



424 Savannah Road, Lewes DE, 19958
beebehealthcare.org | (302) 645-3300

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Br. I

October 11, 2019

Licensing Branch
Nuclear Materials Safety Section
Division of Safety & Safeguards
USNRC Region I DNMS
2100 Renaissance Boulevard
King of Prussia, PA 19406-27134

RE: License No. 07-17792-01
Amendment Request

03013331

Dear Sir or Madam:

Beebe Medical Center would like to amend the above referenced license to add Dr. Steven R. Chmielewski as an authorized user for any byproduct material listed under 10 CFR 35.100, 35.200, and 35.300. Dr. Chmielewski was previously listed for the aforementioned materials on Pennsylvania license PA-0070. A copy of this license is enclosed.

If additional information is required or if there are any questions regarding our request, please contact our Radiation Safety Officer, Dr. Lisa M. Genovese at 443-425-5114 or our Director of Diagnostic Imaging, Mr. Dan Mapes at 302-645-3709.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Schaffner'.

Richard A. Schaffner, Jr., RN, BSN, MHA
Interim CEO, Executive VP & Chief Operating Officer

616991

NMSS/RGN1 MATERIALS-002

Official Use Only – Security Related Information



**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION**

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License No. PA - 0070

RADIOACTIVE MATERIALS LICENSE

Amendment No: 44

Pursuant to the Radiation Protection Act, the Act of July 10, 1984 (No. 147, P.L. 688) (35 P.S. §§ 7110.101 – 7110.703) and Title 25, Rules and Regulations, Article V, Radiological Health of the Pennsylvania Department of Environmental Protection, and in reliance on statements and representations heretofore Licensee to receive, acquire, possess, transfer, and use radioactive material listed below for the purposes and at the places designated below. This license shall be deemed subject to all applicable rules, regulations, or orders of the Pennsylvania Department of Environmental Protection now or hereafter in effect and to any conditions specified below.

Licensee 1. Penn State Health d/b/a St. Joseph Medical Center 2. 2500 Bernville Road P.O. Box 316 Reading, PA 19603-0316		In response to correspondence dated June 26, 2018 and August 21, 2018 3. License No. PA – 0070 is amended as follows: 4. Expiration Date: July 31, 2024 5. Client ID: 28774 Program Code: 2240 Priority: 2	
6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.100 B. Any byproduct material permitted by 10 CFR 35.200 C. Any byproduct material permitted by 10 CFR 35.300 D. Yttrium-90 permitted by 10 CFR 35.1000 E. Yttrium-90 permitted by 10 CFR 35.1000	7. Chemical and/or physical form A. Any B. Any C. Any D. Sirtex SIR-Spheres® Y-90 microspheres E. Nordion (Canada), Inc. TheraSphere® Y-90 microspheres	8. Maximum amount that licensee may possess at any one time under this license A. As needed B. As needed C. 3000 millicuries D. 1000 millicuries E. 2000 millicuries	

9. Authorized use:

- A. Any approved uptake, dilution and excretion procedure permitted by 10 CFR 35.100.
- B. Any approved imaging and localization procedure permitted by 10 CFR 35.200.
- C. Any approved diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. For permanent manual brachytherapy using Sirtex SIR-Spheres® Y-90 microspheres delivery system as permitted by 10 CFR 35.1000.
- E. For permanent manual brachytherapy using Nordion TheraSphere® Y-90 microspheres delivery system as permitted by 10 CFR 35.1000.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 2500 Bernville Road, Reading, PA 19603-0316.
- 11. The Radiation Safety Officer for this license is: Karen E. Wagner, MSHP, DABR.
- 12. Licensed Material is only authorized for use by, or under the supervision of:



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BUREAU OF RADIATION PROTECTION

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License No. PA - 0070

RADIOACTIVE MATERIALS LICENSE

Amendment No. 44

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. Physicians are permitted to work as authorized users for 35.1000 SIR-Spheres® Y-90 microspheres use in accordance with the letter dated October 24, 2014.
- C. The following individuals are authorized users for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Rakesh Barak, M.D.	35.100, 35.200, Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Steven R. Chmielewski, M.D.	35.100; 35.200; 35.300; 35.1000 (Y-90 SIR-Spheres®)
Irving Ehrlich, M.D.	35.100; 35.200; 35.300
Jeffery B. Nemeroff, M.D.	35.100; 35.200; 35.300
Narvesh K. Sharma, D.O., Ph.D.	35.300; 35.1000 (Y-90 SIR-Spheres®) & 35.1000 (Y-90 TheraSphere®)
Barry M. Tom, M.D.	35.100; 35.200

- 13. The licensee shall conduct a physical inventory every 6 months, to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.65 incorporated by reference. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers and the date of the inventory.
- 14. 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 and incorporated by reference in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.
- 15. The licensee may transport licensed material, or deliver licensed material to a carrier for transport, in accordance 25 Pa Code Chapter 230, "Packaging and Transportation of Radioactive Material" and the provisions of 10 CFR Part 71 incorporated by reference.
- 16. Notwithstanding the requirements set forth in this license, the licensee shall comply with the regulations set forth in Title 25 of the Pennsylvania Code, Article V "Radiological Health" and the U.S. Nuclear Regulatory Commission (NRC), Title 10 Code of Federal Regulations Parts 19-150 incorporated by reference.



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

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License No. PA - 0070

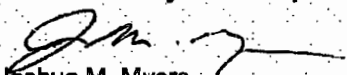
RADIOACTIVE MATERIALS LICENSE

Amendment No. 44

17. 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 Department of Environmental Protection's (DEP) regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Renewal application dated June 20, 2014
- B. Electronic communication dated July 29, 2014
- C. Electronic communication dated August 6, 2014
- D. Letter dated October 24, 2014 (DEP)
- E. Letters dated June 18, 2015 and August 21, 2015
- F. Electronic communications dated December 16, 2015, December 17, 2015 and December 22, 2015
- G. Letter dated June 26, 2018 and August 21, 2018

For the Pennsylvania Department of Environmental Protection


Joshua M. Myers
Bureau of Radiation Protection
P. O. Box 8469
Harrisburg, PA 17105-8469

Date: December 7, 2018



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Lisa Marie Genovese, DMP
Radiation Safety Officer
Beebe Medical Center
c/o Radiology Department
424 Savannah Road
Lewes, Delaware 19958

Date

November 15, 2019

License Number(s)

07-17792-01

Mail Control Number(s)

616991

Licensing and/or Technical Reviewer or Branch

Medical Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: _____

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

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Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239