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

December 20, 2011

Docket No. 03013584 License No. 52-01946-07
Control No. 575754

Ilka Ríos, D.M.D.
Interim 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, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 575754

Dear Dr. Ríos:

This is in reference to your application dated July 22, 2011 requesting to renew Nuclear Regulatory Commission License No. 52-01946-07. In order to continue our review, we need the following additional information:

1. With regard to the licensed material requested, please provide the following:

   a. Please confirm if you wish to be authorized for byproduct material with atomic Numbers 3 through 83 and half life less than 120 days, in addition to the other unsealed byproduct material previously requested in Attachment 5, Chart 5.1.1. Additionally, please indicate if “medical use” should be included with “research use” for this material.

   b. Please clarify the use for 10 CFR 35.100 licensed material (e.g., Medical use identified in 10 CFR 35.100).

   c. You were previously authorized for Americium-241 crystal liquid ampoules. Please confirm you still possess this material or provide disposal documentation.

   d. Please confirm if the Americium-241 sealed source listed on the bottom of Page 4 of your application is a generally licensed source. In addition, please confirm that the sealed sources currently listed on your NRC license as in storage, remain in “storage only incident to disposal.”

   e. 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.

f. 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.

Please note the following with regard to your requested possession limits: (i) I-131 and Sr-89 uses will be included in 10 CFR 35.300 and will not be separately listed on your license; and (ii) many of the sealed sources described in your application are generally licensed sources and will not be listed on your specific NRC license.

2. With regard to your Radiation Safety Committee (RSC), please provide the following additional information:

a. Submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC, and the Radiation Safety Officer (RSO).

b. Provide a list and titles of current members of your RSC and confirm that the membership will include senior research staff.

c. Confirm that final approval of new uses, users, and facilities will be provided by the RSC.

d. Indicate whether the committee's duties include a review of all incidents involving radioactive material.

e. 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 non-medical 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).

f. Attachment 9 and Appendix E of your application describe your criteria for approval of facilities and equipment. Confirm that your RSC will use these criteria to review and approve facilities and equipment. In addition, your method of classifying laboratories, found in Appendix E of your application, indicate values much higher than those provided in Appendix K, Page 2, of NUREG-1556, Volume 11. Please justify these higher values or commit to follow the guidelines

found in Appendix K to NUREG-1556, Volume 11, when classifying laboratories. Additionally, confirm that when reviewing facilities where radioactive materials may become airborne; the review will take into consideration descriptions of the ventilation systems including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Finally, for new medical facilities, the RSC may consider comparing future facilities with similar facilities described in the application.

g. Confirm that the RSC will consider the guidance on NRC's website when reviewing and approving medical emerging technologies (e.g., microspheres).

h. Confirm that meeting minutes will be retained for 5 years in accordance with 10 CFR 35.2024.

i. 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. With regard to your training program:

   a. Describe the method that will be used to assess the effectiveness of training prior to allowing an individual to begin work with licensed material.

   b. Confirm that training will include previous incidents, events, and/or accidents.

   c. Confirm that ancillary personnel will receive training to include the topics found in 10 CFR 19.12 which are summarized on pages J-4 to J-5 of NUREG-1556, Volume 9.

   d. Confirm that authorized users will be included in your training and re-training sessions.

4. With regard to your instrumentation program:

   a. Provide a list of instruments currently possessed to measure radiation levels and contamination.

   b. Discuss how the RSC and/or RSO, as appropriate, will assure that instruments are properly calibrated at prescribed frequencies.

5. With regard to your RSO:

   a. Please submit a new Delegation of Authority for the RSO signed by the current Chancellor. NUREG-1556, Volumes 7 and 9 may be useful in developing your

statement.

b. Provide the number of staff assigned to assist the RSO in his duties.

6. With regard to your internal radiation safety audit program:

a. Confirm that written directives and written directive procedures implemented to ensure that the prescribed dosage is administered are included in audits of the Nuclear Medicine Department.

b. Confirm that audits will include any new facilities/users approved in the future and will review any changes to your policies and procedures. Additionally, provide the audit form used for research areas.

7. With regard to your operating procedures, please clarify the following programs:

a. With regards to occupational exposure monitoring program:

(i) Items 10 and 11 found on page 47 of your application indicate that visitors, including contractors, will be assigned a group monitoring device. Please confirm that for visitors, including contractors, entering restricted areas that "we will monitor each visitor in accordance with the criteria in the section entitled 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 7 (or Vol. 9)."

