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U.S. NUCLEAR REGULATORY COMMISSION

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. MedXray, P.C.	In accordance with letter dated October 20, 2009 3. License number 40-27480-01 is amended in its entirety to read as follows:
2. 1417 South Minnesota Avenue Sioux Falls, South Dakota 57105	4. Expiration date January 31, 2015
	5. Docket No. 030-33335 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. 1.2 curies
D. Any byproduct material permitted by 10 CFR 31.11	D. Prepackaged Kits	D. 5 millicuries
E. Strontium-90 permitted by 10 CFR 35.1000	E. Sealed sources (BEBIG Model Sr0.S03, AEAT SICW.2)	E. 5 millicuries per source; 800 millicuries total

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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 use permitted by 10 CFR 35.300.
   D. In vitro studies
   E. One source assembly for medical use in a Novoste A1000 Series models for intravascular brachytherapy permitted under 35.1000. One source in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.

CONDITIONS

10. A. Licensed material identified in Item 6.A. through 6.D. may be used or stored at the following licensee's facilities:

    1417 S. Minnesota Avenue, Sioux Falls, South Dakota (Main Office)

    B. Licensed material identified in Items 6.E. may be stored at the following licensee's facility:

    1417 S. Minnesota Avenue, Sioux Falls, South Dakota (Main Office)

    C. Licensed material identified in Item 6.E. may be used or stored at the following licensee's facility:

    4500 W. 69th Street, Sioux Falls, South Dakota (Heart Hospital of South Dakota)

    D. Licensed material identified in Item 6.E. may be stored and used for calibration purposes by an Authorized Medical Physicist at the following licensee's facility:

    1417 S. Minnesota Avenue, Sioux Falls, South Dakota (Main Office)

11. The Radiation Safety Officer for this license is Christina P. Osmer, M.S.

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12. Licensed material is only authorized for use by, or under the supervision of individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

A. The following individuals are authorized users for medical use:

Authorized Users	Material and Use
Joseph Jeffery Baka, M.D.	35.100; 35.200; 31.11
Susan M. Duffek, M.D.	35.100; 35.200; 31.11
Thomas E. Masterson, M.D.	35.100; 35.200; 31.11
Patrick A. Nelson, M.D.	35.100; 35.200; 31.11
Matthew T. Pardy, M.D.	35.100; 35.200; 31.11
Brad Alan Paulson, M.D.	35.100; 35.200; 31.11
Josie R. Alpers, M.D.	35.100; 35.200; 35.300; 31.11
Sabina Choudhry, M.D.	35.100; 35.200; 35.300; 31.11
Thomas M. Cink, M.D.	35.100; 35.200; 35.300; 31.11
Charles F. Flohr, M.D.	35.100; 35.200; 35.300; 31.11
Thomas W. Free, D.O.	35.100; 35.200; 35.300; 31.11
Christopher Gregory, M.D.	35.100; 35.200; 35.300; 31.11
Michael J. Kihne, M.D.	35.100; 35.200; 35.300; 31.11
Daryl C. Rife, M.D.	35.100; 35.200; 35.300; 31.11
Andrew I. Soye, M.D.	35.100; 35.200; 35.300; 31.11
Cameron L. Stokka, M.D.	35.100; 35.200; 35.300; 31.11
Gary L. Famestad, M.D.	35.100; 35.200; Oral administration of sodium iodide Iodine-131 for imaging and localization studies; 31.11
Randal L. Welter, M.D.	35.100; 35.200; Oral administration of sodium iodide Iodine-131 for imaging and localization studies; 31.11
Edward J. Czarnecki, M.D.	35.100; 35.200; Oral administration of sodium iodide Iodine-131 for imaging and localization studies; 31.11

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Authorized Users	Material and Use
Kathleen Schneekloth, M.D.	35.300; 35.1000 only for Strontium-90 for intravascular brachytherapy
Steven C. McGraw, M.D.	35.300; 35.1000 only for Strontium-90 for intravascular brachytherapy
Kirsten Erickson, M.D.	35.1000 only for Strontium-90 for intravascular brachytherapy

B. The following individuals are authorized medical physicists:

Authorized Medical Physicists	Material and Use
Charles M. Carver, M.S.	Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks and training.
Richard J. Massoth, Ph.D.	Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks and training.
Jeffrey P. Masten, M.S.	Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks and training.
Christina P. Osmer, M.S.	Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks and training.

C. 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. Intravascular brachytherapy afterloader devices shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only 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 conditions apply:

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. 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.

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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 leak 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.

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. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 612 E. Lamar Blvd., Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

15. Sealed sources 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 6 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.

17. 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.

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.

    A. Application dated September 29, 2004
    B. Facsimile dated February 23, 2005

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: January 20, 2010

By: _____
Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011