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NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 54

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 March 16, 2012,
1. MedStar Washington Hospital Center	3. License number 08-03604-03 is amended in its entirety to read as follows:
2. Administration, Room 2A2 110 Irving Street, NW Washington, D.C. 20010-2975	4. Expiration date December 31, 2016 5. Docket No. 030-01325 Reference No. 08-03604-05

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		

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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
Outside of Scope		
L. Strontium 90	L. Sealed Sources (manufacturer unknown)	L. 0.0097 microcuries
Outside of Scope		

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9. Authorized use:

A. through D. and F. 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.

E. For medical use permitted by 10 CFR 35.600, in a Leksell Gamma System Model 24001 Type C gamma stereotactic radiosurgery unit. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.

G. For irradiation of materials in self-shielded irradiator devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

H. One source for medical use permitted by 10 CFR 35.600, in a Nucletron MicroSelectron Model 106.990 remote afterloader unit. The source activity may not exceed 12 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

I. through U. Possession and storage incident to disposal of sealed sources which do not meet the requirements of 10 CFR 30.32(g).

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Washington Hospital Center, 110 Irving Street, N.W., George Hyman Memorial Research Building, 108 Irving Street, N.W., and MedStar Outpatient Research Facility, 650 Pennsylvania Avenue, S.E., Washington, D.C.

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

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.G. shall be used by, or under the supervision of, individuals who have received the training described in the application dated June 26, 2006, 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 Shashadhar Mohapatra, Ph.D.

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12. Sealed sources permitted by this license include:

Isotope	Source Model Number	Maximum Activity Per Source
Strontium 90	IPL Model BF 90Ti	120 millicuries
Strontium 90	AEAT Model SICW Series	5 millicuries

Outside of Scope

13. 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."

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

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

16. As permitted by 10 CFR 20.1003, footnote 2 to the Organ Dose Weighting Factors table, when an individual's exposure to radiation is from medical procedures using fluoroscopy, and a protective lead apron is worn, the Washington Hospital Center may redefine TEDE as the sum of the effective dose equivalent from external exposures and the effective dose equivalent from internal exposures. For exposure received during the use of fluoroscopy and a protective apron, the licensee may then assign the effective dose equivalent from external exposures using the following formula, known as the Webster formula, which has been determined to provide an acceptable estimate for the effective dose equivalent from external exposures under these exposure conditions:

H_E (estimate) = 1.5 H_W + 0.04 H_N

Where the subscript W indicates a waist radiation monitor worn under the apron and the subscript N indicates a neck radiation monitor worn outside the apron.

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

18. 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.

19. 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. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

D. 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.

E. 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.

F. 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.

G. 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.

H. 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.

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

20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

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22. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

23. 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.

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

25. Notwithstanding the requirements of License Condition 26 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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26. 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 June 26, 2006, except Figures 15-17 [ML061840380]
B. Letter dated October 12, 2006 [ML062860561]
C. Letter received November 16, 2006 [ML063240412]
D. Letter dated January 5, 2007 [ML070110129]
E. Letter dated April 4, 2007 [ML071010374]
F. Letter dated March 11, 2008 [ML080980381]
G. Letter dated February 5, 2009 [ML090510622]
H. Letter dated April 22, 2009 [ML091130527]
I. Letter dated February 23, 2010 [ML100601255]
J. Letter dated February 13, 2012 [ML12045A516]
K. Letter dated March 16, 2012 [ML12089A169]
L. Letter dated April 10, 2012 [ML12115A063]
M. Letter dated June 12, 2012

For the U.S. Nuclear Regulatory Commission

Date June 19, 2012

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

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