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**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

December 18, 2023

Angelica Varela-Llavona, Ph.D., Chancellor
University of Puerto Rico
Rios Piedras Campus
P.O. Box 23305
San Juan, PR 00931-3305

**SUBJECT: UNIVERSITY OF PUERTO RICO, REQUEST FOR ADDITIONAL
INFORMATION, MAIL CONTROL NO. 637817**

Dear Dr. Angelica Varela-Llavona:

This is in reference to your letter dated September 8, 2023, requesting to amend NRC License No. 52-01986-04. In order to continue our review, we need the following additional information:

1. Please confirm that Angelica Varela-Llavona, Ph.D. has replaced Luis A. Ferrao-Delgado, Ph.D. as your management representative so that our records may be updated.
2. Your letter contains a request to add Ratnakar Palai, Ph.D. as an authorized user on your license for the device requested in your letter. The curriculum vitae presents their education, work experience, and research papers put does not present their knowledge of the use of radioactive materials. To grant the authorization requested, please include relevant information regarding the isotopes used, the activities, whether sealed or unsealed, over what time, and where the experience was acquired. This request need not be all inclusive but should contain information relevant to the type of use requested.
3. Your letter requests the addition of a device manufactured by LD Didactic GmbH. Our review noted that the device is of German manufacture and that the manufacturer's insert provided in your letter states that the end user should follow the regulations of the country in which they reside. The NRC's regulations require that foreign made devices should be distributed through licensed American companies and that the devices receive a Sealed Source and Device Registration (SS&D) review before distribution. Outlined below are how an NRC licensee may obtain a foreign made device:
 - A. The foreign company already has an association with an American company through which the foreign company does business. The American company is properly licensed, the device has gone through the SS&D process, and the device is on their license. The university of Puerto Rico should provide the name of the American distributor and the make and model number of the sealed source and device as outlined on the American company's license.
 - B. The American company is either not properly licensed or an SS&D review has not been performed. The SS&D review must be completed, and the license issued or

amended, as appropriate, to allow for the distribution of the device.

- C. The foreign company does not have an American company through which it conducts business.
- i. The foreign company establishes an association with an American company and does not begin distribution until the American company has completed an SS&D review and is properly licensed.
 - ii. The University of Puerto Rico initiates an SS&D review with the NRC regarding the device. Once completed, the foreign manufacturer may distribute the device directly to the university. There are costs associated with the performance of an SS&D review and maintaining the registration.
 - iii. The University of Puerto Rico may amend the license for Americium-241 in "Any" form. This treats the device as being unsealed material. 340 kilobecquerels of Americium-241 is equivalent to 9.189 microcuries. Together with your possession limits of tritium and Carbon-14, the university is at 97.4% of the amount at which financial assurance would be required. Unless the university is willing to provide financial assurance, it is possible that the licensee could become noncompliant with the regulations from a future amendment.
- D. The final option is for the University of Puerto Rico to request that the licensing action be voided in writing until more information is available.

We will continue our review upon receipt of this information. Please reply to my attention at:

Steven Courtemanche, Health Physicist
Mail Control No. 637817
USNRC, Region I
Division of Radiological Safety and Security
475 Allendale Road – Suite 102
King of Prussia, PA 19406

Or

R1DRSSMail.Resource@nrc.gov
Reference – Steven Courtemanche
Mail Control No. 637817

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.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at Steven Courtemanche or via electronic mail at Steven.Courtemanche@nrc.gov.

Thank you for your cooperation.

Sincerely,

Steven Courtemanche, Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 52-01986-04
Docket No. 03001183
Mail Control No. 637817

cc: Lymari Orellana-Ocasio, Radiation Safety Officer

UNIVERSITY OF PUERTO RICO, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637817 DATED DECEMBER 18, 2023

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L52-01986-04.637817.RAI.docx

SUNSI Review Complete: Steven Courtemanche

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NAME	Steven Courtemanche/src						
DATE	12/18/2023						

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