

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 1. St. Clare's Hospital-Dover Campus 2. 400 West Blackwell Street Dover, New Jersey 07801	In accordance with the letter dated March 13, 2009, 3. License number 29-13746-02 is amended in its entirety to read as follows: 4. Expiration date January 31, 2014 5. Docket No. 030-02576 Reference No.
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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
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. 1 curie
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (3M Model 6500 Series; Amersham Model Nos. 6711 and 6715; Bard Brachytherapy, Inc. Model STM 1251; Mills Biopharmaceuticals Models I-125SL and I-125SH)	D. 1.2 curies
E. Strontium 90	E. Sealed Source (3M Model No. 6047)	E. 38 millicuries

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. Cesium-137 sources permitted by 10 CFR 35.400 for storage only. Any manual brachytherapy procedure with iodine-125 sources permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.
- E. For storage only.

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CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 400 West Blackwell Street, Dover, New Jersey.
11. The Radiation Safety Officer for this license is David S. Marsden, Ph.D.
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:

Authorized Users

Material and Use

Arvin Smith, M.D.

35.100; 35.200; Oral administration of sodium iodide iodine-131 for diagnostic studies

Jeff A. Wexler, M.D.

35.100; 35.200; 35.300

Burton Sutker, M.D.

35.100; 35.200; Oral administration of sodium iodide iodine-131 for diagnostic studies

Michael Henderson, M.D.

35.100; 35.200; Oral administration of sodium iodide iodine-131 for diagnostic studies; Strontium 89 for uses permitted by 10 CFR 35.300

Richard Claps, M.D.

35.100; 35.200; 35.300

Jeffrey Plutchok, M.D.

35.100; 35.200; 35.300

Neil J. Freeman, M.D.

35.100; 35.200; 35.300

Donald Cann, M.D.

35.300; 35.400

Durgesh Hajela, M.D.

35.300; 35.400

Robert M. Wall, M.D.

35.200 for cardiovascular clinical procedures

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C. The following individuals are authorized users for non-medical uses as indicated:

Users

Material and Use

David S. Marsden, Ph.D.

Strontium-90 Eye Applicator Source and Cesium-137 Manual Brachytherapy Sources (supervision of storage)

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 shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. 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.
15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - C. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

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- E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. 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 October 2, 2003, except HDR [ML032820100]
B. Letter dated January 22, 2004, except HDR [ML040340473]

For the U.S. Nuclear Regulatory Commission

Original signed by Héctor BermúdezDate April 24, 2009

By

Héctor Bermúdez
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406