



June 30, 2021

US Nuclear Regulatory Commission  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60532-4352

NRC License #: 13-06009-01  
Community Health Network

To Whom It May Concern:

Please accept this letter as a request to amend the Nuclear Regulatory Commission license for Community Health Network in Indianapolis, Indiana.

Please add the following Authorized User to our NRC license:

Derek Zipkin, MD- Conditional approval for 10 CFR35.1000- (limited to yttrium-90 as SIR-Spheres and Theraspheres)

Attached, please find the following supporting documentation:

- 1) Copy of ABR certification letter specifying he is AU-eligible (hard copies will not be mailed for several months) – (Attachment A)
- 2) Copy of Interventional Radiology fellowship training completion certificate with dates (Attachment B)
- 3) Therasphere™ Training Record summary including three in-vitro procedures (Attachment C)
- 4) Therasphere™ AU Training form (Attachment D)
- 5) SIR-Spheres AU training documentation and IR clinical documentation with dates (Attachment E)
- 6) SIR-Spheres AU Training summary form including three in-vitro procedures (Attachment F)

Please add 35.100 and 35.200 to Dr. Mark Sparrow's Authorized User status. Attached, please find a copy of his approval on the Johnson County Memorial Hospital (Attachment G)

If you require additional clarification or documentation, please contact our Radiation Safety Officer, Erin Bell, at 317.355.5528 or via email at [ebell2@community.com](mailto:ebell2@community.com).

Sincerely,

A handwritten signature in black ink, appearing to read "D. Kiley", is written over a light blue rectangular background.

David L. Kiley, M.D., MBA  
SVP - Indianapolis Region President  
Community Health Network  
[dkiley@community.com](mailto:dkiley@community.com)

RECEIVED JUL 13 2021

**ABR** | AMERICAN  
BOARD OF  
RADIOLOGY

Diagnostic Radiology  
ABR ID: 74320

Derek Zipkin, MD  
3825 Carwinion Way  
Carmel, IN 46032

Dear Dr. Zipkin:

I am pleased to inform you that you passed the Diagnostic Radiology Certifying Exam held on April 5, 2021. The American Board of Radiology hereby grants you certification in diagnostic radiology.

In addition, because you completed the appropriate training for Authorized User eligibility and passed the NRC-related portions of the Core and Certifying exams, you will receive the AU-Eligible (AU-E) designation on your certificate. To obtain AU Status, please contact the radiation safety officer for your facility and request to be added to the facility's NRC license. A form will be submitted by your facility to the NRC to get approval for you to be an Authorized User.

All new diplomates are enrolled in Continuous Certification, a process that links the ongoing validity of certificates to meeting the requirements of Maintenance of Certification (MOC). Certificates no longer have "valid-through" dates, but instead have the date of initial certification accompanied by the statement that "ongoing validity of this certificate is contingent upon meeting the requirements of Maintenance of Certification." MOC for your certificate will start January 1, 2022. Further information regarding the MOC process will be provided to you in future communications.

You now may use the ABR's registered certification mark, DABR® (Diplomate, American Board of Radiology), following your name and degree. More information can be found on the ABR website at [ABR Logo Usage Policy](#).

Our printer will send your certificate to the above address in approximately four months. If you have an address change, you must update your address using the myABR portal by May 10, 2021. Your name will appear on the certificate as it is shown above. If you wish to have your name displayed differently on your certificate, please email [information@theabr.org](mailto:information@theabr.org) with your requested change and supporting documentation by May 10, 2021. Please be sure to title the email "Certificate Name Change."

Your name and demographic information also will be included in a directory published by the American Board of Medical Specialties. It is your responsibility to notify other local, state, or national organizations of your certification.

Personally, and on behalf of the Boards of Governors and Trustees of the American Board of Radiology, I wish to congratulate you for this distinguished achievement.

