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

June 14, 2024

John F. Rossi, Vice President
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

SUBJECT: ST. VINCENT'S MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639741

Dear John Rossi:

This is in reference to your application dated February 15, 2024, requesting to renew NRC License No. 06-00843-03. A review of your application found that you have submitted many documents that are not required in the licensing process. It is our recommendation that you re-submit the application in its entirety addressing the items listed below and removing the extraneous documents. The required information is specified in NUREG 1556 Vol. 9 Rev 3 Appendix C.

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. Your request was signed by someone other than you, please indicate if you approve of the request as submitted. If you wish to change the management representative, please confirm this change, and provide name, title, and contact information including telephone and business e-mail address for the new appointment. If not, when submitting future license renewals, please have the document signed by the designated management representative. The NRC views a letter signed by the management representative as an indication that management has reviewed the application and concurs with the statements and representations contained therein.

    a. In addition, you have included an organizational chart in your license application. Please explain the roles, responsibilities and reporting structure of the following individuals: Susan Pagan, Kelli Hannan and William Jennings.

2. Section 8.3, Item 3: *"Address(es) Where Licensed Material Will Be Used or Possessed"*– On your Form 313, you referred to an "Item 6 of supplemental information" regarding locations of possession and use. We were unable to identify this attachment in your application although Item 8.3 & 8.6 in your application lists the addresses of use and type of use at each location. Please confirm what locations should be approved and what will be used in each location. See 9.h. below regarding the inclusion of a facility diagram for 40 Cross Street.

3. Section 8.5, Item 5: *"Radioactive Material"*– In Section 8.5.1, you have requested for any byproduct material permitted by 10 CFR 35.300 in the Chemical/Physical form "Any" for which patient can be released under the provisions of 10 CFR 35.75. Please confirm that all therapies performed under 10 CFR 35.300 will result in patients being immediately released. If you are performing any in-patient administrations, please provide information concerning patient accommodations consistent with NUREG-1556, Volume 9, Rev. 3, Item 8.9.1. This must include: room diagrams and location of any patient isolation rooms as well as principal use and shielding of adjacent spaces (including above and below), in addition to any additional decay-in-storage, if necessary.

4. Section 8.7, Item 7: *"Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience"*– In your application, you have listed the Radiation Safety Officer (RSO) as Greg Hisel. It appears that Greg Hisel is a contractor/consultant RSO for this license. For a proposed RSO who is a consultant, please address the following items:

    i. 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).

    ii. Identify an in-house representative who will serve as the point of contact during the RSO's absence. Please indicate what duties this individual will be responsible for performing.

    iii. 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.

    iv. 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/her presence.

5. Please confirm if the contact information provided for Greg Hisel is business or personal information. If it is personal, please provide business information if available, or indicate if the information provided can be made publicly available. We also noted two different email addresses in the application. Please confirm the correct email address and indicate if it is a business or personal email address.

6. Section 8.7.2*, "Authorized Users (AUs)"*– Your license lists two physicians who are limited to 35.200. Please indicate if you wish to have them expanded to 35.100. This is not a requirement, but rather acknowledging that 35.200 qualified AUs are automatically considered qualified for 35.100. You may also elect to leave them as-is.

7. Section 8.7.4, *"Authorized Medical Physicist (AMP)"*– In your application, Qinghui Zhang, Ph. D. is requested as an AMP for Ir-192 for High Dose Rate Remote Afterloader (HDR). However, this individual was removed in Amendment #85 and Nicholas A. Mongillo, M.S. was added as an AMP for HDR. Please confirm if you would like to keep Qinghui Zhang, Ph. D. and/or Nicholas A. Mongillio, M.S. as an AMP on your license or if you would like to remove either of them.

