

**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.

<p style="text-align: center;"><b>Licensee</b></p> <p>1. Northwest Health-LaPorte LaPorte Hospital Company, LLC</p> <p>2. 1331 State Street La Porte, IN 46350</p>		<p>In accordance with letter dated November 30, 2020,</p>	<p>4. Expiration Date: August 31, 2024</p>
		<p>3. License No.: 13-15151-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-08653 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As Needed</p> <p>B. As Needed</p> <p>C. 5 curies total</p>	<p>9. Authorized use</p> <p>A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.</p> <p>B. For use in imaging and localization studies permitted by 10 CFR 35.200.</p> <p>C. For any use permitted by 10 CFR 35.300.</p>

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SUPPLEMENTARY SHEET**

License No.: 13-15151-01

Docket or Reference No.:  
030-08653

Amendment No. 55

6. Byproduct, source,  
and/or special nuclear  
material

D. Yttrium-90

7. Chemical and/or physical form

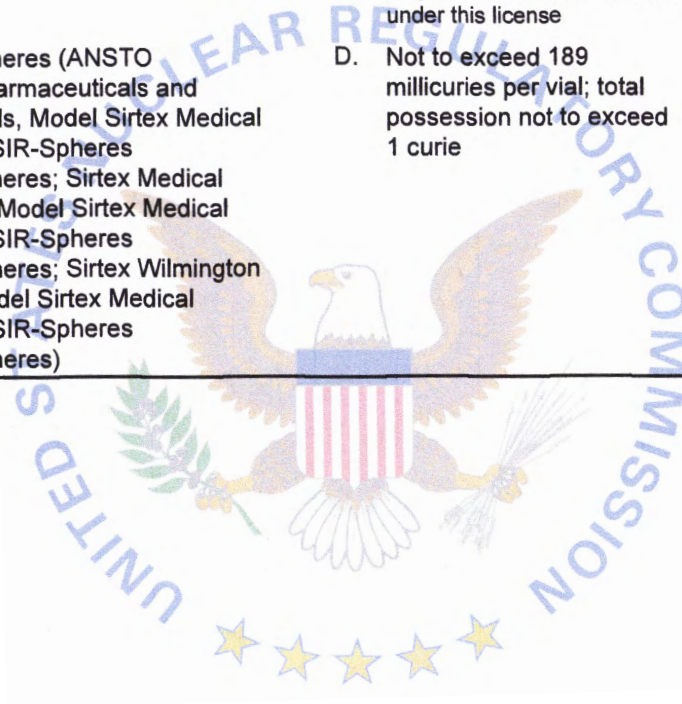
D. Microspheres (ANSTO  
Radiopharmaceuticals and  
Industrials, Model Sirtex Medical  
Limited SIR-Spheres  
microspheres; Sirtex Medical  
Limited, Model Sirtex Medical  
Limited SIR-Spheres  
microspheres; Sirtex Wilmington  
LLC, Model Sirtex Medical  
Limited SIR-Spheres  
microspheres)

8. Maximum amount that licensee  
may possess at any one time  
under this license

D. Not to exceed 189  
millicuries per vial; total  
possession not to exceed  
1 curie

9. Authorized use

D. For medical use permitted by 10 CFR  
35.1000 in Sirtex Medical Limited  
SIR-Spheres® microspheres therapy  
delivery systems.



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**CONDITIONS**

10. Licensed material may be used or stored at the licensee's facilities located at:  
1331 State Street, La Porte, Indiana, 46350
11. The Radiation Safety Officer (RSO) for this license is James C. Hatten.
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

Irfan Ahmad, M.D.

10 CFR 35.100, 35.200 and 35.300 (limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)

Syed I. Ali, M.D.

10 CFR 35.100, 35.200, 35.300 (limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries), and 35.1000 (limited to yttrium-90 in SIR-Spheres therapy delivery system)

Suzanne Bosman, M.D.

10 CFR 35.100, 35.200, and 35.300

Charles Bower, M.D.

10 CFR 35.100, 35.200, and 35.300

Stephen J. Kim, M.D.

10 CFR 35.100 and 35.200

Jack D. Markiewicz, M.D.

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

Krishna R. Pillai, M.D.

10 CFR 35.100 and 35.200

Smari Thordarson, M.D.

10 CFR 35.100, 35.200, and 35.300

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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 February 24, 2014 (ML14056A307)
- B. Letter dated February 25, 2013 (ML13059A725)
- C. Letter received May 22, 2013 (ML13158A282)
- D. Letter dated August 13, 2014 (ML14247A223)
- E. Letter dated April 30, 2015 (ML15125A424)



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- F. Letter dated December 10, 2015 (ML15356A461)
- G. Letter dated February 3, 2016 (ML16035A408)
- H. Letter dated March 9, 2016 (ML16077A173)
- I. Letter dated June 22, 2020 (ML20178A560)
- J. Letter dated November 30, 2020 (ML20178A560)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: February 8, 2021

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

*Colleen Carol Casey*  
Colleen Carol Casey  
Region 3