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

February 1, 2005

Docket No. 03014475 License No. 45-18103-01
Control No. 135942

Sean Dardeau
CEO
Southampton Memorial Hospital
100 Fairview Drive
P.O. Box 817
Franklin, VA 23851

SUBJECT: SOUTHAMPTON MEMORIAL HOSPITAL, ISSUANCE OF LICENSE AMENDMENT, CONTROL NO. 135942 AND NOTICE OF VIOLATION

Dear Mr. Dardeau:

This refers to your license amendment request dated October 21, 2004, and your notification letter dated February 4, 2004. Enclosed with this letter is the amended license. This amendment adds the new facility for nuclear medicine as requested.

However, in your October 21, 2004 letter, Ms. Cynthia Carr stated that the move was completed by Thursday, July 1 (2004). 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 July 1, 2004, and that date was prior to the receipt of the enclosed amendment, this is a violation of 10 CFR 35.13. In addition, please note that even if your NRC license only authorized activities under 10 CFR 35.100 and 200, 10 CFR 35.14(b)(4) requires that the NRC be notified no later than 30 days after a licensee changes the areas of use for byproduct materials authorized under 10 CFR 35.100 and 35.200. Your notification letter dated February 4, 2004, was sent before the change to your areas of use. Also, your letter dated October 21, 2004, would have exceeded this 30-day notification requirement.

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.

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 October 21, 2004 letter, the old facilities used by the Nuclear Medicine Department and Stress Lab may be released for unrestricted use.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. Please note that some portions of your license have been modified to reflect the current standard format for NRC licenses. These modifications include the removal of requirements for sealed sources since you are not specifically authorized to possess and use sealed sources for other than medical use in the 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).

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.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

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. 14
2. Notice of Violation
3. NRC Information Notice 96-28

cc:
Cynthia S. Carr, C.N.M.T, Radiation Safety Officer

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Enclosure 2

NOTICE OF VIOLATION

Southampton Memorial Hospital
Franklin, Virginia

Docket No. 030-14475
License No. 45-18103-01

During a review of a license amendment request completed on January 10, 2005, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 35.13(e) states that a licensee shall apply for and must receive a license amendment before it adds to or changes the area of use identified in the application or on the license, except for areas of use only in accordance with either 10 CFR 35.100 or 35.200.
>
> Contrary to the above, on or before July 1, 2004, the licensee changed the areas of use for byproduct material authorized on the license under 10 CFR 35.100, 35.200, and 35.300; but the licensee did not apply for and receive a license amendment prior to this change. Specifically, the license amendment request to change the area of use was not sent until October 21, 2004.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Southampton Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because 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, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must

specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 1st day of February 2005

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 letter dated October 21, 2004,
1. Franklin Hospital Corporation d/b/a Southampton Memorial Hospital	3. License number 45-18103-01 is amended in its entirety to read as follows:
2. 100 Fairview Drive Franklin, VA 23581	4. Expiration date May 31, 2005
	5. Docket No. 03014475 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. 1.5 curies
D. Any byproduct material permitted by 10 CFR 31.11	D. Prepackaged Kits	D. As needed

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 for which the patient can be released under the provisions of 10 CFR 35.75.
D. In vitro studies.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
45-18103-01

Docket or Reference Number
03014475

Amendment No. 14

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 100 Fairview Drive, Franklin, Virginia.
11. 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:

Authorized Users	Material and Use
Elizabeth H. Moseley, M.D.	35.100; 35.200; 31.11
Allison M. Smith, M.D.	35.100; 35.200; 31.11
Lori Keith Taylor, M.D.	35.100; 35.200; 31.11
John V. Whitbeck, M.D.	35.100; 35.200; 31.11
Robert A. Woolfit, M.D.	35.100; 35.200; 31.11
George H. Christian, M.D.	35.100; 35.200; 35.300; 31.11
Patsy J. Liacono, M.D.	35.100; 35.200; 35.300 except iodine-131 in quantities greater than 33 millicuries; 31.11
Lamar H. Smith, M.D.	35.100; 35.200; 35.300 except iodine-131 in quantities greater than 33 millicuries; 31.11

12. 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.

13. 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
45-18103-01

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03014475

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14. 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 January 26, 1995
    B. Letter dated April 30, 1995
    C. Letter dated February 4, 2004 (ML040410106)

For the U.S. Nuclear Regulatory Commission

Date February 1, 2005

By ***Original signed by Pamela J. Henderson***

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406