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Department of Cardiovascular Services

NMSB2

Licensing Assistance Team
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03036212

License#47-25620-01

To Whom It May Concern:

Please amend our radioactive Material License as follows:

1. Add authorization for material identified in 10 CRF 35.100

   All radiation safety policies currently used for materials identified in 10 CFR 35.200 will be applied to the use of materials 10 CFR 35.100.

2. Add Ralph A. Stevens, MD as an authorized user for materials identified in 10 CFR 35.100 and 35.200

   Verification of Dr. Steven's training and experience can be referenced on the license for St. Mary's Medical Center. A copy of this document is attached for reference.

Thank you for your attention to this matter

Sincerely,

Tina M. Sims MD

Radiation Safety Officer

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NMSS/RGN1 MATERIALS-002

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Amendment No. 45

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 July 5, 2005,
1. St. Mary's Medical Center	3. License number 47-09576-01 is amended in its entirety to read as follows:
2. 2900 First Avenue Huntington, West Virginia 25702-1241	4. Expiration date February 28, 2013
	5. Docket No. 030-03388 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. 1.5 curies
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (Best Medical Model 81-01)	D. 800 millicuries
E. Strontium-90 permitted by 10 CFR 35.400	E. Sealed Sources (Tracerlab RA-1)	E. 100 millicuries
F. Nickel 63	F. Plated Foils (Perkin-Elmer 330-0119)	F. 5 sources, not to exceed 15 millicuries each and 75 millicuries total
G. Strontium-90	G. Sealed Sources (Bebig Model SrO.SO3; AEA Technology Model SICW series [SICW.1 and SICW.2])	G. 5 millicuries per source and 800 millicuries total
H. Iridium-192 permitted by 10 CFR 35.600	H. Sealed source (Nucletron Model 105.002 [manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.])	H. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies

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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.
D. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
E. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
F. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State
G. For use in Novoste A1000 series models for intravascular brachytherapy.
H. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Model 105.999 remote afterloader unit. The source activity may not exceed 10 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 2900 First Avenue, Huntington, West Virginia.

11. The Radiation Safety Officer for this license is M. Douglass Allan, M.S.

12. 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.

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

Authorized Medical Users	Material and Use
Marsha S. Anderson, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Richard A. Ansonelli, M.D.	35.100; 35.200
Paul D. Akers, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Paul V. Akers, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies

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Authorized Medical Users	Material and Use
Rodger A. Blake, M.D.	35.100; 35.200; 35.300
Silvestre P. Cansino, M.D.	35.100; 35.200
Linda Gail Carr, M.D.	35.200; 35.300; 35.400
Bruce S. Chertow, M.D.	35.100; 35.200; 35.300
Peter A. Chirico, M.D.	35.100; 35.200; 35.300
James Allen Cochrane, M.D.	35.100; 35.200
Ricky Jack Compton, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Hans G. Dransfeld, M.D.	35.100; 35.200; 35.300
Joseph Dransfeld, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Lee Corey Haikal, M.D.	3.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Raed A. Jitan, M.D.	35.100; 35.200
Michael V. Korona, Jr., M.D.	35.100; 35.200
Eric Lawrence Leonard, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Phillip P. Lepanto, MD.	35.300; 35.400;Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium-90 for intravascular brachytherapy procedures
Donald Lewis, M.D.	35.200; 35.200; 35.300
George J. Linsenmeyer, III, M.D.	35.100; 35.200
Charles A. McKown, M.D.	35.100; 35.200; 35.300 (except iodine 131 for treatment of carcinoma)
Richard E. McWhorter, M.D.	35.100; 35.200; 35.300

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Authorized Medical Users	Material and Use
Sanjeev Sharma, M.D.	35.300; 35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium-90 for intravascular brachytherapy procedures
William S. Sheils, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies
Charles Seigler, M.D.	35.100; 35.200
Tina M. Sias, M.D.	35.100; 35.200
Ralph A. Stevens M.D.	35.100; 35.200
George J. Vettiankal, M.D.	35.100; 35.200
Torin P. Walters, M.D.	35.100; 35.200; oral administration of sodium iodide iodine-131 for imaging and localization studies

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

Medical Physicist	Material and Use
M. Douglass Allan, M.S., DABR	Strontium-90 ophthalmic sources for physical decay corrections and calibrations; Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training
C. Thomas Brannan, M.S., DABR	Strontium-90 ophthalmic sources for physical decay corrections and calibrations; Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training
Marylene Brodeur, M.S.	Strontium-90 ophthalmic sources for physical decay corrections and calibrations; Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 in an Intravascular Brachytherapy Device for calibrations, spot-checks, and training

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

Users	Material and Use
Paul V. Akers, M.D.	Nickel-63
James Allen Cochrane, M.D.	Nickel-63
Phillip P. Lepanto, M.D.	Nickel-63
Charles A. McKown, M.D.	Nickel-63
Richard E. McWhorter, M.D.	Nickel-63

E. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

13. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

14. For sealed sources not associated with 10 CFR Part 35 use, the following condition applies:

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 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.

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E. The leak test shall be capable of detecting the presence of 185 becquerels (Bq) (0.005 microcurie) of radioactive material on the test sample. If the test reveals the presence of 185 Bq 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.

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

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

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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 and letters dated January 30, 2003 [ML030350061]
B. Letter dated August 29, 2003 [ML022460072]
C. Letter dated March 22, 2004 [ML040900227]
D. Letter dated April 30, 2004 [ML041340096]
E. Letter dated June 4, 2004 [ML041740737]

.For the U.S. Nuclear Regulatory Commission

Date September 9, 2005

By Sandra Gabriel

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406-1415
Friday, September 09, 2005 4:35:39 PM

This is to acknowledge the receipt of your letter/application ~~dated~~ undated Received 1/10/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☑ Docket # 47-25620-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141582. When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader