



August 17, 2021

Robin Elliott, Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety and Security
U.S. NRC, Region I
2100 Renaissance Boulevard, Suite 100
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Via Email to: Robin.Elliott@nrc.gov

Re: License No.: 55-25547-01
Docket No: 03035612
Control No: 627189

Dear Ms. Elliott:

This correspondence is in response to your email dated July 16, 2021. Our replies are below and the numbers correspond to the inquiries made on the above date. Thank you for your interest and your assistance in maintaining our license and our pursuing of a medical use license on St. Croix.

- 1. Contact me with a date on which a virtual inspection can be arranged of the materials in storage to confirm their presence and security.**

As you are aware, our virtual inspection was completed on August 12, 2021. The sealed sources are in the location of the original license with access to the room controlled by management and the radiation safety officer. There are two secure access point wooden doors that are key only to the nuclear lab.

- 2. Provide a list of the reasons why your plans to re-open by 7/31/2021 were delayed.**

The main reason for the delay in re-opening the medical use program by July 31, 2021 includes the use of the proposed location for nuclear medicine services as an inpatient unit from October 2017 to March 2021 as a result of Hurricanes Irma and Maria which impacted the island in September 2017. The COVID-19 pandemic which is now surging in the Virgin Islands has placed significant stress on medical staffing and resources. Our proposed nuclear medicine room in the Virgin Islands Cardiac Center (VICC), which is the



intended primary location for the lab, is presently being used for COVID-19 patient overflow.

The current unavailability of the VICC nuclear lab room and the lack of a funding source for nuclear equipment are two of the most significant limiting factors affecting the development of this important service. In addition, the move from the existing hospital to the Juan F. Luis North (JFL North) temporary hospital has had unanticipated delays due to planning and project changes and has significantly complicated our ability to move forward with this project.

We are judiciously studying and planning in a multidisciplinary manner (physicians, pharmacy, executives, human resources, Nuclear Regulatory Commission (NRC), and physicists) the implementation of current NRC regulations and USP 797 and 825 standards.

3. Provide a timeline, with milestones, for the re-establishment of the Nuclear Medicine activities.

Date	Milestone
August 12, 2021	Virtual inspection of existing nuclear medicine space, sealed source storage, inventory, security, etc.
August 22, 2021- October 31, 2021	Discussion and planning of implementation of USP 797 and USP 825 Standards.
September 1, – October 31, 2021	<ul style="list-style-type: none"> • Finalize equipment list, budget and resource needs for reinstatement of the nuclear medicine program. • Explore and identify funding source options • Identify Radiation Safety Committee members
October 1- 31, 2021	Finalize USP 797 and USP 825 implementation plans; determine possible construction, hot lab location, and equipment needs for USP compliance.

November 1, 2021- January 31, 2022	Continue planning, site assessment and standard requirements with key stakeholders for the implementation of a compliant nuclear medicine program. This has to be integrated into the overall space planning and design schedules for the Virgin Islands Cardiac Center which are currently under review.
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4. Build in a contingency for future unforeseen delays and provide a date when you expect the re-start of the program.

Depending on the COVID-19 pandemic and its local effects, access to the VICC room, funding, and yearly hurricane threats, we would expect to be operational on St. Croix by July 1, 2022 with an extended window to December 1, 2022 at the latest. At present, we have obtained three quotes for a newly refurbished nuclear medicine camera, and contingent on the move to JFL North, resolution of the increased census of COVID-19 inpatients and the securing of funding, we will move forward with the purchase of nuclear medicine equipment. The hospital is actively working on the transition to JFL North within the shortest time frame feasible. In the upcoming months as we continue to stabilize the hospital's infrastructure, we will keep you posted on new developments and any other pertinent updates which would directly impact nuclear medicine services. We are currently in the planning phase for this project. We anticipate that by January 2022, projected dates for the implementation of program requirements to allow for the transition to medical use should be available based on current status of factors outlined therein which may impact the reinstatement of this program.

Thank you for your consideration and we look forward to your response. Our physicist is Daniel Kane of Associates in Medical Physics, LLC [Phone # (216) 663-7000 & E-mail address d.kane@ampmedicalphysics.com]. Please feel free to contact us for more information and/or provide us with instruction (s).

Sincerely,



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