

U.S. NUCLEAR REGULATORY COMMISSION

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, 39, 40, and 70, 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>Licensee</p> <p>1. Centro Médico del Turabo, Inc. d/b/a Hospital HIMA - San Pablo Bayamón</p> <p>2. P.O. Box 236 Bayamón, Puerto Rico 00960-6036</p>	<p>In accordance with the application received April 20, 2016,</p> <p>3. License number 52-21325-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date September 30, 2024</p> <p>5. Docket No. 03020510 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>D. Yttrium 90</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Resin microspheres [Sirtex Medical Limited Model SIR-Spheres® microspheres (manufactured by Sirtex Wilmington LLC, Sirtex Medical Limited, or ANSTO Radiopharmaceuticals and Industrials)]</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. 1500 millicuries</p> <p>D. 189 millicuries per vial and 1134 millicuries total</p>
<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> <p>C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.</p> <p>D. For permanent brachytherapy use in the Sirtex Medical Limited SIR-Spheres delivery system.</p>		

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03020510

Amendment No. 20

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Hospital HIMA – San Pablo Bayamón, Centro de Imágenes, 70 Santa Cruz Street, Urb. Santa Cruz, Bayamón, Puerto Rico.
11. The Radiation Safety Officer for this license is María M. Palacios.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|--------------------------------|---|
| Reinaldo Laguna Figueroa, M.D. | 35.100; 35.200; 35.300 |
| César Borri Solá, M.D. | 35.100; 35.200; Oral administration of sodium iodide iodine-131 |
| Javier Nazario, M.D. | Yttrium 90 SIR-Spheres |
13. 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 in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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15. 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 received April 29, 2014 [ML14126A385]
- B. Letter dated August 11, 2014 [ML14237A231]
- C. Application dated April 20, 2016 [ML16125A235]
- D. Letter dated July 19, 2016 [ML16214A034]



For the U.S. Nuclear Regulatory Commission

Date August 1, 2016

By

Original signed by Janice Nguyen

Janice Nguyen
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406