



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

May 20, 2005

Docket No. 03010302  
Control No. 136583

License No. 52-16061-01

Ramon López Maldonado  
Executive Director  
St. Luke's Episcopal Hospital  
P.O. Box 332027  
Ponce, PR 00733-2027

SUBJECT: ST. LUKE'S EPISCOPAL HOSPITAL, LICENSE AMENDMENT, CONTROL NO.  
136583

Dear Sr. López:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, effective October 24, 2002. In addition, please note the following:

1. Byproduct material permitted by 10 CFR 31.11 used for *in vitro* studies has been limited to 5 millicuries, as discussed with your new Radiation Safety Officer, on May 5, 2005.
2. The sealed source manufacturer for the iodine-125 sources has been corrected to list the manufacturers as Medi-Physics and Amersham Health.
3. Palladium-103 is not byproduct material, and therefore not regulated by the NRC. You should contact the Commonwealth of Puerto Rico regarding licensing of this radioactive material.

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 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. 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 site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and [http://www.nrc.gov/who-we-](http://www.nrc.gov/who-we-are.html)

R. Lopez Maldonado  
St. Luke's Episcopal Hospital

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[are/governing-laws.html](http://www.gpo.gov/are/governing-laws.html) 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 Penny Lanzisera***

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 11

cc:  
Carmelo Perez, Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\52-16061-01.136583.05252005.wpd

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NAME	PLanzisera/PAN							
DATE	5/20/2005							

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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. St. Luke's Episcopal Hospital</p> <p>2. P.O. Box 332027 Ponce, Puerto Rico 00733-2027</p>	<p>In accordance with the letter dated February 21, 2005,</p> <p>3. License number 52-16061-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2012</p> <hr/> <p>5. Docket No. 03010302 Reference No. 52-11534-01</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>D. Iodine-125 permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed Sources (Medi-Physics, Inc. or Amersham Health Model 6711 OncoSeed™)</p> <p>E. Prepackaged Kits</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. 1.5 curies</p> <p>D. 2 curies</p> <p>E. 5 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 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. Iodine 125 manual brachytherapy permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75.
  - E. In vitro studies.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
52-16061-01

Docket or Reference Number  
03010302

Amendment No. 11

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at St. Luke's Episcopal Hospital, Calle Guadalupe Final, Ponce, Puerto Rico, and St. Luke's Memorial Hospital, Machuelo Road 14, Ponce, Puerto Rico.
- 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:

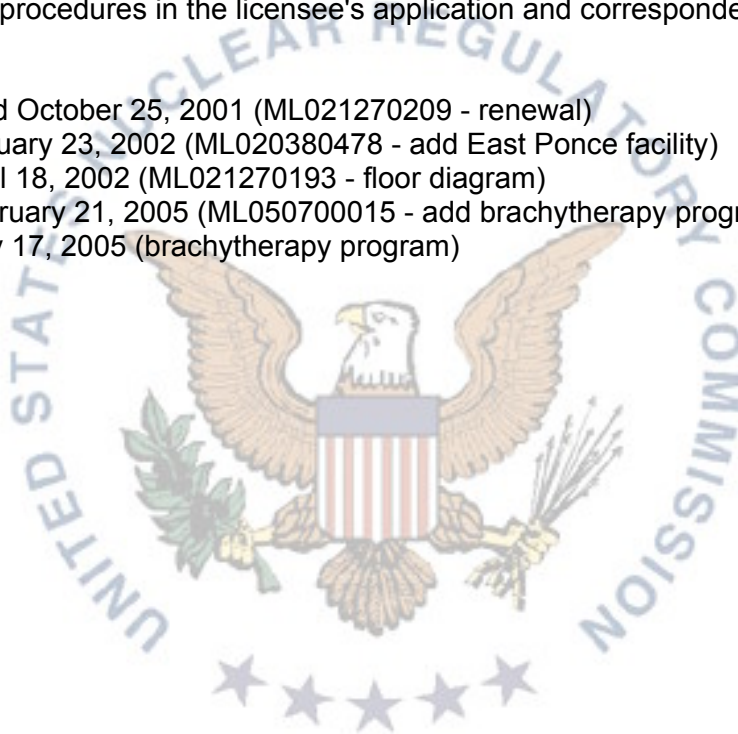
<u>Authorized Users</u>	<u>Material and Use</u>
Eileen Hart, M.D.	35.100; 35.200; 35.300; 31.11
Jesús M. Vidal, M.D.	35.100; 35.200; 35.300; 31.11
José O. Morales, M.D.	35.100; 35.200; 35.300; 31.11
Miguel A. Serpa, M.D.	35.100; 35.200; 35.300
Carlos Remedios, M.D.	35.400

- 12. The Radiation Safety Officer for this license is Carmelo Pérez.
- 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  
52-16061-01Docket or Reference 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 October 25, 2001 (ML021270209 - renewal)
  - B. Letter dated January 23, 2002 (ML020380478 - add East Ponce facility)
  - C. Letter dated April 18, 2002 (ML021270193 - floor diagram)
  - D. Letter dated February 21, 2005 (ML050700015 - add brachytherapy program)
  - E. Letter dated May 17, 2005 (brachytherapy program)



For the U.S. Nuclear Regulatory Commission

Date May 20, 2005

By

***Original signed by Penny Lanzisera***

Penny Lanzisera  
Medical Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406