Puerto Rico
Nuclear Center, Inc.

ESPECIALISTAS EN CARDIOLOGIA NUCLEAR Y MEDICINA NUCLEAR
123 ESTE CALLE DE DIEGO - MAYAGUEZ, PUERTO RICO 00680 - TELS. 833-1000 / 833-1030

May 25, 2011

U.S. Nuclear Regulatory Commission
Region II- Material Licensing/Material Safety
61 forsyth S.T. S.W. Suite 23 T 85
Atlanta GA. 30303-3931

03031892

Re: License Renewal
52-25121-01

Gentlemen:

Our license is due or renewal on May 31, 2011. This letter represents our renewal request your document titled, "Instruction for Preparation of Application for License Renewal' was followed. Only the essential information necessary to assess our current program is submitted.

A. A license review indicates that our current license remains the same for the Radionuclides quantities and chemical forms. The license conditions with respect to location for use and staff remains the same and additional authorized user is added to our staff. Doctor Eileen Hart License 52-19984-01 will be part of our visiting medical staff.

B. The documents previously submitted and indicated in our license are up to date and represents our management control program.

C. A review of NRC Regulations demonstrate that we are covered and in compliance At the present time. Last inspection in August 2010 so demonstrated.

Thanks in advance for this renewal consideration and let us know if any additional information is needed.

Edgar J. Vazquez Gonzalez, M.D.
President
Puerto Rico Nuclear Center Inc.

REC'D IN LAT MAY 3 1 2011

575219
NMSS/RGN1 MATERIALS-002

NRC FORM 313 (6-2000) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 06/31/2002

Estimated burden per response to comply with this mandatory collection request: 7.4 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 Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), 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.

APPLICATION FOR MATERIAL LICENSE

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

03031892

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 _____
- [X] C. RENEWAL OF LICENSE NUMBER 52-25121-01

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

PUERTO RICO NUCLEAR CENTER,INC
123 ESTE CALLE DE DIEGO
MAYAGUEZ, P.R. 00680

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

123 EAST DE DIEGO STREET
MAYAGUEZ, PR 00680

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

EDGAR J. VAZQUEZ, MD

TELEPHONE NUMBER

787- 833-1000

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.
SEE ENCLOSURED

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

9. FACILITIES AND EQUIPMENT.
SEE ENCLOSURED

10. RADIATION SAFETY PROGRAM.
SEE ENCLOSURED

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY | AMOUNT ENCLOSED $ 400.00

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

THE APPLICANT 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
EDGAR J. VAZQUEZ, MD.	Edgar Vazquez as agent	5-24-2011

FOR NRC USE ONLY

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

NRC FORM 313 (6-2000) PRINTED ON RECYCLED PAPER

575219

ATTACHMENTS TO THIS RENEWAL
LICENSE NUM. 52-25121-01

ITEM 5 RADIOACTIVE MATERIAL

A. Any byproduct material with a half-life less than 120 days	A. Any form for uses described in 35.100 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72, or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. As needed
B. Any byproduct material with a half-life less than 120 days	B. Any form for uses described in 35.200 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or a specific license issued to the manufactured by an Agreement State pursuant to equivalent State regulations, except gases	B. As needed
C. Iodine 131	C. Sodium iodide in capsule Form only for preparation and administration as specified in 35.300	C. 55.5 gigabecquerels (Gbq) (1.5 curies)
D. Strontium 89	D. Any form uses described in 35.300 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	D. As needed, unit doses only

ITEM 6 PURPOSES
FOR MEDICAL USE

ITEM 7 - R. S. O. Actual Incumbent and a Consultant;
Dr. Edgar J. Vazquez Gonzalez
Consultant: Mr. Daniel Torres – M.S.

7-1 AUTORIZER USERS:

ATT 7-1 Dr. Edgar J. Vazquez
For cardiac function and imaging studies identified in 10 CFR 35.100 and 10 CFR 35.200

7-1 2 Dr. Ricardo E. Santiago for medical use identified in 10 CFR 35.100, 35,200, Iodine 131 for treatment of hyperthyroidism, thyroid carcinoma And Strontium 89 specified in 10 CFR 35.300.

ITEM 8 TRAINING PROGRAM

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8 Rev .2

ITEM 9 Facilities and Equipment:

9-1 Facilities Drawing : Same drawings submitted in original application dated September 6, 1990- December 20, 1990.

9.1.1 Equipment : We have the same equipment since our original license application dated September 6, 1990 except the following new surveys meters.

a. G.M. Model 3700
b. Mini-motor I – Nuclear Associates

9.2 Survey Instrument Calibration:

The applicant will not calibrate the survey instruments but will have an outside contractor doing the calibration. The contractor will be authorized laboratory with a Nuclear Regulatory Commission or Agreement State License to perform calibrations. Each survey meter will be calibrated at least annually or after any repair.

