From: Jonathan Pfingsten
To: lberdiel@hospitalpaviaarecibo.com
Cc: crmidmr@aol.com; Jan Nguyen (She/Her)
Subject: NRC License Renewal - Hospital Pavia Arecibo - Request for Additional Information
Date: Tuesday, October 11, 2022 7:04:00 AM

Licensee: Hospital Pavia Arecibo
Nuclear Medicine Division
License No. 52-25589-01
Docket No. 030-35990
Mail Control No. 632091

PLEASE REPLY TO THIS EMAIL TO CONFIRM RECEIPT

Dear Mr. Berdiel Torres:

This is in reference to your letter dated March 15, 2022, received July 11, 2022, requesting to renew NRC License No. 52-25589-01. In order to continue our review, we need the following additional information. Please be aware that all "Item", "Section", and "Appendix" references below are referring to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/docs/ML1925/ML19256C219.pdf.

1. Item 3, Address Where Licensed Materials Will Be Used or Possessed – Your application lists the location where materials will be used or stored as Road 129, Arecibo, PR 00613. However, your current amendment lists the official address as Road 129, **Km 8**, Arecibo, Puerto Rico. Please confirm that the currently listed address, namely with the specific marker Km 8, is correct.

2. Items 5 and 6, Radioactive Material and Use – Your application stated "10 CFR 35.300 isotopes (the use of I-131) will NOT be performed at this facility". Please confirm that no byproduct material permitted by 10 CFR 35.300, not just limited to I-131, will be used under this license.

3. Items 5 and 6, Radioactive Material and Use – Your application stated "PET isotopes (the use of F-18) will NOT be performed at this facility". Please confirm that no PET materials, not just limited to F-18, will be used under this license.

4. Item 7, Radiation Safety Officer (RSO) – Your application names David Rhoe as your RSO. Since Mr. Rhoe is an outside consultant or contractor, please address the following:

    a. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program.

    AND

    b. Identify an in-house representative who will serve as the point of contact during

the RSO's absence.

AND

c. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

AND

d. Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his presence.

5. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Your application did not describe the training for required for individuals working in or frequenting restricted areas. Therefore, please provide the following commitment:

> A statement that, "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

6. Item 9, Facility Diagram – Your application did not contain a facility diagram. Please submit a facility diagram containing the necessary components as listed in the NUREG.

7. Item 9, Radiation Monitoring Instruments – Your application contained the following commitment:

> "A person qualified to perform survey meter calibrations will calibrate radiation monitoring instruments."

However, the wording of the commitment has been updated in Revision 3. Therefore, please update your commitment to the following:

> "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

8. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application did not contain a description of the equipment used to measure dosages. Therefore, please provide the following:
   a. Provide a description of the equipment used to measure the dosages.
   b. If applicable, for measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

9. Item 10, Occupational Dose – Your application contained the following commitment

> 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 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9, Rev.3 dated September 2019.

However, the wording of the commitment has been updated in Revision 3. Therefore, please update your commitment by providing either of the following:

> A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."
>
> OR
>
> A statement that: "We will monitor individuals in accordance with the criteria in the section titled, **'Radiation Safety Program–Occupational Dose'** in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"

10. Item 10, Material Receipt and Accountability – Your application did not contain any commitments concerning material receipt and accountability. Therefore, please provide the following:

> "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
> - license possession limits are not exceeded
> - licensed material in storage is secured from unauthorized access or removal
> - licensed material not in storage is maintained under constant surveillance and control
> - records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

11. Item 10, Leak Tests – Your application did not contain any commitments pertaining to leak testing sealed sources. Therefore, please provide the following:

> For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:
> - A statement that: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67."

12. Item 10, Safe Use of Unsealed Licensed Material – Your application contained the following commitment:

> "We have developed and will implement and maintain procedures for safe

use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR1301 (sic)."

However, the wording of the commitment has been updated in Revision 3. Therefore, please update your commitment by providing either of the following:

"We have developed and will implement and maintain **written** procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR **20.1201**."

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov.

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

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as 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 "Rules of Practice," 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 form 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 610-337-5170 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jonathan Pfingsten
Sr. Health Physicist
U.S. Nuclear Regulatory Commission
RI/DRSS/MLA
(610) 337-5170