

St. Luke's Episcopal Hospital

PO Box 332027
Ponce Puerto Rico 00733-2027

February 21, 2005

Mr. David J. Collins, Health Physicist
Division of Nuclear Materials Safety
Sam Nunn Atlanta Federal Center
U.S. Nuclear Regulatory Commission, Region II
61 Forsyth Street, S.W., Suite 23T85
Atlanta, GA 30303-8931

05 MAR -1 A10:58

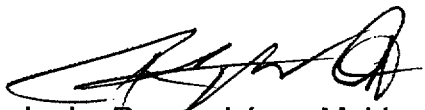
RECEIVED
REGION I

Amendments to License No. 52-16061-01 Docket Number 030-10302

It is hereby requested that the following amendments added to our license:

- I. Please add the attachment A. part 35.400 to conduct brachytherapy implant and inventory of sources.
- II. Please add the attachment B. new authorized user of part 35.400 and new Radiation Safety Officer.
- III. Please add the attachment C. as area of use to conduct brachytherapy implant which is located in the third floor of St. Luke's Episcopal Hospital.
- IV. Please find the emergency equipment description.

If additional information is needed you can call my office, phone number 1-787-844-7385.



Lcdo. Ramon López Maldonado, MHSA
Executive Director

St. Luke's Episcopal Hospital
PO Box 332027
Ponce PR 00733-2027

Attachments:

1. Form 313
2. Attachment A and B
3. Attachment C. Diagram Map (Surgery Area) and the emergency equipment description.

136583
NMSS/RGNI MATERIALS-002

(10-2002)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND
APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA,
OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR
WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐

A. NEW LICENSE

☒B. AMENDMENT TO LICENSE NUMBER 52-16061-01☐

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Ramón López, MHSA
PO Box 332027
Ponce PR 00733-2027

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

St. Luke's Episcopal Hospital
PO Box 332027
Ponce, PR 00733-2027

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ramón López, MHSA

TELEPHONE NUMBER

(787) 844-7385

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount
which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Ramón López, MHSA, COO

SIGNATURE



DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

S.T LUKE'S HOSPITAL

ATTACHMENT A

I. RADIOACTIVE MATERIAL AND PURPOSE

Byproduct Material	Chemical/Physical form	Maximum Amount	Purpose
35.400 (f)- I-125	Sealed source	2 Curies	Medical Use
35.400 (g)- I-125	Sealed source	2 Curies	Medical Use
35.400 (f)- Pd-103	Sealed source	2 Curies	Medical Use
35.400 (g)- Pd-103	Sealed source	2 Curies	Medical Use

II. INVENTORY OF SOURCE

1. For I-125

- a. Manufacturer – North American Scientific**
- b. Model and Number- Oncoseed 6711 And Rapidstrand M7000**

2. For Pd-103

- a. Manufacturer – North American Scientific**
- b. Model and Number-MED 3633 (NIST-00)**

S.T LUKE'S HOSPITAL

ATTACHMENT B.

I. INDIVIDUAL USERS FOR MEDICAL USE OF PART 35.400

- 1. Carlos Remedios, M.D.**
For material and use of 35.400
He is authorized user under license No. 52-10270-01

II. RADIATION SAFETY OFFICER

- 2. Sr. Carmelo Pérez, Physicist**
as new radiation safety officer for this license
He is radiation safety officer under license No. 52-10270-01

S.T LUKE'S HOSPITAL

DESCRIBE EMERGENCY EQUIPMENT

- 1. According to our safety program, the sources to used are I-125 Model 7000 (Rapid Strand) and model 6711 Oncoseed and Pd-103 supplied by Amershan Health and North American Scientific preloaded by Custom Care Pharmacy.**
- 2. When the material arrives (by FedEx) to the Nuclear Medicine Department according with the quantities requested, the material will be verified by the RSO or a qualified technician using the protocols and procedures of the NRC regulations.**
- 3. If during the verification the prescribed material do not corresponds with the initial prescription or other identified deficiency, immediately the RSO, the Physician and the Manufacturer are notified. The material is returned according with the NRC regulations.**
- 4. In the day of the procedure, the material to be used is picked up following the safety precautions from Nuclear Medicine's Hot Lab. to the Operating Room (OR).**
- 5. During the procedure the Physician uses fluoroscopy and sonography to assure that the sources are correctly implanted according to the treatment planning. Also the needles used in the procedure are numbered according to the treatment planning and they are verified after being used.**
- 6. To assure the all sources are implanted, an X-Ray film is taking to the patient and the Operating Room area is verified by the RSO or the qualified technician.**

7. If for any reason the procedure is not perform, the RSO will make the arrangement with the Manufacturer to return the material following the regulations of the NRC.

This is to acknowledge the receipt of your letter/application dated

2/21/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 52-16061-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136583.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

License Fee Management Branch, ARM
and
Regional Licensing Sections

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:      (FOR LFMS USE)
:      INFORMATION FROM LTS
:      -----
:
:  Program Code: 02120
:  Status Code: 0
:  Fee Category: 7C
:  Exp. Date: 20120430
:  Fee Comments: CODE 21
:  Decom Fin Assur Req'd: N
:  .....

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A. REGION

Applicant/Licensee: ST. LUKE'S EPISCOPAL HOSPITAL
Received Date: 20050301
Docket No: 3010302
Control No.: 136583
License No.: 52-16061-01
Action Type: Amendment

Amount :

Check No. :

3. COMMENTS

Signed

Date _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /___/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment

Renewal

License

3. OTHER

Signed

Date _____