



ESCUELA DE MEDICINA
San Juan Bautista

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(52-24907-02)

February 14, 2008

Licensing Assistance Team
Division of Nuclear Material Safety
US Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Re: Byproduct Material License Application

Enclosed please find completed license application for the San Juan Bautista School of Medicine. We are also enclosing application fee in the amount of \$8,100.00 as required.

If further information is necessary, please contact us.

Sincerely,


Yocasia Brugal, MD
President / Dean of Medicine

142242

NMSB/BNM MATERIALS-002

NRC FORM 313

(10-2005)

10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.4 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 and FOIA/Privacy Services Branch (T-5 F53), 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:

IF YOU ARE LOCATED IN:

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

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, 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 BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

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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



C. RENEWAL OF LICENSE NUMBER

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

San Juan Bautista School of Medicine
PO Box 4968
Caguas, PR 00726-4968

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

San Juan Bautista Medical Center
Road PR 172, Urb. Turabo Gardens
Caguas, PR

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Heriberto Torres, Ph.D.

TELEPHONE NUMBER

(787) 412-4084

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

\$ 8,100.00

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

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

SIGNATURE

DATE

Yocasta Brugal, MD President-Dean

FOR NRC USE ONLY

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

DATE

San Juan Bautista School of Medicine

License Application (cont.)

5- Radioactive Material

<u>Byproduct material</u>	<u>Chemical/physical form</u>	<u>Maximum amount</u>
Any permitted by 10CFR35.100	any	as needed
Any permitted by 10CFR35.100	any	as needed
Fluorine-18	FDG	as needed
Gallium-67	any	as needed
Gallium-68	any	as needed
Thallium-201	any	as needed
Indium-111	any	as needed
Carbon-11	any	as needed
Cs-137 Calibration	sealed source	not to exceed 30 mCi (1110 MBq)
C0-57 Calibration	sealed source	not to exceed 30 mCi (1110 MBq)
Na-22 Calibration for PET scanner	sealed source	not to exceed 30 mCi (1110 MBq)

6- Purpose (s) for which licensed material will be used.

10CFR35.100

Medical use of unsealed byproduct material for uptake, dilution and excretion studies for which a written directive is not required.

10CFR35.200

Medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Fluorine-18, Ga- 67 and 68, Thallium-201, Indium-111 and Carbon-11-medical use, written directive not required.

Cs-137, Co-57, Na-22

For calibration purposes.

7- Individual(s) responsible for radiation safety program and their training and experience.

7.1 Radiation safety officer

Heriberto Torres, Ph.D. is proposed as radiation safety officer for this program. Dr. Torres is listed in licenses numbers 52-25621-01 and 52-31059-01 as radiation safety officer. Signed Delegation of Authority and RSO Acceptance are enclosed as ATTACHMENT 7.1.

7.2 Authorized users

Samuel Sostre, MD and José Díaz, MD are proposed as authorized users. Both Dr. Sostre and Dr. Díaz are listed as AU in License #'s 52-25621-01 and 52-25519-01. All uses are requested for these physicians.

8- Training for individuals working in or frequenting restricted areas. Refer to item 7.

9- Facilities and equipment.

9.1 Equipment

The following equipment and accessories will be acquired for the radiation safety program:

Capintec CRC-15 dose calibrator
Johnson 506 survey meter with pancake probe
675-586 wipe counter
042.413 Deluxe L-Block shield
042-417 Lead brick cave
3cc, 5cc syringe shields and carriers
Manual dose injectors
Shielded syringe holder

Sharp container shield
SS lead waste container

9.2 Facility diagram

The diagram for the Nuclear Medicine Departments is enclosed as
ATTACHEMENT 9.1

Specific information concerning this diagram is as follows:

- 1- Doors to gamma camera, PET room, control room and uptake room are wood with 1/8 inches lead.
- 2- Wall dividing uptake room and gamma camera is 4 inches concrete plus 1/8 inches lead.
- 3- Wall dividing uptake room and injection room is 4 inches concrete plus 1/8 inches lead.
- 4- All others walls are 6 inches concrete filled blocks plus 1/2 inches concrete.
- 5- The nuclear medicine facility is located on the ground floor (there is no basement).
- 6- On the top floor are located a dietician office and a freezer room.
- 7- On the north side of the PET room there will be a patient waiting room for nuclear medicine.
- 8- On the south side of the gamma camera room there are office facilities.

9.3 Radiation monitoring instruments

"Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibration"

9.4 Dose calibrator and other equipment used to measure dosages of unsealed by product material.

"Equipment use to measure dosages will be calibrated in accordance with nationally recognized standards and the manufacture's instructions."

The description of the survey meters is as follows:

Johnson 506 survey meter with pancake probe.