Sincerely,

Brent Wagner, MD, MBA  
Executive Director

# The University of Michigan

Hereby certifies that

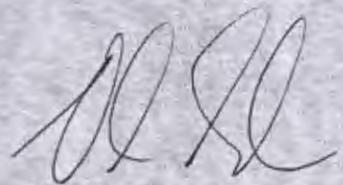
**Derek Benjamin Zipkin, M.D.**

has successfully completed an ACGME-accredited Fellowship Training in

## Vascular and Interventional Radiology

July 1, 2019 to June 30, 2020

Department of Radiology  
Michigan Medicine  
Ann Arbor, Michigan



Chair, Department of Radiology



CAQ Fellowship Program Director

Attachment C

**TheraSphere™ Y-90 Glass Microspheres Training Record**

**Derek Zipkin, MD**

Community Health Network

NRC License Number 13-060009-01

March 10, 2021 - Safe Handling Practices Training

January 11, 2020 - Mock infusion training, 3 in-vitro administrations

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

1. 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 emitters<sup>4</sup>; and
2. 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 material<sup>5</sup>; 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.
3. 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

*Robert M. Erb*

Robert M. Erb

Sr. Medical Science Liaison

May 4, 2021

**Attachment D**  
**THERASPHERE™ Y-90 Glass Microspheres**

**AU TRAINING FORM**

**Part 1. Individual**

Name **Derek Zipkin, MD** Specialty **Interventional Radiology**  
Institution **Radiology of Indiana** City **Indianapolis** 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 **03/10/2021**

- 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 **Jeffrey Ramkaransingh, MD**  
Institution/Address **Roudebush VAMC / IU School of Medicine, Indianapolis, IN**

Signature ***[Signature]*, MD** Date **3/10/21**

Supervisor is  TheraSphere Authorized User

# Attachment E

To Whom It May Concern:

This letter is to acknowledge that Dr. Derek Zipkin has been working full-time in Interventional Radiology from July 1 2020 at Radiology of Indiana, prior to that time Dr. Derek Zipkin was doing his Interventional Radiology fellowship which started on July 1 2019.

Dr. Zipkin is board certified by the American Board of Radiology in Diagnostic Radiology and is documented as AU Eligible.

Dr. Zipkin has had the following training for Y-90 Sirsphere microspheres, including:

- a. Preparing and administering patient dosage.
- b. Using administrative controls to prevent a medical event involving the use of byproduct material, 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.

Please also find documentation attached of the following training from a Sirtex representative:

- 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; and
- d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures.

  
\_\_\_\_\_  
Signature of Authorized User

5/17/21  
\_\_\_\_\_  
Date

Daniel LoCascio  
\_\_\_\_\_  
Printed Name of Authorized User

NRC License Number 13-060009-01  
Community Health Network

Attachment F

SIRTeX

**SIRTEX MEDICAL INC.**  
300 Unicorn Park Drive  
Woburn, MA 01801  
Tel: +1 (781) 721 3800  
Fax: +1 (781) 721 3880

Ref: 104US07

July 22, 2020

Derek Zipkin, MD  
Community Hospital South  
1402 E County Line Rd  
Indianapolis, IN 46227

Dear Dr. Zipkin,

**Re: SIR-Spheres® Microspheres Authorized User Training and Certification**

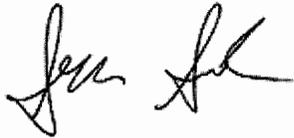
This letter certifies that on July 21st, 2020, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- 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;
- c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's case history for Y-90 microspheres

Once your licence has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

Sirtex would like to thank you for your support in this process.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Steve Schilt". The signature is written in a cursive style with a horizontal dashed line above it.

