U.S. Nuclear Regulatory Comission
Materials Licensing
Region III
2443 Warrenville Road STE 210
Lisle, Il 60532-4352

November 2, 2004

Reference: Amendment of NRC license # 22-32236-01
HealthEast Woodwind Hospital, Woodbury, MN 55125

Dear Sirs:
Enclosed please find two (2) copies of a request to amend our NRC License # 22-32236-01 to add Authorized Users for radiopharmaceutical therapy under 35.300 and conduct clinical procedures using greater than 30 microcuries of Iodine-125 or Iodine I-131. Information regarding the Authorized Users for radiopharmaceutical therapy under 35.300 is provided.

Amend the current NRC License to add:
Authorized Users for radiopharmaceutical therapy under 35.300 for clinical procedures using ≥ 30 microcuries of Iodine-125 or Iodine 131

As per NRC Form 313 and Applicable Items from NRC Regulatory Guide 10.8 Revision 2 and 10 CFR Part 35 the following information applies:

Item 7. Individuals Responsible for Radiation Safety Program (Authorized Users):
All of the following proposed Authorized Users are currently listed as Authorized Users on NRC License # 22-01448-01, HeathEast-St. Joseph's Hospital, 69 West Exchange Street, St Paul, MN 55102 for 35.300

Authorized Users	Materials and Use For material in CFR Part—
1. Carl Bretzke, MD	35.300
2. Steven C. Hommeyer, MD	35.300
3. Timothy V. Myers, MD	35.300
4. Jeffrey M Barkmeier, MD	35.300
5. Mark W. Berger, MD	35.300
6. Joseph J. Baraga, MD	35.300
7. Dominic F. Frecentese, MD	35.300
8. Ronnell A Hansen, MD	35.300
9. Michael Steven Rosenberg, MD	35.300

Contact Person:

Deb Bauer
HealthEast Woodwinds Hospital
Outpatient Services
1925 Woodwinds Drive
Woodbury, MN 55125 Phone: 615-232-6802 Fax: 615-232-0654

Sincerely,

Debra f Friend Director of Patient Care Services
Deb Bauer, Management

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 64

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 application dated June 4, 2004,
1. HealthEast - St. Joseph's Hospital	3. License number 22-01448-01 is amended in its entirety to read as follows:
2. 69 West Exchange Street St. Paul, MN 55102	4. Expiration date November 30, 2004
	5. Docket No. 030-02200 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. As needed (not to exceed one curie of I-131)
D. Any byproduct material permitted by 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 2 curies
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged kits	E. As needed
F. Uranium depleted in Uranium-235	F. Cadmium plated metal	F. As needed
G. Gadolinium-153	G. Sealed sources (North American Scientific Model 3601)	G. 4 sources not to exceed 300 millicuries each
H. Strontium-90	H. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)	H. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-01448-01

Docket or Reference Number
030-02200

Amendment No. 64

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. Medical use permitted by 10 CFR 35.300.

   D. Medical use permitted by 10 CFR 35.400.

   E. In vitro studies.

   F. Shielding in a linear accelerator.

   G. Two sources to be used in ADAC Laboratories Transmission Line Source Housing VANTAGE devices for diagnostic medical use permitted by 10 CFR 35.500. Two sources in shipping containers for replacement of the sources.

   H. The source assemblies may be used in Novoste, Model A1000 series devices for medical use permitted by 10 CFR 35.1000; source assemblies may also be used for physics calibrations and quality assurance testing; one source assembly in a shipping container for replacement and disposal.

CONDITIONS

10. Locations of Use:

   A. 69 West Exchange Street, St. Paul, Minnesota.

   B. Licensed material in 10 CFR 35.100 and 35.200 may also be used at Bethesda Lutheran Medical Center, 559 Capital Blvd., St. Paul, Minnesota and at the Divine Redeemer Complex located at 725 19th Avenue North, South St. Paul, Minnesota.

   C. Licensed material in Subitem No. 6.H. may be used and stored at the licensee's facilities located at 69 West Exchange Street, St. Paul, Minnesota.

