



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

January 31, 2012

Docket No. 03013584  
Control No. 575754

License No. 52-01946-07

Rafael Rodríguez Mercado, M.D.  
Chancellor  
University of Puerto Rico Medical Sciences Campus  
Chancellor's Office  
P.O. Box 365067  
San Juan, PR 00936-5067

SUBJECT: UNIVERSITY OF PUERTO RICO, LICENSE AMENDMENT, CONTROL NO.  
575754

Dear Dr. Mercado:

This refers to your license renewal request dated July 22, 2011. Enclosed with this letter is the amended license extending the license expiration date to July 31, 2012. In order to continue our review of the full license renewal, we need the following additional information as was originally requested in our letter dated December 20, 2011:

1. With regard to the licensed material requested, please provide the following:
  - a. Incineration of licensed material was not included in your license renewal request. Please provide a list of radionuclides incinerated over the years and estimate a maximum total activity remaining in the incinerator as contamination for inclusion on your NRC license. In addition, please note that if the incinerator is located in a separate building or outdoor area, decommissioning of the device and surrounding area must be completed in accordance with 10 CFR 30.36.
  - b. During a previous NRC inspection, an area of contamination was noted in a radioactive waste bunker that was believed to be cesium-137 from a leaking source that was possessed several years ago. Please estimate the amount of cesium-137 contamination embedded in the table and the floor of the waste bunker for inclusion on your NRC license.
2. With regard to your Radiation Safety Committee (RSC), please provide the following additional information:
  - a. Describe in greater detail the information provided to the RSC for approval of users. For instance, indicate whether detailed training is documented on forms, such as whether training supplements to NRC Form 313 are provided to the RSC for authorized users, medical physicists, and nuclear pharmacists. For nonmedical authorized users, please indicate whether the training will require "hands-on" experience with the isotopes requested for use. In addition, describe the criteria used by the RSC for approval of new users. For instance, will medical

users be required to meet the training and experience requirements in 10 CFR Part 35 and on NRC's website for emerging technologies (e.g., microspheres). Additionally, will research users be confirmed by the RSC to meet your training and experience requirements described in Appendix F of your application (e.g., degree and 40 hours of training and experience applicable to handling radioactive material).

- b. Provide the procedures that your RSC will use to review proposed changes in the radiation safety program previously submitted to the NRC. Indicate which procedures your RSC is requesting authorization to change and confirm that the RSC duties and responsibilities will include: (i) review and approval of permitted program and procedural changes prior to implementation; (ii) implementation of program and procedural changes; (iii) audit of licensed operations to determine compliance; and (iv) taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.
3. In regard to your current facilities for survey instrument calibration, where sealed sources are also stored, please confirm that background levels of radiation in that area are acceptable to perform instrument calibration.
4. With regards to your financial assurance maintained with the NRC, please note that the following documents currently provide your financial assurance: (i) Certification of Financial Assurance dated April 1, 2008 [ML081130147]; (ii) Statement of Intent enclosed with letter dated May 23, 2008 [ML081560616]; and (iii) University of Puerto Rico Act Num.1, January 20, 1966, ss-606 [ML081130147]. Since submission of these documents several changes have occurred to your possession limits, including addition of new long-lived radioisotopes like Am-241. Based on these changes, please re-submit a revised Certification of Financial Assurance. Sample financial assurance documents may be found in NUREG-1757, Volume 3.
5. Describe the method used to ensure that the Chancellor is aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.
6. In your response dated January 25, 2012, you submitted radiation safety audit forms for Nuclear Medicine and research laboratories. However, the forms were submitted in Spanish. Please provide copies of the audit forms in English.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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 expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and 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. In particular, 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 of any change in mailing address.
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) change Radiation Safety Officers;
  - b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - c) add or change the areas of use, or addresses of use identified in the license application or on the license; or
  - d) change the name or ownership of your organization.
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.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the 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, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

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 included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

R. Mercado

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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. 34

cc:  
Jossian J. Pagan-Lisboa, C.N.M.T., Radiation Safety Officer

DOCUMENT NAME: G:\WordDocs\Current\Lic Cvr Letter\L52-01946-07.575754.doc

**SUNSI Review Complete: PLanzisera**

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DATE	1-31-12		1-31-12				

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