ITEM 10 RADIATION SAFETY PROGRAM

Our Radiation Safety Program will continue in effect with Dr. Edgar J. Vazquez authorized use. and R.S.O. Mr. Daniel Torres M.S. will be our medical physicist consultant. The ALARA concept will continue to be in effect as originally established

cont; item 10

and submitted.

10-1 Enclosed is our Quality Management Program or activities involving the use of Iodine 123, 131 in amounts above 30 microcuries.

11 The Radiation Safety Officer for this license is Edgar Vazquez Gonzalez, M.D.

12 Authorized users:

A. Edgar Vazquez Gonzalez, M.D. for cardiac function and imaging studies Identified in 10 CFR 35.100 and 10 CFR 35.300.

B. Ricardo E Santiago, M.D. for medical use identified in 10 CFR 35.100, 35,200, Iodine 131 or the treatment of hyperthyroidism and thyroid carcinoma, and strontium 89 for the preparation and administration as specified in 10 CFR 35.300.

C. Miguel Serpa, M.D. for medical use identified in 10 CFR 35.100, 35.200, iodine 131 for the treatment of hyperthyroidism and thyroid carcinoma, and strontium 89 for the preparation and administration as specified in 10 CFR 35.300.

D. Eileen Hart, M.D. for medical use identified in 10 CR 35.100, 35.200, iodine 131 for the treatment of hyperthyroidism and thyroid carcinoma, and strontium 89 for the preparation and administration as specified in 10 CFR 35.300.

13 Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

14 The licensee is authorized to transport licensed material in accordance with the provision of 10 CFR Part 71, "Packing and Transportation of Radioactive Material.'

Puerto Rico
Nuclear Center, Inc.

ESPECIALISTAS EN CARDIOLOGIA NUCLEAR Y MEDICINA NUCLEAR

CALLE DE DIEGO 123 ESTE - MAYAGUEZ, PUERTO RICO 00680 - TELS. 833-1000 / 833-1030

December 12, 1995

QUALITY MANAGEMENT PROGRAM
Lic Num: 52-25121-01

A. Procedure for the use of more than 30 microcuries of I 123/ I 131.

The authorized user shall prepare a written order containing the following.

- Patient name
- Study to be performed
- Date of order
- Dose to be administered
- Authorized signature

The laboratory will not accept telephone or verbal orders to carry Iodine procedures.

B. Procedure to identify the patient.

The receptionist and technologist identify the patient at least by two of the following methods.

- Corroboration of name and last name
- Asking social security
- Confirm birthdate
- Patient address
- Patient Hospital I.D.

C. Before the administration of the dose the technologist will do the following.

- verify the dose requested and route of administration
- calculate and measure the dose with the dose calibrator
- before administration a brief interview will take place with the patient.

If the technologist do not understand or have andy doubt concerning the procedure to be performed, advice shall be requested from the authorized user.

After dosage administration, the technologist shall document in the patient record the dose, the radiopharmaco, the route of administration and his initials.

D. In case of any recordable event or of any misadministration the authorized user shall do the following.

- Notify within 30 days the N.R.C..
- Take necessary corrective action with the patient
- Retain records for at least three years
- Take corrective action to prevent recurrence of events

E. A procedure to evaluate the Quality Management Program will be implemented with a frecuency of at least every 12 months, including the following.

1. Revision of a representative sample of 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20, include.

   - Recordable events or misadministration
   - Deviation from written directive
   - Radiopharmaco used
   - Doses prescribed
   - Route of administration

F. As part of the continous education program the personnel will received trainning in relation to the Quality Management Program.

G. The anual review will be performed by either the R.S.O. or the physicist consultant.

EDGAR J. VAZQUEZ, M.D.
RADIATION SAFETY OFFICER

Rico
Nuclear Center, Inc.

ESPECIALISTAS EN CARDIOLOGIA NUCLEAR Y MEDICINA NUCLEAR

CALLE DE DIEGO 123 ESTE - MAYAGUEZ, PUERTO RICO 00680 - TELS. 833-1000 / 833-1030

QUALITY MANAGEMENT PROGRAM - ANNUAL REVIEW

Subjects to be checked:	YES	NO	N/A
1. Written order from "Authorized User"			
2. Identification by two persons and by two methods each patient.			
3. Dose given as ordered.			
4. Isotope ordered and route of administration as ordered.			
5. Occurrence of events requiring documentation.			
6. Events representing a misadministration			

Number of Records checked _____

Summary of findings :

Evaluation performed by:

_____