(ii) Item 5 of your Prenatal Occupational Exposure Program indicates that employees will be re-assigned. Please confirm that your RSC will review the guidance found in Regulatory Guide 8.13 prior to re-assigning an employee. For instance, the guidance suggests that limiting of some duties may only be required.

b. With regards to your survey program, your program did not include details for air monitoring, airborne/liquid effluent monitoring, or bioassays. In addition, the statement in Section 10.8.3, Item D.1, found on page 59 of your application conflicts with statements found in Section 10.7.2 of your application. Finally, the Laboratory Surveillance Frequency, Table M.1, does not rely on annual limits on intake as suggested by the paragraph preceding the table and the modifying factors, as listed, should be used to divide the activity range by instead of multiply. Additionally, Table P.1, "Area Survey Contamination Maximum Permissible Limits" conflicts with Table N.1, "Acceptable Surface Contamination Levels for Equipment." Appendix S of NUREG-1556, Volume 11 provides a survey program acceptable to the NRC. To clarify your survey program you may provide the following statement "we will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, Volume 11, 'Program-Specific Guidance About Licenses of Broad Scope.'"

c. Item B.2 on Page 58 of your application indicates that an end window Geiger Mueller counter may be used for measuring removable contamination. Please

note that the detection efficiency may not be sufficient in all cases; for instance, in high background areas, the detector will be incapable of measuring contamination at your action level limits. Therefore, please confirm that you will assess the capability of the detector in the environment and for the radionuclides that it will be used to ensure that it will be capable of measuring contamination at or below your actions levels; and if not, that you will select more appropriate instrumentation.

d. Confirm that for radionuclides with a half-life greater than 120 days, you will use the criteria described in NUREG-1757 for release of facilities and equipment.

e. With regards to your leak test program, confirm that sources in storage will be tested every 10 years. In addition, please confirm that your will correct the notification requirement on the bottom of Page 60 or your application to 0.005 microcurie and that the NRC will also be notified when this limit is exceeded.

f. Item 10.3.3 of your application provides package opening procedures and indicates that a NaI well counter will be used for measuring package wipes. Please note that this instrument is sufficient for gamma emitters only. Please describe alternative instrumentation used for measuring beta or alpha contamination (e.g., liquid scintillation counter or gas proportional counter).

g. Item 10.6.3 of your application provides procedures for safe use of radioactive material. Please confirm that the procedures will include a commitment that "either after each procedure or before leaving the area, workers will monitor their hands, shoes and clothing for contamination in low background area."

h. With regards to your waste procedures, confirm that: (i) container labels will include "Caution, Radioactive Material" in accordance with 10 CFR 20.1904; (ii) any transfers of radioactive waste, including long-lived waste with half-lives greater than 120 days, will meet the criteria in Appendix W of NUREG-1556, Volume 9, and 10 CFR 30.41; and (iii) waste compaction, if performed, will meet the criteria found on Page V-5 of NUREG-1556, Volume 11.

8. With regard to your current facilities described, please clarify the following:

a. Confirm what areas are located directly above the nuclear medicine laboratory located at Dr. Isaac González Martinez Hospital.

b. To demonstrate that occupational and public dose limits are met, as required by 10 CFR Part 20, describe shielding installed/used (including in the ceiling and in the floor) in therapy patient rooms. Alternatively, you may confirm that therapy treatments are performed on an outpatient basis only. Note that if all therapies are performed on an outpatient basis, Item 9 on your license will be updated to include the statement: "for which the patient can be released under the provisions of 10 CFR 35.75." In addition, please provide room numbers for therapy patient rooms and identify your storage areas for 10 CFR 35.300 licensed materials.

c. Your application and facility diagrams did not indicate any use of PET materials, which are now regulated by the NRC. Please indicate if there will be any use of

PET isotopes (e.g., C-11, N-13, O-15, F-18, Rb-82), and if so, provide a detailed description of PET facilities, including shielding calculations. Alternatively, you may confirm that you do not currently use PET radionuclides and that you will design any future facilities, including shielding, in accordance with nationally recognized standards for PET facilities.

d. Please clarify the name of the facility located in Carolina (e.g., Hospital Dr. Federico Trilla or Carolina Regional Hospital).

e. Provide room numbers and diagrams of facilities designed or established for special uses (e.g., iodination laboratories, alpha laboratories, source fabrication facilities, radioactive waste processing facilities, instrument calibration facilities, individual laboratories processing 100 millicuries or more of radioactive materials per experiment or process, sealed source storage areas, and animal/veterinary facilities).

9. 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.

10. Section 9 of your current license includes the use of licensed material for instrument calibration. Please indicate if you would like to continue this authorization and if so, describe the sources used and clarify the types of instruments that you will calibrate (e.g., Geiger Mueller counter, sodium-iodide counter, liquid scintillation counters, etc.).

11. 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.

Current NRC regulations and guidance are included on the NRC's website at 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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 575754. If you have any technical questions regarding this deficiency letter, please call Janice Nguyen at (610) 337-5006.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Penny Lanzisera

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

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

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