

~~Official Use Only - Security-Related Information~~

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

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Amendment No. 97

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 August 16, 2012,
1. Christiana Care Health Services	3. License number 07-12153-02 is amended in its entirety to read as follows:
2. Room 1127 - MAP 2 4755 Ogletown-Stanton Road Newark, Delaware 19718	4. Expiration date March 31, 2014
	5. Docket No. 030-01303 Reference No. 07-18391-01

- | | | |
|---|----------------------------------|--|
| 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

- | | | |
|-----------------|---|-------------------|
| F. Strontium 90 | F. Sealed Source (Tracerlab Model RA-2) | F. 50 millicuries |
|-----------------|---|-------------------|

Outside of Scope

- | | | |
|-----------------|--|--------------------|
| I. Strontium 90 | I. Sealed Sources (Physikalisch-Technische Werkstätten Model PTW-09) | I. 900 microcuries |
|-----------------|--|--------------------|

9. Authorized use:

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Information in this record was deleted in accordance with the Freedom of Information Act. Exemptions: Outside Scope FOIAPA 2013-0003

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- 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.
- D. and E. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- F. Storage with intent to dispose.
- G. For manual brachytherapy use in Sirtex Medical Limited SIR-Spheres delivery system.
- H. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Corporation MicroSelection Model 105.999 HDR remote afterloader unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- I. Constancy check source for thimble ionization chamber.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Christiana Hospital, 4755 Ogletown-Stanton Road, Newark, Delaware. Licensed material specified in Items 6.A. and 6.B. may be used or stored at Wilmington Hospital, 501 West 14th Street, Wilmington, Delaware; Smyrna Health and Wellness Center, 100 Main Street, Smyrna, Delaware; the Helen F. Graham Center, 4701 Ogletown-Stanton Road, Newark, Delaware. Licensed material specified in Items 6.B. may be used or stored at Cardiac Diagnostic Center, Pike Creek Sports Medicine Building, 3105 Limestone Road, Suite 202, Wilmington, Delaware; Cardiac Diagnostic Center North, 3521 Silverside Road, Concord-Plaza-Quillen Building, Suite 1-A, Wilmington, Delaware; Cardiac Diagnostic Center-Middletown, 114 Sandhill Drive, Suite 203, Middletown, Delaware. Licensed material specified in Items 6.A. through 6.C. may be used or stored at Medical Arts Pavillion, 4735 Ogletown-Stanton Road, Newark, Delaware.

11. The Radiation Safety Officer for this license is Joseph F. Solge, Jr.

<u>Isotope</u>	<u>Source Model Number</u>	<u>Maximum Activity Per Source</u>
Iodine-125	Bard Brachytherapy, Inc. Model STM1251	1 millicurie
Iridium-192	Best Medical International, Inc. Model 81-01	1 millicurie
Palladium-103	Theragenics Corporation TheraSeed Model 200	2.5 millicuries
Palladium-103	IsoAid, LLC Model IAPd-103A	2.5 millicuries
Iodine-125	IsoAid, LLC Model IAI-125A	1 millicurie
Iodine-125	Theragenics Corporation Model AgX100	1 millicurie

13. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

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

<u>Authorized Users</u>	<u>Material and Use</u>
Timothy Manzone, M.D.	35.100; 35.200; 35.300
Hung Q. Dam, M.D.	35.100; 35.200; 35.300
Erin E. Grady, M.D.	35.100; 35.200; Oral administration of sodium iodide I-131; 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
Robin A. Horn, M.D.	35.100; 35.200
Lawrence G. Narun, M.D.	35.100; 35.200
Viroon Donavanik, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Michael Dzeda, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Sunjay Aruind Shah, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Michael Sorensen, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Christopher Koprowski, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Adam Raben, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device
Jon F. Strasser, M.D.	35.400; Yttrium-90 SIR-Spheres; Iridium-192 in a remote afterloader brachytherapy device

C. The following individuals are authorized medical physicists as indicated:

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Authorized Medical Physicists
Dayee Jacob

Material and Use
Iridium-192 in a High Dose Rate Remote
Afterloader Unit for calibrations, spot-checks, and
training

Larry Simpson, Ph.D.

Iridium-192 in a High Dose Rate Remote
Afterloader Unit for calibrations, spot-checks, and
training

Hungcheng Chen

Iridium-192 in a High Dose Rate Remote
Afterloader Unit for calibrations, spot-checks, and
training

Abhirup Sarkar

Iridium-192 in a High Dose Rate Remote
Afterloader Unit for calibrations, spot-checks, and
training

Firas Mourtada, Ph.D.

Iridium-192 in a High Dose Rate Remote
Afterloader Unit for calibrations, spot-checks, and
training

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

Users

Material and Use

Larry Simpson, Ph.D.

Strontium-90 for supervision of storage; Strontium-90 for calibration of thimble ionization chamber

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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. 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.
17. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

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- 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 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.
 - D. 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.
 - E. 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.
 - F. 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.
 - G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
18. 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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19. 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.

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|----|--|-----------------------------|
| A. | Application dated September 18, 2003, except 31.11 use | [ML032731182] |
| B. | Letter with attachments dated December 12, 2003 | [ML040050631] |
| C. | Facsimiles received March 17, 2004 | [ML040830581 & ML040830585] |
| D. | Letter dated May 2, 2005 | [ML051440747] |
| E. | Letter dated March 31, 2006 | [ML060960280] |
| F. | Letter dated October 2, 2006 | [ML062770362] |
| G. | Letter dated May 15, 2008 (PET only) | [ML081640232] |
| H. | Letter dated July 14, 2008 | [ML082060544] |
| I. | Letter dated March 19, 2009 | [ML090840108] |
| J. | Letter dated November 17, 2010 | [ML103230046] |
| K. | Letter dated December 16, 2010 | [ML103540374] |
| L. | Letter dated December 28, 2010 | [ML103640028] |
| M. | Letter dated January 28, 2011 | [ML110320251] |
| N. | Letter dated January 27, 2012 | [ML12032A113] |

For the U.S. Nuclear Regulatory Commission

Date November 13, 2012

Original signed by Penny Lanzisera
By _____
Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406