8. Section 8.9.1, *"Facility Diagram"*– Please provide the following information:

    a. For all diagrams:
        i. Please note that drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information- Withhold Under 10 CFR 2.390."

        ii. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.

        iii. Location including building, floor and room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.

        iv. Doors should be indicated, and specify which doors are access controlled (i.e., locked) and how security is maintained for any areas where material is used, prepared or stored.

    b. You included a master floor plan for 2800 Main Street, that has various areas numbered; however, the numbered areas are not labelled. Please indicate what numbered areas correlate to the NM, Cardiology and PET locations at this address.

    c. In your application, you have included a close-up diagram labeled "2.8". Please confirm that this diagram is referring to your 2800 Main Street, Nuclear Medicine location. Please also indicate the room numbers, location relevant to the rest of the facility (does the 2.8 refer back to the 2.8 area on the previous floor plan diagram?), and principal use of each room, specifically a detail illustration of hot lab location and layout, stress lab, injection areas, imaging areas and any other areas of byproduct storage or use.

    d. For the SVMC Diagnostic Cardiology at 2800 Main Street, please indicate what area this refers to on the master floor plan. The hot lab diagram indicates M-level Room 23019. Is this the same as the second floor and is this the hot lab break out for the 2800 Main Street Cardiology location?

    e. For the 2979 Main Street, 32 Knight Street and 205 Sub Way locations, please submit a detailed diagram of the hot lab, specifically including areas of byproduct preparation, use and storage (i.e. l-block, syringe shields, remote handling devices, equipment used and radioactive waste storage).

    f. Please provide the address for the diagram illustrating the IR room used for Yttrium-90 treatment and describe the location relevant to other locations of use on your license including building, floor, and room number if applicable.

    g. You have provided a detailed facility diagram for the hot lab at the 1177 Summer Street location. In the illustration, we noted three access doors to the hot lab. In another illustration of this facility, we noted four access doors to the hot lab. Please confirm how many access doors the hot lab has and specify on the

diagram which doors are access controlled (i.e., locked). Specifically, please describe how security is maintained of any areas where material is used, prepared, or stored (i.e. hot lab and waste room). Also indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003.

h. Please provide the following information specific to your PET facilities and confirm at which locations PET imaging is being performed:

   i. There was no facility diagram for PET submitted separate from the shielding evaluation. Please indicate the PET location relative to the master floor plan provided and indicate if the drawing used for the shielding calculations is still applicable for the detail. Include a detailed illustration of the PET/CT hot lab including areas of byproduct preparation, use and storage. Provide information regarding what lies above and below the PET locations.

   ii. You have included shielding calculations dated July 29, 2008, in your application. Please confirm that shielding was installed as designed and recommended. Also, please indicate if there have there been any facility changes since 2008 and if so, confirm that if the shielding was affected it was re-evaluated and any concerns addressed. Please indicate if there has been any change in workload assumptions since 2008 and if so, please update shielding evaluations.

   iii. In your attachment dated October 27, 2009, it is mentioned that the Brachytherapy Hot Lab will be located in the PET/CT area and will be used to store and prepare brachytherapy sources. It is indicated that the room will also be used to store the new HDR unit prior to installation. Please state if this is still the current configuration. If not, please remove this attachment from the application if no longer applicable. Please also remove any other attachments that are no longer applicable.

   iv. For PET and radiopharmaceutical therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

i. You have provided a facility diagram for the 40 Cross Street hot lab. Did you mean for this to be Norwalk hot lab? Our records indicate that this location was removed from your license in 2023 and is not on your list of current requested locations. Please confirm and remove this from your application if it was submitted accidentally.

j. We were not able to locate a facility diagram for your HDR facility. Please provide a diagram and include all relevant information required in Section 8.9.1. Indicate who will have access to the vault and HDR unit and how access is controlled. Additional facility requirements will be requested in item 13b below. Note: You previously submitted to the NRC HDR vault drawings and shielding calculations in a letter dated February 20, 2014, and your daily tests were described in a letter

dated March 14, 2014.

9. Section 8.9.2, *"Radiation Monitoring Instruments*"– In Attachment 8.9 Equipment List of your renewal letter, you have specified the make and model of your survey meters. To confirm that these instruments are adequate to measure the type and level of radioactive material used, please provide both the make and model numbers of the probe attachments used as well, respective to each survey meter. Please also provide make/model and probe information for survey meter designated to HDR.