The description of the wipe counter is as follows:

Sun Nuclear Wipe Counter

10- Radiation Protection Program

10.1 Safety Procedures and instructions

N/A for byproduct material permitted by 10CFR35.100 and 10CFR35.200

10.2 Occupational dose

Either we will perform a prospective evaluation demonstrating that *unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10CFR Part 20* or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, vol.9, Consolidated Guidance About Materials Licenses; Program Specific Guidance About Medical Licenses" dated October 2002.

10.3 Area surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10CFR20.1101 that meet the requirements of 10CFR20.1501 and 10CFR35.70

10.4 Safe use of Unsealed Licensed Material

We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10CFR20.1101 and 10CFR20.1301

10.5 Spill procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10CFR20.1101

11- Waste disposal

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10CFR20.1101 that also meet the requirements of the applicable section of subpart K to 10CFR part 20 and 10CFR35.92

ATTACHMENT 7.1

Delegation of Authority

Memo to: Radiation Safety Officer

From: Yocasta Brugal, MD, President- Dean
San Juan Bautista School of Medicine

Subject: Delegation of Authority

You, Heriberto Torres, Ph.D. from Porfirio Toledo y Asociados, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend four (4) hours per month conducting radiation protection activities.

I accept the above responsibilities,



Signature of President-Dean

Date



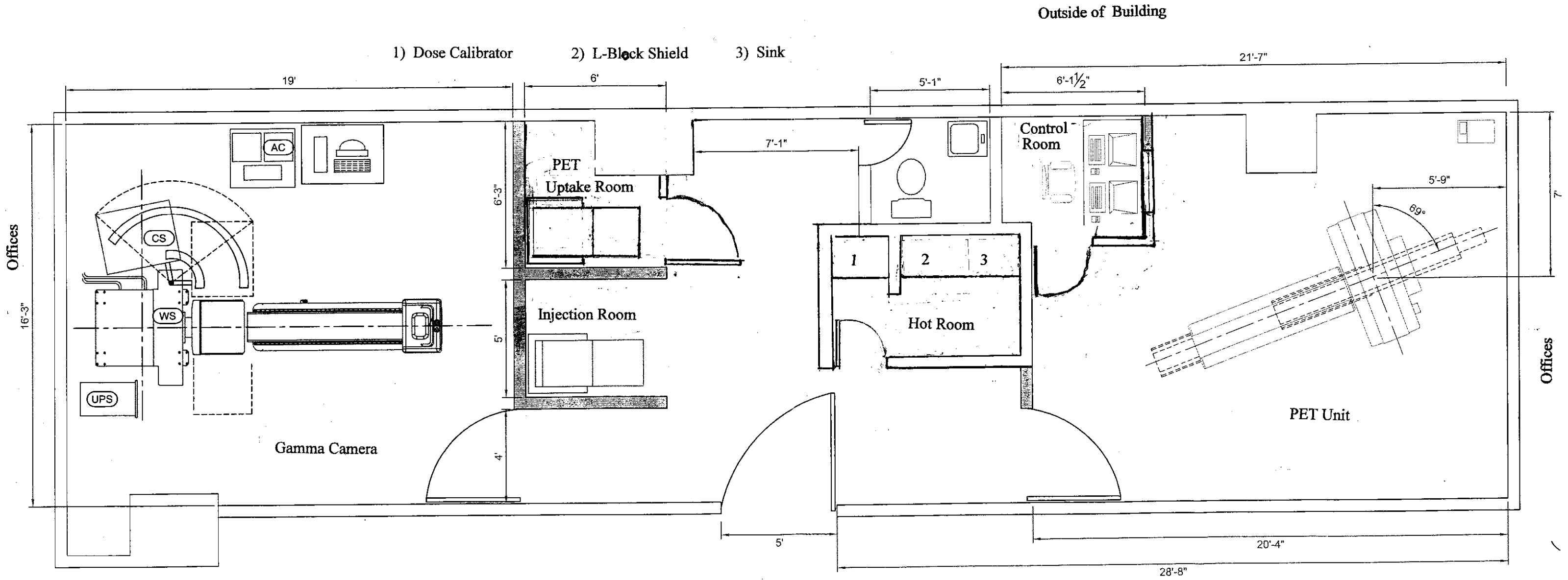
Signature of Radiation Safety Officer



Date

SAN JUAN BAUTISTA MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT
CAGUAS, P. R.

→ N



Corridor (For patients and nuclear medicine personnel only)

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

2/14/2008 (RECEIVED 3/18/2008), and to inform you that the initial processing which includes an administrative review has been performed.

☒ NEW LICENSE APPLICATION (03037739)
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** 142242.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.