11. A. Radiation Safety Officer: Christopher A. Jackson, M.D.

   B. Authorized Medical Physicist: Guy Sherwood, DABR.

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

   A. 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.

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-01448-01

Docket or Reference Number
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Amendment No. 64

B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users	Material and Use
Jeffrey E. Magnuson, M.D.	10 CFR 35.200, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Carl Bretzke, M..D.	10 CFR 35.100, 35.200, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Steven C. Hommeyer, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
William C. Doebler, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding I-131 for treatment of thyroid carcinoma), 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Frank Maguire, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding I-131 for treatment of thyroid carcinoma) and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Timothy V. Myers, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding I-131 for treatment of thyroid carcinoma) and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Graydon T. Page, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding I-131 for treatment of thyroid carcinoma) and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Dennis Runck, Jr., M.D.	10 CFR 35.100, 35.200, 35.300 (excluding I-131 for treatment of thyroid carcinoma) and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
David Eckmann, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Steve Johnson, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Douglas Bruce Ketcham, M.D.	10 CFR 35.100, 35.200, 35.300 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Robert H. Weinmann, IV, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Duane O. Ytredal, M.D.	10 CFR 35.400 and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices for medical use permitted by

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-01448-01

Docket or Reference Number
030-02200

Amendment No. 64

	35.1000.
Michael T. Madison, M.D.	10 CFR 35.100, 35.200 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Jeffrey M. Barkmeier, M.D.	10 CFR 35.100, 35.200 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Mark W. Berger, M.D.	10 CFR 35.100, 35.200, 35.300 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Christopher A. Jackson, M.D.	10 CFR 35.100, 35.200, 35.300 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Joseph J. Baraga, M.D., Ph.D.	10 CFR 35.100, 35.200 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Dominic F. Frecentese, M.D.	10 CFR 35.100, 35.200, 35.300 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Ronnell A. Hansen, M.D.	10 CFR 35.100, 35.200, 35.300 and Gd-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Michael Steven Rosenberg, M.D.	10 CFR 35.100, 35.200 and gadolinium-153 in VANTAGE devices for diagnostic medical use permitted by 35.500.
Warren McGuire, M.D.	10 CFR 35.400 and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices for medical use permitted by 35.1000.
Vichaivood Liengswangwong, M.D.	10 CFR 35.400 and strontium-90 in Novoste Model A1000 series intravascular brachytherapy device for medical use permitted by 35.1000.
Ellen E. Bellairs, M.D.	10 CFR 35.300 and 35.400.
Janel Anne Cox, M.D.	10 CFR 35.400

13. Licensed material listed in No. H. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition 12., and in the physical presence of an authorized user named in Condition 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition 12. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.

14. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., manual dated March 2, 1982.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-01448-01

Docket or Reference Number
030-02200

Amendment No. 64

15. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instructions manual dated June 20, 1983.

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

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. In lieu of 10 CFR 35.404(b), immediately after retracting the source from the patient into its shielded position in the Novoste A1000 series intravascular brachytherapy device, a radiation survey shall be made of the patient and the Novoste Beta-Cath System devices 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).

19. 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 Novoste A1000 series 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.

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

20. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

    B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    C. Sealed sources need not be leak tested if:

        (i) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

        (ii) they are not designed to emit alpha particles, 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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Amendment No. 64

D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(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 III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

21. The licensee shall conduct a physical inventory every 6 months to account for all sealed 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.

22. 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. Applications dated August 17, 1994 (excluding attachment 10.C.) and March 20, 2001;

B. Letters received April 5, 1991, and July 8, 1991; and

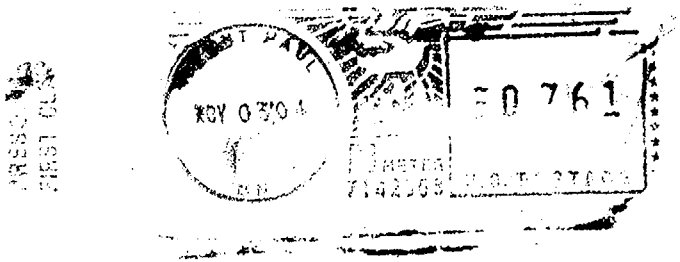
C. Letters dated September 29, 1995, February 15, 1996 (with enclosed letters dated February 15, 1996 and February 16, 1996), July 18, 1996 (with attachments), September 20, 1996, March 20, 2001, and June 21, 2001.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 13 2004

By _____
Patricia J. Pelke
Materials Licensing Branch
Region III

Woodwinds
Health Campus



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