Steve Schilt

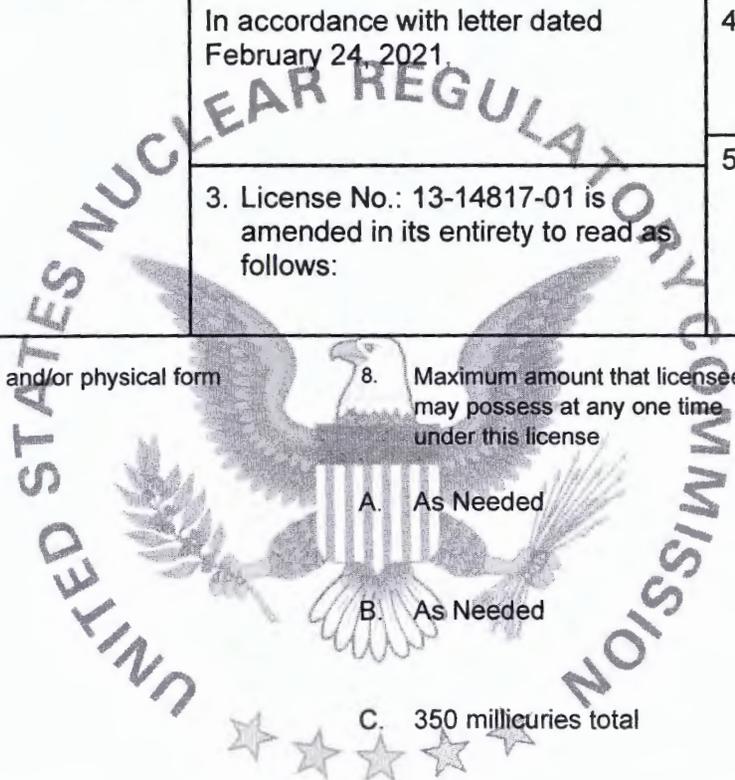
Regional Sales Manager

cc: Derek Webster  
Area Sales Director

**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, 37, 39, 40, 70 and 71, 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.

Licensee 1. Johnson County Memorial Hospital  2. P.O. Box 549 1125 Jefferson St. Franklin, IN 46131		In accordance with letter dated February 24, 2021.	4. Expiration Date: December 31, 2023
		3. License No.: 13-14817-01 is amended in its entirety to read as follows:	5. Docket No.: 030-08553 Reference No.:
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 350 millicuries total	C. For any use permitted by 10 CFR 35.300.
D. Any byproduct material permitted by 10 CFR 31.11	D. Prepackaged Kits	D. 10 millicuries total	D. For use in in-vitro studies.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License No.: 13-14817-01

Docket or Reference No.:

030-08553

Amendment No. 33

**CONDITIONS**

10. A. Licensed material shall be used or stored at the licensee's facilities located at 1125 W. Jefferson St., Franklin, Indiana 46131.  
B. Licensed material listed in Subitem No. 6.B. shall be used at the licensee's facilities located at 1155 W. Jefferson St., Franklin, Indiana 46131.
11. The Radiation Safety Officer for this license is Patrick J. Byrne, DABR, CHP, DABSNM.
12. Licensed material shall only be used by or under the supervision of:
- A. Individuals permitted to work as authorized users in accordance with 10 CFR 35.13 and 10 CFR 35.14.
- B. The following individuals are authorized users for the material and medical uses as indicated:

Authorized User (M.D., D.O., etc.)

Material and Use

Mary Below, M.D.

10 CFR 35.100, 10 CFR 35.200

James Blahunka, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Stefan Andrew Hoff, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 300 (limited to the oral administration of sodium iodide I-131)

Tarun R. Jindal, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 300 (limited to the oral administration of sodium iodide I-131)

Michael L. Lutz, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Ronald Mastouri, M.D.

10 CFR 35.200

Gregory A. Merchun, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Thomas N. Murphy, M.D.

10 CFR 35.100, 10 CFR 35.200

Mark Joseph Paluszny, M.D.

10 CFR 35.100, 10 CFR 35.200

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License No.: 13-14817-01

Docket or Reference No.:  
030-08553

Amendment No. 33

Authorized User (M.D., D.O., etc.)

Orin W. Perkins, M.D.

Richard L. Scales, M.D.

Paul W. Sheets, M.D.

Chandraban Singh, M.D.

Mark Allan Sparrow, M.D.

Material and Use

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200

10 CFR 31.11

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131).



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License No.: 13-14817-01

Docket or Reference No.:

030-08553

Amendment No. 33

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated July 15, 2013 (ML13198A571)
- B. Letter dated November 27, 2013 (ML13338A662)
- C. Letter dated March 26, 2014 (ML14085A195)
- D. Letter dated December 28, 2016 (ML17003A062)
- E. Letter dated November 1, 2019 (ML19319C716)
- F. Letter dated January 12, 2020 (ML20014E722)
- G. Letter dated July 21, 2020 (ML20205L424)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Magdalena R. Gryglak

By: \_\_\_\_\_

Magdalena R. Gryglak  
Region 3Digitally signed by Magdalena R.  
Gryglak

Date: 2021.06.04 08:59:06 -05'00'

Date: June 4, 2021

 **Community  
Health Network**

*E. Bell 220002*  
**Community Hospital East**  
1500 North Ritter Avenue  
Indianapolis, Indiana 46219-3095

**RETURN SERVICE  
REQUESTED**

U.S. POSTAGE  PITNEY BOWES  
ZIP 46256 \$ 000.86<sup>0</sup>  
02 4th  
0000379330 JUL 06 2021

US Nuclear Regulatory Commission  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60532-4352



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22 FMEHNS 60532

