

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 19, 2005

Docket No. 03031046 Control No. 136598 License No. 37-28359-01

John Kristel
Chief Operating Officer
Tenet Health System Graduate, LLC
d.b.a. Graduate Hospital
One Graduate Plaza
Philadelphia, PA 19146

SUBJECT: TENET HEALTH SYSTEM GRADUATE, LLC, d.b.a. GRADUATE HOSPITAL,

ISSUANCE OF LICENSE AMENDMENT, CONTROL NO. 136598

Dear Mr. Kristel:

This refers to your license amendment request. Enclosed with this letter is the amended license

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 available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Michelle Beardsley

Michelle Beardsley Health Physicist Medical Branch Division of Nuclear Materials Safety

Enclosure: Amendment No. 22

NRC Web site addresses NRC regulations

J. Kristel 2

Tenet Health System Graduate, LLC

http://www.nrc.gov/reading-rm/doc-collections/cfr/

Licensing guidance

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

General Policy and Procedure for NRC Enforcement Actions

Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf

206 of the Energy Reorganization Act of 1974

http://www.nrc.gov/who-we-are/governing-laws.html

CC:

Gary Coren, M.D., Radiation Safety Officer

| J. Kristel | | |
|------------------------------|-----------|--|
| Tanat Haalth System Graduata | \square | |

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| OFFICE | DNMS/RI | Ν | DNMS/RI | DNMS/RI | | |
|--------|----------------|---|---------|---------|--|--|
| NAME | MBeardsley/MRB | | | | | |
| DATE | 4/19/2005 | | | | | |

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OFFICIAL RECORD COPY

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 4 PAGES
Amendment No. 22

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.

| below. | | | |
|--|--|--|---|
| Licensee | | In accordance with | n the letter dated |
| | | March 1, 2005, | |
| 1. Tenet Health System Graduate, L. | L.C. | 3. License number 37 | 7-28359-01 is amended in |
| d.b.a. Graduate Hospital | CLEAR A | its entirety to read | as follows: |
| 2. One Graduate Plaza | Cr | 4. Expiration date Jar | nuary 31, 2014 |
| Philadelphia, Pennsylvania 19146 | / | 5. Docket No. 030-3 | 1046 |
| (S) | | Reference No. | 2 |
| Byproduct, source, and/or special nuclear material | 7. Chemical and/or p | ohysical 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 Shills | A. As needed |
| B. Any byproduct material permitted by 10 CFR 35.200 | B. Any | E | 3. As needed |
| C. Any byproduct material permitted by 10 CFR 35.300 | C. Any | No. | C. 500 millicuries |
| D. Any byproduct material permitted by 10 CFR 35.400 | D. Sealed source Physics, Inc. N 6711,6715, 67 Best Medical I Inc. Model 81- | Models 733 and 6735, nternational, | D. 2000 millicuries |
| E. Any byproduct material permitted by 10 CFR 35.400 | E. Sealed source series 6500, M Inc. Model CD | /ledi-Physicis, | E. 600 millicuries |
| F. Strontium 90/ Yttrium 90 | | es (BEBIG F 3 or AEAT SICW 1 and SICW.2) | F. 5.0 millicuries per source; 500 millicuries total |

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 iodine-131 study or procedure permitted by 10 CFR 35.300.

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| | | License Number 37-28359-01 | | | | | |
| | WATERIALS LICENSE | Docket or Reference Number 030-31046 | | | | | |

Amendment No. 22

- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- F. Notwithstanding the requirements of 10 CFR 35.400, for use in Novoste A1000 series devices (BEBIG Model Sr0.S03 or AEAT SICW Series (SICW.1 and SICW.2) for intravascular brachytherapy.

CONDITIONS

- 10. Licensed material may be used or stored at the licensee's facilities located at 1800 Lombard Street except the Atrium Suite, Philadelphia, Pennsylvania; and the Diagnostic Services Building, 19th and South Streets, Philadelphia, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Gary Coren, 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, authorized nuclear pharmacist, 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 |
|----------------------------|--|
| Lydia Komarnicky, M.D. | 35.400; Strontium90/Yttrium 90 in Novoste A1000 series systems |
| Franco Maria Nichini, M.D. | 35.400; Strontium90/Yttrium 90 in Novoste A1000 series systems |
| Mark Alden, M.D. | 35.400; Strontium90/Yttrium 90 in Novoste A1000 series systems |
| Jorge Freire, M.D. | 35.400; Strontium90/Yttrium 90 in Novoste A1000 series systems |
| Gary Coren, M.D. | 35.100; 35.200 |
| Marc Silver, D.O. | 35.100; 35.200; 35.500 |
| Martin Friedman, D.O. | 35.100; 35.200; 35.300 |
| Eli Dweck, M.D. | 35.100; 35.200; 35.300 |
| Michael Brian Kates, M.D. | 35.100; 35.200; 35.300, except thyroid carcinoma |
| Steven Greensweig, D.O. | 35.100; 35.200 |
| Lesley Hughes, M.D. | 35.400 |
| | |

| License Number 37-28359-01 | | | |
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| MATERIALS LICENSE SUPPLEMENTARY SHEET 37-28359-01 Docket or Reference Number 030-31046 Amendment No. 22 Bruce Thaler, M.D. 35.100; 35.200; 35.300 | NRC FOR | 2M 374A U.S. NUCLEAR REGULATORY COMMIS | SION PAGE 3 of 4 PAGES |
| 030-31046 030-31046 Amendment No. 22 | | | |
| Bruce Thaler, M.D. 35.100; 35.200; 35.300 | | | |
| | | | Amendment No. 22 |
| | | | |
| | | Bruce Thaler, M.D. | 5.100; 35.200; 35.300 |
| Alan Rebenstock, M.D. 35.100; 35.200; 35.300 | | Alan Rebenstock, M.D. 35 | 5.100; 35.200; 35.300 |
| C. Intravascular brachytherapy procedures shall be conducted under the supervision of an 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. | C. | user, who will consult with the interventional card prior to initiating treatment. The procedures shall | iologist/physician and authorized medical physicist be conducted in the physical presence of the |
| D. The following individuals are authorized medical physicists as indicated: | D. | The following individuals are authorized medical | physicists as indicated: |
| Authorized Medical Physicists <u>Material and Use</u> | | Authorized Medical Physicists Ma | <u>iterial and Use</u> |
| Patrick Glennon, CHP Strontium 90/Yttrium 90 in a Novoste Beta-Cath System for calibrations, spot-checks, and training | | | |

- 13. 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.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. 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.

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- 16. 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 July 26, 2004 (ML042250346)
 - B. Letter received December 20, 2004(ML043640155)
 - C. Letter dated January 4, 2005 (ML050210266)
 - D. Letter dated March 1, 2005 (ML050970028)



Date ____ April 19, 2005

Original signed by Michelle Beardsley

Michelle Beardsley Medical Branch Division of Nuclear Materials Safety Region I King of Prussia, Pennsylvania 19406