

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. Straub Clinic & Hospital		In accordance with letter dated October 26, 2016	4. Expiration Date: October 31, 2025
2. 888 South King Street Department of Nuclear Medicine Honolulu, HI 96813		3. License number: 53-18126-01 is amended in its entirety to read as follows:	5. Docket No.: 030-14529 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. 1 curie 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. 5 millicuries total	D. For use in in-vitro studies.
E. Yttrium-90	E. Liquid (IDEC Pharmaceuticals Zevalin)	E. Not to exceed 2 sources, 110 millicuries total activity	E. To be used for dose calibration checks and calibrations and quality assurance testing.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
53-18126-01

Amendment No. 29

Docket or Reference Number
030-14529

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|---|--|--|--|
| 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 |
| F. Yttrium-90 permitted by 10 CFR 35.1000 | F. Microspheres (Sirtex Medical Limited, Model Sirtex Medical Limited SIR-Spheres® microspheres; Sirtex Singapore Manufacturing Pte Ltd, Model Sirtex Medical Limited SIR-Spheres® microspheres; Sirtex Wilmington, LLC, Model Sirtex Medical Limited SIR-Spheres® microspheres) | F. 189 millicuries per vial and 650 millicuries total | F. SIR-Spheres® for permanent brachytherapy using delivery system as listed in SSDR MA-1229-D-101-S permitted by 10 CFR 35.1000. |

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 888 South King Street, Honolulu, Hawaii (island of Oahu).
11. The Radiation Safety Officer for this license is Ronald W. Frick.
12. Licensed material shall only be used by, or under the supervision of:
- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists, 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:
- | <u>Authorized User(M.D.,D.O.,etc.)</u> | <u>Material and Use</u> |
|--|-------------------------|
| Shay J. Lee, M.D. | 35.100; 35.200; 35.300 |
| Brian T. Sinclair, M.D. | 35.100; 35.200; 31.11 |

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

Marc Coel, M.D.

Douglas A. Prager, M.D.

John P. Kristofich, M.D.

Sandi Kwee, M.D.

James S. Sheperd, M.D.

Kristi Takaki, M.D.

Material and Use

35.100; 35.200; 35.300; 31.11

35.100; 35.200; 35.300

35.100; 35.200

35.100; 35.200; 35.300; 31.11

35.1000 Y-90 Sir-Spheres use

35.100; 35.200

13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
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 in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
15. 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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16. 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 and letter dated November 27, 2012 with enclosures for Y-90 SIR-Spheres® microspheres only. 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. Letter with enclosures dated November 27, 2012 (ML12352A137)

B. Application dated April 6, 2015 (ML15110A473)

C. Letter dated October 8, 2015 (ML15288A424)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: January 30, 2017By: _____
Robert J. Torres, M.S., Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4511