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

March 28, 2025

Hazel Philbert, Interim CEO
Governor Juan F. Luis Hospital and Medical Center
4007 Estate Diamond Ruby
Christiansted
St. Croix, VI 00820

SUBJECT: GOVERNOR JUAN F. LUIS HOSPITAL AND MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 644983

Dear Hazel Philbert:

This is in reference to your application dated January 27, 2025, requesting to renew NRC License No. 55-25547-01. In order to continue our review, we need the following additional information. Please be aware that, unless stated otherwise, 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 13, Certification – Your application was signed by Angelo Galiber, M.D., Radiation Safety Officer for the license. Please confirm Dr. Angelo Galiber is still authorized to make legally binding commitments on behalf of the licensee. If he is not, please have an officer of the licensee's organization authorized to make legally binding commitments confirm the statements, commitments, and representations presented in the application dated January 27, 2025.

2. Items 5 and 6, Radioactive Material and Use - Confirm you are requesting to transition from possession and storage in standby status to active use status. For questions concerning Possession and Storage in Standby licenses, such as your current license, please refer to NUREG-1556, Volume 20, Revision 1, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures" Section 4.18 found at https://www.nrc.gov/docs/ML2031/ML20318A384.pdf.

3. Items 5 and 6, Radioactive Material and Use – Your application did not explicitly discuss the possession and use of Positron Emission Tomography (PET) materials. Please confirm you do not intend to possess and utilize PET materials in the future.

4. Item 7, Radiation Safety Officer (RSO) – Please provide a current copy of the delegation of authority letter with signatures from both your RSO and senior management. An example delegation of authority letter may be found in Appendix I of the NUREG.

5. Item 7, Authorized Users (AU) – Your license has been in standby mode for a prolonged period over the last decade. The regulations in 10 CFR 35.59 require that the training and experience to become an AU must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. Examples of

continuing education may be found in Appendix D of the NUREG under the heading "Recentness of Training". Please provide evidence of continuing education and experience for each of your AUs.

6. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Your application did not address training for individuals working in or frequenting restricted areas. Therefore, please confirm and provide the following statement:

   "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."

7. Item 9, Facility Diagram – Your facility diagram indicated the positioning of doors but did not specify which doors are access controlled (i.e., locked). Therefore, please indicate on your facility diagram which doors are access controlled.

8. Item 9, Facility Diagram - Please either update the facility diagram or describe in writing where byproduct material is received, prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property. For example, you may confirm that the materials are received, prepared, and stored in the hot lab, administered in injection or imaging rooms, and all waste is stored in the hot lab.

9. Item 9, Radiation Monitoring Instruments – Your application contained a description of the instrumentation that will be used to perform required surveys. However, your application did not include any commitments concerning the calibration of radiation monitoring instruments (i.e., survey meters). Please note that you are not currently authorized for materials necessary for the calibration of survey meters; as such, if the second option is chosen, additional materials would need to be authorized and possessed. Therefore, confirm 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." –

   AND/OR

   "We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."

10. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application included a description of the equipment used to measure dosages. However, your application did not include any commitments concerning the calibration of the equipment used to measure dosages. Therefore, confirm and provide the following commitment:

    "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

11. Item 10, Material Receipt and Accountability - Your application included a commitment concerning compliance with the National Source Tracking System (NSTS) reporting requirement, as described in 10 CFR 20.2207. This requirement does not apply to your program as you are not authorized for, nor possess, materials requiring this reporting. Therefore, this commitment was not reviewed or approved and will not be tied down in your license.

12. Item 10, Leak Tests – Your application contained a commitment to have leak test sample collection and analysis be performed by a licensed service provider. However, if you so choose, you may retain the right to perform leak testing of sealed sources used pursuant to 10 CFR Part 35 by confirming and committing to the following statement as well:

    "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67."

13. Item 11, Waste Management – Your application contained a request for guidance from the NRC regional office on the treatment of disposal of waste by incineration or compaction. Please confirm that, instead of incineration or compaction, you intend to hold all your waste generated by use of licensed materials for decay-in-storage before disposal without regard to radioactivity in accordance with 10 CFR 35.92 or transfer to another licensee authorized to possess such materials.

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 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 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

Digitally signed by JONATHAN PFINGSTEN
Date: 2025.03.28 09:14:37 -04'00'

Jonathan Pfingsten, Senior Health Physicist,
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 55-25547-01
Docket No. 030-35612
Mail Control No. 644983

cc: Angelo Galiber, Radiation Safety Officer

GOVERNOR JUAN F. LUIS HOSPITAL AND MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 644983 DATED MARCH 28, 2025

SUNSI Review Complete: Jonathan Pfingsten

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	RI:DRSS	N						
NAME	JPfingsten/JBP							
DATE	3/28/25							

OFFICIAL RECORD COPY