10. Section 8.9.3, *"Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material"*– In section 8.9.2 of your application, you have committed to establish and implement the model procedure for calibrating the dose calibrator published in Appendix G to regulatory Guide NRC NUREG–1556, Vol. 9, Rev. 3. In section 8.9.3 of your application, you have committed to calibrate equipment used to measure dosages in accordance with nationally recognized standards or the manufacturer's instructions. Please confirm if you would like to keep both commitments for calibration of dose calibrators or commit to one of the statements.

    a. If you are using any alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify any specialized measurement equipment being used and the nationally recognized standard used to calibrate the instruments or provide a copy of the manufacturer's instructions to calibrate the instruments. Alternatively, please confirm if you are not using any alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator.

11. Section 8.9.4, *"Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use"*– In your application, you have provided us with procedures for full calibration for your HDR unit. If the daily QA log you have submitted mimics your spot-check procedure, please note that it is missing items 10 CFR 35.643(d)(4,6,7 and 8). You have also attached model procedures for daily spot-checks in your application that are not consistent with the daily QA log. Please provide your procedure for daily spot-check measurements with the form that will be used to document it as required by 10 CFR 35.643.

12. Section 8.9.5, *"Other Equipment and Facilities*"–

    a. For locations where PET radionuclides are being utilized, describe the additional equipment for these uses specific to each location, as applicable (i.e., L-block, lead cave, syringe shields, etc. that are specific to 511 keV).

    b. For the remote afterloader facility, you indicated that you possess the following but please also provide specific descriptions of the following as indicated in Section 8.9.5 referenced above:

        i. Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room

        ii. Area radiation monitoring equipment

iii. Viewing and intercom systems

iv. Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room.

v. Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

vi. Emergency response equipment (i.e. shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device)

13. Section 8.10.2, *"Occupational Dose"*– Action levels and procedures response not required, thus were not reviewed.

    a. You have listed Landauer as the designated dosimetry processor. Please confirm if you would like to "reserve the right to upgrade your dosimetry processor, as necessary, as long as they are processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor."

14. Section 8.10.6, *"Emergency Procedures for Therapy Devices Containing Sealed Sources*"– Please provide procedures needed to meet requirements of 10 CFR 35.610, including instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions, the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure and the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

    a. Please confirm that a copy of these procedures is physically located at the therapy unit console. Please confirm that the instructions inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position or remove the patient from the radiation field with controls from outside the treatment room.

15. Section 8.10.11, *"Leak Tests"*– You have provided a statement that you have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67. Please indicate if you will conduct leak tests in-house and confirm that you will use the model leak test procedures attached to your application. Otherwise provide the following commitment: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

16. Section 8.11, *"Waste Management"*– Although not required, you have submitted waste disposal procedures in which you indicate that no waste will be disposed of through a

commercial waste broker. Please address how you would dispose sealed sources that cannot be returned to the manufacturer or any waste that does not meet the 120-day decay-in-storage regulation such as Y-90 contaminants.

17. Regarding Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated March 20, 2020, Revision 10.1. Section 6.2.1, "*Termination of Treatment Due to Stasis"*– Please provide the following statement:

    a. "If an administration is terminated because of stasis, then the total dose or activity to the treatment site will be the value of the total dose or activity administered when stasis occurred, and the administration was terminated. We will prepare the record within 24 hours after the completion or termination of the administration and will include the name of the individual who determined the administered dose or activity, the signature of an AU for Y-90 microspheres, and the date signed."

    b. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance may request a license amendment to commit to following the most current revision of the guidance instead. Please indicate if you request the right to make program changes to conform to future revisions of the guidance. This change needs to be reviewed and approved by the Radiation Safety Committee, and training provided to applicable staff before adopting any changes.

We will continue our review upon receipt of this information. Please reply to my attention at *hiba.ahmed@nrc.gov* referencing *Mail Control No*. 639741

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. If you require additional time, please contact me to arrange an alternate schedule.

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 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 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 or would like to set up a meeting to discuss this, please contact me at 610-337-5283 or via electronic mail at hiba.ahmed@nrc.gov.

Thank you for your cooperation.

Sincerely,

Hiba Ahmed

Digitally signed by Hiba Ahmed
Date: 2024.06.14 16:49:09 -04'00'

Hiba Ahmed, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-00843-03
Docket No. 030-01245
Mail Control No. 639741

cc: Greg Hisel, Radiation Safety Officer
Kelli Hannan, Radiology Manager

ST. VINCENT'S MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639741 DATED JUNE 14, 2024

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