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

December 3, 2004

Docket No. 03009047 License No. 37-15400-01
Control No. 135131

Edward C. Maher
Vice President, Finance
St. Mary Hospital
Langhorne-Newtown Road
Langhorne, PA 19047

SUBJECT: ST. MARY HOSPITAL, ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 135131

Dear Mr. Maher:

This refers to your request for renewal of your NRC license. Please review the enclosed document carefully and be sure that you understand all conditions.

Please note the following:

a) Based on a telephone conversation with Paul Weiser, M.D. of your staff on October 12, 2004, we have withdrawn your request to name Frank J. Ammaturo, M.D. as an Authorized User. The additional information submitted on October 26, 2004 was not sufficient to approve Dr. Ammaturo as an Authorized User.

b) In Item 7.D. of your license, the manufacturers and model numbers of your manual brachytherapy sources have been updated to correspond to the current listings in the Sealed Source and Device Registry.

c) Item 9.D. of your license restricts your authorization for manual brachytherapy procedures to those for which the patient may be released under the provisions of 10 CFR 35.75. If you wish to perform inpatient treatments using your cesium 137 manual brachytherapy sources, please submit a diagram of rooms used to house these patients, including a description of any shielding (portable or structural).

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.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, “Request for Taxpayer Identification Number,” is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the

public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing when:

   a) an authorized user, authorized medical physicist, or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;

   b) the mailing address changes;

   c) the name on the license changes; or

   d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license Amendment before you:

   a) permanently change Radiation Safety Officers;

   b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or

c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);

d) change the name or ownership of your organization;

e) change the address(es) of use identified on the license;

f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license;

g) permit anyone to work as an authorized user or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a);

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

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, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html.

Thank you for your cooperation.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosures:
1. Amendment No. 38
2. 10 CFR Parts 19, 20, 21, 30, 33, 35, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

cc:
Paul Weiser, M.D., Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML043380233.wpd
To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	S Xu/SSX		S Gabriel/SLG2					
DATE	12/3/2004		12/3/2004					

OFFICIAL RECORD COPY

Amendment No. 38

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 application dated June 1, 2004,
1. St. Mary Hospital	3. License number 37-15400-01 is amended in its entirety to read as follows:
2. Langhorne-Newtown Road Langhorne, Pennsylvania 19047-1295	4. Expiration date December 31, 2014
	5. Docket No. 030-09047 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 curie
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources [Medi-Physics, Inc. Models 6711 (manufactured by Medi-Physics, Inc. or Amersham Health) and CDC.T1 (manufactured by AEA Technology)]	D. 2 curies
E. Any byproduct material permitted by 10 CFR 35.500	E. Sealed sources (North American Scientific Model MED 3601)	E. 300 millicuries per source; 1 curie total
F. Strontium 90	F. Sealed sources (BEBIG Model Sr0.S03 or AEAT SICW Series)	F. 5.0 millicuries per source; 800 millicuries total

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-15400-01

Docket or Reference Number
030-09047

Amendment No. 38

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. Any manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.
E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
F. For medical use in Novoste A1000 series devices for intravascular brachytherapy.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at St. Mary Hospital, Langhorne-Newtown Road, Langhorne, Pennsylvania.

11. The Radiation Safety Officer for this license is Paul Weiser, 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, 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
Laurence Oliver, M.D.	35.100; 35.200; 35.300; 35.500
Joel Namm, M.D.	35.100; 35.200; 35.300; 35.500
Paul Weiser, M.D.	35.100; 35.200; 35.300; 35.500
Steven L. Meshkov, M.D.	35.100; 35.200; 35.300; 35.500
Laurence Ratner, M.D.	35.100; 35.200; 35.500
Ethan Tarasov, M.D.	35.100; 35.200; 35.500; oral administration of iodine 131 sodium iodide for imaging and localization studies and treatment of hyperthyroidism and cardiac dysfunction
Sophia Chan Young, M.D.	35.100; 35.200; 35.500

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-15400-01

Docket or Reference Number
030-09047

Amendment No. 38

Authorized Users	Material and Use
Gustavo Sanchez, M.D.	35.100; 35.200; 35.500
Roy Prager, M.D.	35.100; 35.200; 35.500
William Ross, M.D.	35.100; 35.200; 35.300; 35.500
Michael Rieder, M.D.	35.100; 35.200; 35.500
Teresa Ecker, M.D.	35.100; 35.200; 35.500
Roy Lawrence Greenbaum, M.D.	35.100; 35.200; 35.500
Daniel J. Cohen, M.D.	35.100; 35.200; 35.300; 35.500
Larry A. Le Cavalier, M.D.	35.100; 35.200; 35.500
JoAnn Chalal, M.D.	35.400; Strontium 90 for intravascular brachytherapy procedures
Deirdre V. Walsh, M.D.	35.200; 35.500
Sangeeta Tyerech, M.D.	35.300; 35.400; Strontium 90 for intravascular brachytherapy procedures
Eric Bosworth, M.D.	35.100; 35.200; 35.300; 35.500
Despina Terris, M.D.	35.300 except iodine 131; 35.400; Strontium 90 for intravascular brachytherapy procedures
Derek J. Plakyda, M.D.	35.100; 35.200; 35.500
Lisa M. Sheppard, M.D.	35.100; 35.200; 35.500

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

Authorized Medical Physicists	Material and Use
Quiet Ncube, M.S.	Strontium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training

D. 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-15400-01

Docket or Reference Number
030-09047

Amendment No. 38

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 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.

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

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 June 1, 2004
    B. Letter dated September 3, 2004 (IVB emergency source recovery procedures only)
    C. Letter dated November 15, 2004
    D. Letter dated November 22, 2004

For the U.S. Nuclear Regulatory Commission

Date December 3, 2004

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

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