UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 12, 2007

Docket No. 03003348 License No. 45-11035-01
Control No. 139636

Robert W. Hoefer
Vice President, Operations
Sentara Virginia Beach General Hospital
1060 First Colonial Road
Virginia Beach, VA 23454

SUBJECT: SENTARA VIRGINIA BEACH GENERAL HOSPITAL, LICENSE AMENDMENT, CONTROL NO. 139636

Dear Mr. Hoefer:

This refers to your license amendment requests dated October 6 and December 8, 2006. Enclosed with this letter is the amended license adding Deepak R. Talreja, M.D. as authorized user for imaging and localization studies, and authorizing you to perform radiopharmaceutical therapy at the Princess Anne Health Campus.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Sandra Gabriel***

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 43

cc:
Sandy J. Wolff, M.S., Radiation Safety Officer

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**SUNSI Review Complete:** SGabriel
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U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 43

# 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 letters dated October 6 and December 8, 2006, |
|---|---|
| 1. Sentara Virginia Beach General Hospital | 3. License number 45-11035-01 is amended in its entirety to read as follows: |
| 2. 1060 First Colonial Road<br>Virginia Beach, Virginia 23454 | 4. Expiration date August 31, 2014 |
| | 5. Docket No. 030-03348<br>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. 500 millicuries |
| D. Any byproduct material permitted by 10 CFR 35.400 | D. Sealed source (Theragenics Model 200) | D. 1,000 millicuries |
| E. Strontium 90/Yttrium 90 | E. Sealed Source (BEBIG Model Sr0.S03; AEAT Model SICW.2 Series) | E. 5 millicuries per source and 800 millicuries total |
| F. Yttrium 90 | F. Any | F. 200 millicuries |
| G. Strontium 90 | G. Sealed sources (ARC Model B-1 and Radiochemical Centre Model SIC.7) | G. 60 millicuries |

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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. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
E. For use in Best Vascular, Inc. A1000 series models for intravascular brachytherapy.
F. Calibration of the licensee's instruments.
G. For storage incident to disposal of an ARC Model B-1 ophthalmic applicator and a Nuclear Enterprises, Ltd. Model 2503 Thimble Ionization Chamber Calibrator.

CONDITIONS

10. A. Licensed material in Items 6.A. through 6.G. may be used or stored at the licensee's facilities located at 1060 First Colonial Road, Virginia Beach, Virginia.

B. Licensed material in Item 6.B. may be used or stored at the licensee's facilities located at Tidewater Cardiovascular Institute (TCI), 1708 Old Donation Parkway, Virginia Beach, Virginia, and Advanced Imaging Center, 1080 First Colonial Road, Virginia Beach, Virginia.

C. Licensed material in Item 6.C. may be used or stored at the licensee's facilities located at Princess Anne Health Campus, Suite 100, 1950 Glenn Mitchell Drive, Virginia Beach, Virginia.

11. The Radiation Safety Officer for this license is Sandy J. Wolff, CHP, DABR.

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 Users | Material and Use |
|---|---|
| Harry Alexander Allan, M.D. | 35.100; 35.200 |
| Ricardo De la Torre, M.D. | 35.100; 35.200; 35.300 |
| Mark Cramer, M.D. | 35.100; 35.200; 35.300 except Iodine 131 in quantities greater than 33 millicuries |
| John G. Kenerson, M.D. | 35.200 |

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| Authorized Users | Material and Use |
|---|---|
| Man Hyong Kim, M.D. | 35.100; 35.200 |
| John D. O'Neil, M.D. | 35.100; 35.200 |
| Jeffrey A. Klein, M.D. | 35.100; 35.200; 35.300 except Iodine 131 in quantities greater than 33 millicuries |
| Douglas Charles Brown, M.D. | 35.100; 35.200 |
| Alan Zabell, M.D. | 35.300; 35.400; Strontium 90 for intravascular brachytherapy procedures; Yttrium 90 for instrument calibration |
| Mark E. Shaves, M.D. | 35.300; 35.400; Strontium 90 for intravascular brachytherapy procedures |
| Granville Batte, M.D. | 35.100; 35.200; 35.300 |
| Robert Mariano, M.D. | 35.100; 35.200 |
| Demetrios James Kazakis, M.D. | 35.100; 35.200 |
| Jonathan C. White, M.D. | 35.100; 35.200; 35.300 |
| Deepak R. Talreja | 35.200 |

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

| Authorized Medical Physicists | Material and Use |
|---|---|
| Holly S. Dalton, M.S. | Strontium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training |
| Alexander Gray, M.S. | Strontium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training |
| Wen-Jong Wang, M.S. | Strontium 90 in an Intravascular Brachytherapy Afterloader 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 |
|---|---|
| Sandy J. Wolff, CHP, DABR | Strontium 90 (supervision of storage) |

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. The authorized medical physicist shall perform independent measurement of intravascular brachytherapy source output, before the first patient treatment, using a dosimetry system that meets the requirements of 10 CFR 35.630(a).

15. The licensee shall survey the patient and intravascular brachytherapy catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10 CFR 35.404.

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 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. 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.

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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.

E. 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.

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.

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. 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.

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

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

20. 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), 40.36(b), and 70.25(d) for establishing decommissioning financial assurance.

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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 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 February 19, 2004, excluding attachments 9.2-9.4 and Item 10 (ML040620116)
    B. Letter dated May 12, 2004 (ML041390243)
    C. Letter dated June 25, 2004 (ML041950373)
    D. Letter dated January 4, 2006 (ML060230101)
    E. Letter dated May 24, 2006 (ML061660533)
    F. Letter dated October 6, 2006 (ML063110365)
    G. Letter dated January 11, 2007

For the U.S. Nuclear Regulatory Commission

Date January 12, 2007

By ***Original signed by Sandra Gabriel***

Sandra Gabriel
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406