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U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 59

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 May 8, 2012,
1. Yale-New Haven Hospital Radiological Physics	3. License number 06-00819-03 is amended in its entirety to read as follows:
2. 20 York Street - WWW 204 New Haven, Connecticut 06504	4. Expiration date May 31, 2016
	5. Docket No. 03001244 Reference No. 06-17434-01, 06-31070-01

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
Outside of Scope		
E. Strontium 90/Yttrium 90	E. Sealed Sources (Best Vascular, Inc. [formerly Novoste Corp.] BEBIG Model Sr0.S03 and AEAT SICW Series)	E. Not to exceed 5 millicuries per source and and 120 millicuries per device and 840 millicuries total
F. Strontium 90	F. Sealed Sources (Tracerlab, Inc. Model RA-2)	F. Not to exceed 200 millicuries per source and 600 millicuries total
G. Strontium 90	G. Sealed Sources (Baldwin Ind. Control Model BIS 183)	G. 10 millicuries

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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
H. Strontium 90	H. Sealed Sources (MDS Nordion Model TheraSpheres and Sirtex Medical Limited Model SIR-Spheres)	H. Not to exceed 540 millicuries per source and 2,160 millicuries total

Outside of Scope

Outside of Scope

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9. Authorized use:

A. through S. Medical diagnosis, therapy, and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in vitro studies.

C. For medical use in a Guidant, Inc. Model Galileo Series intravascular brachytherapy remote afterloader unit.

E. For medical use in a Best Vascular Inc. (formerly Best Medical International, Inc.) Model Novoste A1000 Series intravascular brachytherapy remote afterloader unit.

F. Eye applicator for ophthalmic radiotherapy permitted by 10 CFR 35.400.

H. Medical use with the MDS Nordion TheraSphere delivery system and the Sirtex SIR-Sphere delivery system.

L. For medical use in the Proxima Therapeutics Inc. Model GliaSite RTS and Spectrum Systems.

P. One source for medical use in a GammaMedplus or GammaMedplus iX high dose rate remote afterloader unit. The source activity may not exceed 10 curies at the time of clinical use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

Q. One source assembly for medical use in a Cordis Checkmate Catheter System intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.

T. and U. Medical diagnosis, therapy, and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR 30.4, including animal studies and student instruction.

V. For medical use permitted by 10 CFR 35.600, in an ELEKTA Instruments AB Model Leksell Gamma Knife Perfexion gamma stereotactic radiosurgery unit. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.

W. and X. Storage only.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 20 York Street, New Haven, Connecticut (medical center campus); the Shoreline Medical Center, 111 Goose Lane, Guilford, Connecticut; and Temple Medical Center, 40 Temple Street, New Haven, Connecticut.

11. A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.

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B. Individuals designated to work as authorized users, authorized nuclear pharmacists or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.

C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

D. Licensed material in Item 6.V. shall be used by, or under the supervision of, individuals who have received the training described in the letter dated April 23, 2010 and have been designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

E. The Radiation Safety Officer for this license is Michael J. Bohan.

12. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Iodine 129	100 microcuries
Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	100 microcuries

13. By August 31, 2011, provide all available information identified in 10 CFR 32.210(c) concerning the radium-226 sources not registered with the Commission, and, if applicable, the devices, in accordance with 10 CFR 30.32(g)(3). Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test. Alternatively, you may elect to consider the radium-226 as unsealed byproduct material and provide a decommissioning funding plan with associated financial assurance in accordance with 10 CFR 30.35.

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14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

15. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

16. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

17. 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. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

    C. 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.

    D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

    E. 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.

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F. 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.

G. 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.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

19. 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.

20. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

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21. The licensee will comply with the requirements for the "Order Imposing Increased Controls" (ADAMS Accession No. ML053130183) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting Order) (ADAMS Accession No. ML073230738) published in the Federal Register on December 13, 2007 (72 FR 70901). The licensee will complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the fingerprinting Order. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders otherwise, or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations, that the revisions are to supersede these Orders. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U. S. NRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Withhold From Public Disclosure Under 10 CFR 2.390."

22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

23. Notwithstanding the requirements of License Condition 24, the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:

    A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation.

    B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.

    C. The licensee's staff is trained in the revised procedures prior to implementation.

    D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

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24. 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 November 30, 2005	[ML053430238]
B.	Letter dated March 3, 2006	[ML060740625]
C.	Letter dated October 2, 2006	[ML062920450]
D.	Letter dated July 7, 2009	[ML091940114]
E.	Letter dated September 14, 2009	[ML092610598]
F.	Letter dated October 20, 2009	[ML092940690]
G.	Letter dated October 26, 2009	[ML093000327]
H.	Letter dated January 6, 2010	[ML100110527]
I.	Letter dated February 12, 2010	[ML100431141]
J.	Attachment to Letter dated February 12, 2010	[ML100431069]
K.	Letter dated April 23, 2010	[ML101160111]
L.	Letter dated April 26, 2010	[ML101170047]
M.	Letter dated November 15, 2010	[ML103210187]
N.	Letter dated May 8, 2012	

For the U.S. Nuclear Regulatory Commission

Original signed by James Dwyer for Penny Lanzisera

Date May 9, 2012 By _____

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