



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

February 24, 2005

Docket No. 03011706
Control No. 136317

License No. 37-16826-01

Joseph Edgar
Senior Vice President for Operations
Gettysburg Hospital Wellspan
147 Gettys Street
Gettysburg, PA 17325

SUBJECT: GETTYSBURG HOSPITAL WELLSPAN, ISSUANCE OF LICENSE
AMENDMENT, CONTROL NO. 136317, AND INSPECTION 03011706/2005001
AND NOTICE OF VIOLATION

Dear Mr. Edgar:

This refers to your license amendment request dated February 14, 2005, and your notification letter dated January 11, 2005. Enclosed with this letter is the amended license. This amendment adds the new facility for nuclear medicine as requested. Please note that your license was written in a format compatible with the revised 10 CFR Part 35.

However, in your February 14, 2005, letter, you stated that the move was completed by January 2005. Based on the results of the review of your amendment request, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. Because your license permits activities that include the use of byproduct materials authorized under 10 CFR 35.300, 10 CFR 35.13 requires that you apply for and receive a license amendment before adding to or changing areas of use identified on the license. Since you moved these activities by January 2005, and that date was prior to the receipt of the enclosed amendment, this is a violation of 10 CFR 35.13.

This violation was evaluated in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Enforcement Policy**. The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited in the Notice because the violation was identified by the NRC during the review of the license amendment request.

J. Edgar
Gettysburg Hospital Wellspan

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You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Based on the information submitted with your February 14, 2005 letter, the old facilities used by the Nuclear Medicine Department and Stress Lab may be released for unrestricted use.

Please review the enclosed amended license carefully and be sure that you understand and fully implement all the conditions incorporated into it. 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).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:

1. Amendment No. 29
2. Notice of Violation
3. NRC Information Notice 96-28

cc:

Joseph C. Jones, M.D., Radiation Safety Officer

J. Edgar
Gettysburg Hospital Wellspan

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DATE	2/24/2005		2/24/ 2005					

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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.

<p style="text-align: center;">Licensee</p> <p>1. Gettysburg Hospital Wellspan</p> <p>2. 147 Gettys Street Gettysburg, Pennsylvania 17325</p>	<p>In accordance with the letters dated January 11, 2005, and February 14, 2005,</p> <p>3. License number 37-16826-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date August 31, 2013</p> <hr/> <p>5. Docket No. 030-11706 Reference No.</p>
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 1000 millicuries</p> |
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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 therapy procedure permitted by 35.300, except iodine-131, for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities at 147 Gettys Street, Gettysburg, Pennsylvania.
11. The Radiation Safety Officer for this license is Joseph C. Jones, M.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
37-16826-01Docket or Reference Number
030-11706

Amendment No. 29

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

- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Amy-Beth Garazo, M.D.	35.100, 35.200
Marie V. Spagnoli, M.D.	35.100, 35.200
Rukhsana Rahman, M.D.	35.100, 35.200
Joseph C. Jones, M.D.	35.100, 35.200
Frank L. D'Amelio, M.D.	35.100; 35.200
Michael R. Watson, M.D.	35.300, except iodine-131

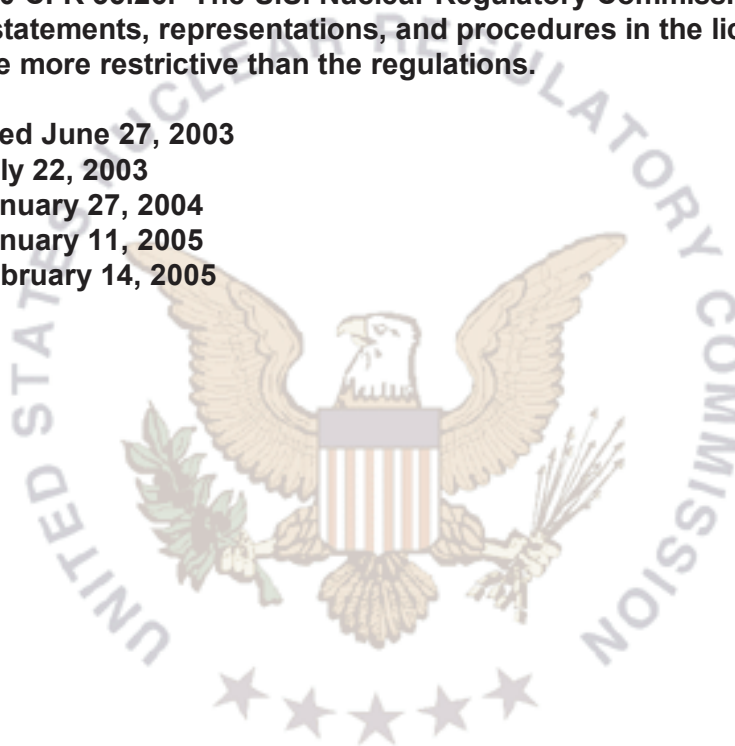
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
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15. 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 June 27, 2003
- B. Letter dated July 22, 2003
- C. Letter dated January 27, 2004
- D. Letter dated January 11, 2005
- E. Letter dated February 14, 2005



For the U.S. Nuclear Regulatory Commission

Date February 23, 2005
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By Original signed by Richard McKinley
Richard McKinley
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406