranske has successfully completed the Authorized User training program. The full scope of training included the following.

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 letter 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 materials; 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.

Cynthia Ann Hollenbeck

Cynthia Ann Hollenbeck, PhD — December 20, 2021

Medical Science Liaison

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed
Andrew Ceranske, M.D.	Indiana

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. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), 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.

c. Stop here.

☐ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, 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 or authorized nuclear pharmacist

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) ☐ 35.55 ☐ 35.57 for 35.200 uses

c. If board certified, provide a copy of the certificate and stop here. If not board certified, skip to and complete Part II Preceptor Attestation.