U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 64

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.

Licensee	In accordance with the letter dated September 11, 2014,
1. Middlesex Hospital	3. License number 06-00649-03 is amended in its entirety to read as follows:
2. 28 Crescent Street Middletown, Connecticut 06443	4. Expiration date October 31, 2023
	5. Docket No. 030-01242 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
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 1000 millicuries
D. Iodine-125 permitted by 10 CFR 35.400	D. Sealed Sources [Best Medical International, Inc. Model 2301; IsoAid, L.L.C. Model IAI-125A (Advantage I-125)]	D. 2000 millicuries
E. Yttrium 90	E. Glass microspheres (Nordion (Canada), Inc. Model TheraSphere)	E. 540 millicuries per source and 1000 millicuries total

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.
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.
D. Any manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.
E. For permanent brachytherapy use in the Nordion (Canada), Inc. TheraSphere delivery system.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
06-00649-03

Docket or Reference Number
030-01242

Amendment No. 64

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 28 Crescent Street, 530, 534 and 536 Saybrook Road, Middletown, Connecticut.

11. The Radiation Safety Officer for this license is Joan Merton.

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. Physicians permitted to work as authorized users for Yttrium 90 TheraSpheres in accordance with the notification commitments in the letter dated June 7, 2012 and the application dated May 24, 2013.

    C. The following individuals are authorized users for medical use as indicated:

Authorized Users	Material and Use
Ravi Jain, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Joseph B. Weissberg, M.D.	35.300; 35.400
Diana Miller Hull, M.D., Ph.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Michael Crain, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies
Craig A. Walden, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies
Erik Pingoud, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies
Jeffrey Takahashi, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies; Yttrium 90 TheraSpheres
Robert Wolek, M.D.	35.100; 35.200; 35.300

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
06-00649-03

Docket or Reference Number
030-01242

Amendment No. 64

Authorized Users	Material and Use
Nancy Rini, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 for imaging and localization studies
Anwar M. Khan, M.D.	Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; 35.400
Zaixiang Sherry Zhang, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Julie Savina Lee, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Adam Y. Abou-Elias, M.D	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Bruce Kovalenko, M.D.	35.100; 35.200; Oral administration of sodium iodide iodine-131 in quantities less than or equal to 33 millicuries
Neil B. Goldberg, M.D.	Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

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."

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
06-00649-03

Docket or Reference Number
030-01242

Amendment No. 64

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 and in the application dated May 24, 2013. 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 dated June 7, 2012 [ML12174A307]
B. Application dated May 24, 2013 [ML13157A359]
C. Letter dated September 6, 2013 [ML13256A143]

For the U.S. Nuclear Regulatory Commission

Date October 14, 2014

By ***Original signed by Penny Lanzisera***

Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406