NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 61

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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 letter dated **December 19, 2007,**
1. Providence Hospital Department of Nuclear Radiology	3. License number 21-02802-03 is amended in its entirety to read as follows:
2. 16001 West Nine Mile Road Southfield, MI 48037	4. Expiration date October 31, 2013
	5. Docket No. 030-02022 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 curie
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (For Cesium-137, 3M Model No.6D6C-CA and for Iodine-125, Amersham Health/Medi-Physics Model Nos. 6711 (OncoSeed) and 6733 (EchoSeed)	D. 1 curie
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged kits	E. As needed
F. Depleted Uranium	F. Metal	F. As needed
G. Iridium-192 permitted by 10 CFR 35.1000	G. Sealed source seeds encased in nylon ribbon (Best Industries Model No. 81-01)	G. No single source seed to exceed 35 millicuries; in a 3 ribbon set containing 6, 10, or 14 seeds per ribbon; 1.1 curies total per ribbon set; 2 ribbon sets total.
H. Phosphorus-32 permitted by 10 CFR 35.1000	H. Sealed source wires (Guidant Corporation Model GDT P-32 Series)	H. Three source assemblies not to exceed 600 millicuries each.

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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
I. Strontium-90 permitted by 10 CFR 35.1000	I. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)	I. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries

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. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

E. In-vitro studies.

F. Shielding in a linear accelerator.

G. One ribbon set to be used in the Cordis Checkmate Catheter System intravascular brachytherapy device for medical use permitted by 10 CFR 35.1000; and one ribbon set in a shipping container for ribbon set replacement.

H. One source assembly to be used in a Guidant Corporation Model GALILEO SERIES intravascular brachytherapy HDR device for medical use permitted by 10 CFR 35.1000; source assemblies may also be used for physics calibrations and quality assurance testing; two source assemblies in a shipping containers for replacement and disposal.

I. For use in Novoste Model A1000 series devices for intravascular brachytherapy, physics calibrations and quality assurance testing, as permitted by 10 CFR 35.1000.

CONDITIONS

10. Locations of use:

A. 16001 West Nine Mile Road, Southfield, Michigan.

B. Licensed material in 10 CFR 35.100, 35.200, 35.300 (excluding those iodine-131 administrations which require hospitalization of the patient for radiation protection purposes), 35.400 (limited to iodine-125 seeds for prostate implants) and Item 6.F. may be used at 47601 Grand River Avenue, Novi, Michigan.

C. Licensed material in 10 CFR 35.100, 35.200 and 35.300 (excluding those iodine-131 administrations which require hospitalization of the patient for radiation protection purposes) may be used at 30055 Northwestern Highway, Farmington Hills, Michigan.

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11. Radiation Safety Officer: Allan D. Fraiberg, M.D.

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

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

B. The following individuals are authorized users for medical uses:

Authorized Users	Material and Use
Allan D. Fraiberg, M.D.	10 CFR 35.100, 35.200, 35.300 and in-vitro studies.
David Lawrence Osher, M.D.	10 CFR 35.100, 35.200, 35.300 and in-vitro studies.
Roger L. Gonda, Jr., M.D.	10 CFR 35.100, 35.200, 35.300 and in-vitro studies.
J. F. Brown, M.D.	10 CFR 35.100, 35.200, 35.300 and in-vitro studies.
Sheldon S. Stoffer, M.D.	10 CFR 35.200 (limited to technetium 99m for thyroid imaging) and 35.300.
Laura Freedman, M.D.	10 CFR 35.400.
Janice LaRouere, M.D.	10 CFR 35.400.
Patrick W. McLaughlin, M.D.	10 CFR 35.400. and iridium-192 in the Cordis Checkmate Catheter system, phosphorus-32 in the Guidant Galileo intravascular brachytherapy device for medical use permitted by 35.1000 and strontium-90 in the Novoste Model A1000 system.
June Lee Chan, M.D.	10 CFR 35.400, phosphorus-32 in the Guidant Galileo intravascular brachytherapy device for medical use permitted by 35.1000 and strontium-90 in the Novoste Model A1000 system.
Charlie C. Pan, M.D.	10 CFR 35.400.
Gerard K. Surmann, M.D.	10 CFR 35.100, 35.200 and 35.300.

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

Authorized Medical Physicists	Material and Use
Vrinda Narayana, Ph.D.	Iridium-192 in a Cordis Checkmate intravascular brachytherapy device for calibrations, spot-checks, and training, Phosphorus-32 in a Guidant Corporation Model GALILEO SERIES intravascular brachytherapy HDR device for physics calibrations and quality

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	assurance testing and strontium-90 in the Novoste Model A1000 system intravascular brachytherapy devices.
Peter Roberson, Ph.D.	Iridium-192 in a Cordis Checkmate intravascular brachytherapy device for calibrations, spot-checks, and training, Phosphorus-32 in a Guidant Corporation Model GALILEO SERIES intravascular brachytherapy HDR device for physics calibrations and quality assurance testing and strontium-90 in the Novoste Model A1000 system intravascular brachytherapy devices.
Brett Miller, M.S.	Iridium-192 in a Cordis Checkmate intravascular brachytherapy device for calibrations, spot-checks, and training, Phosphorus-32 in a Guidant Corporation Model GALILEO SERIES intravascular brachytherapy HDR device for physics calibrations and quality assurance testing and strontium-90 in the Novoste Model A1000 system intravascular brachytherapy devices.

D. Licensed material listed in **Subitem Nos. G., H. and I.** of Item Nos. 6., 7., 8., and 9. shall be used by or under the supervision of an Authorized User, as defined in 10 CFR 35.2, and in the physical presence of an Authorized User or an Authorized Medical Physicist, as defined in 10 CFR 35.2. The Authorized User shall consult with an Authorized Medical Physicist and an interventional cardiologist prior to each treatment.

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. In lieu of 10 CFR 35.404(b), immediately after retracting the source from the patient into its shielded position in the Cordis Checkmate System and/or the Guidant Galileo Series and/or the Novoste Model A1000 Series System intravascular brachytherapy device, a radiation survey shall be made of the patient and the Cordis Checkmate System and/or the Guidant Galileo Series and/or the Novoste Model A1000 Series System intravascular brachytherapy device, as appropriate, with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(c).

15. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

    A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each Cordis Checkmate System treatment and/or Guidant Galileo Series and/or the Novoste Model A1000 Series System intravascular brachytherapy treatment.

    B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

    C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

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D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(c).

16. 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.

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.

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.

17. 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.

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

19. 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.

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

21. 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 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. Applications dated March 20, 2001, October 18, 2002 (with attachments including application received October 22, 2002), February 13, 2003, April 14, 2003, August 20, 2003, April 12, 2004 and June 29, 2004; and

    B. Letters dated August 19, 2003, September 17, 2003, November 6, 2003, June 29, 2004, September 21, 2004, October 4, 2005 (excluding Items 1, 2 and 3), **December 19, 2007 and February 12, 2008.**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 16 2008

By _____
Loren J. Hueter
Materials Licensing Branch
Region III