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

October 11, 2022

Janette Edwards, MPH, MBA
VP of Operations, Central Region
The Hospital of Central Connecticut
100 Grand Street
New Britain, CT 06050

SUBJECT: THE HOSPITAL OF CENTRAL CONNECTICUT, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 632335

Dear Janette Edwards:

This is in reference to your application dated May 31, 2022, requesting to renew NRC License No. 06-02388-01. The items listed below are referenced back to the cited sections of NUREG 1556 Vol. 9 Rev. 3 Consolidated Guidance About Materials Licenses: Program Specific About Medical Use Licenses, https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html

In order to continue our review, we need the following additional information:

1. On page 2 of your renewal application you requested the authorization for Nathaniel D. Dueker, M.D. to be limited to less than 33 mCi of I-131. Your current license authorizes this physician for less than **and greater than** 33 mCi of NaI. Please confirm that you intended to limit the authorization as indicated on the application.

2. Section 8.8 Training of Individuals Working in or Frequenting Restricted Areas of NUREG 1556 Vol 9 rev 3 provides licensees with information regarding their training program. Please provide the following commitment:

   "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."

3. Section 8.9.1 Facility Diagram of NUREG 1556 Vol 9 Rev 3 provides licensees with information regarding what to submit relative to their facilities. Please provide the following:
   a. 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."
   b. It appears that you may have neglected to submit a diagram of the 201 North Mountain Road location. Submit a diagram for this location.
   c. Provide the addresses for the facility descriptions provided on the diagrams.
   d. For each location specify which doors are controlled (i.e. locked) and any other

relevant information regarding material security.

e. For hot labs, provide a description of the safety equipment utilized (i.e. L-block, syringe shields, shielded waste containers, remote handling devices, etc.)
f. Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use, and High Dose-Rate Remote Afterloader locations. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
g. For PET and sealed-source 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.

4. Section 8.9.4 Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use provides licensees with information to submit relative to the use of their therapy devices. Relative to your spot check and calibration information please provide the following:
    a. Indicate whether the emergency equipment available in the treatment room will include wire cutters.
    b. Under the section "Mechanical Integrity of the HDR equipment," indicate how the HDR equipment is determined to be free of defects and is functioning properly; what criteria is evaluated?
    c. You have indicated that placing a portable survey meter may be used if the prime alert fails on a temporary basis. Indicate what is the maximum amount of time you would rely on this temporary measure.
    d. Under the section, "Source exchange Policy and Procedure," you reference a spreadsheet. Please provide a sample of this sheet.
    e. In the timer accuracy and linearity section you go to 600 seconds. Confirm that your total treatment time does not go beyond 600 seconds or indicate that the unit has independent timers for dwell time and total treatment time.

5. Section 8.9.5 Other Equipment and Facilities provides licensees with information to submit relative to facilities and equipment needed to protect health and property. Please provide the following:
    a. For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable.
    b. For manual brachytherapy facilities, provide a description of the emergency response equipment.
    c. For remote afterloader facilities, provide a description of the following:
        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 (except for LDR units)
        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

6. Section 8.10.2 Occupation Dose of NUREG-1556, Vol. 9, Rev. 3 provides information needed regarding your exposure monitoring program. Please provide one of the following commitments:
   a. "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**
   b. "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.'" **OR, IN LIEU OF THESE STATEMENTS,**
   c. Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

7. Section 8.10.5 Spill/Contamination Procedures indicates what should be provided relative to these procedures. Provide the following commitment:

   "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

8. Section 8.10.10 Material Receipt and Accountability indicates what should be provided relative to receipt and accountability of by-product material. Provide the following commitment:

   "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: 1)license possession limits are not exceeded, 2) licensed material in storage is secured from unauthorized access or removal, 3) licensed material not in storage is maintained under constant surveillance and control, 4) records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

9. Section 8.10.11 Leak Tests indicates what should be provided relative to sealed source leak tests. Provide the following:

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

10. You have requested the use of Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere. Please refer to the licensing guidance found at https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html for information relative to the request for additional information. Please provide the following commitments:
    a. "We will adhere to the newest guidance for the use of Y-90 Theraspheres as published on the NRC website."
    b. "We will provide training on the Y-90 procedure to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed.

This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres."

c. "We commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:"
    i. "We will have procedures for administration requiring a written directive as specified in 10 CFR 35.41, specifically to ensure high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive."
    ii. "We will determine and record the activity of each dosage before medical use in accordance with 10 CFR 35.63 and 10 CFR 35.60 even though Y-90 microspheres are listed as sealed sources in their Sealed Source and Device Registries."
    iii. "We commit to following the manufacturer's procedures or submit alternative methods for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and determining if a medical event has occurred (e.g., performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging)."
    iv. "We will record the dose or activity delivered to the treatment site. The record shall be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the dose or administered activity and the date the record is completed."
    v. "The written directive shall include the patient or human research subject's name; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the model of spheres (e.g. TheraSphere® or SIR-spheres®) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."
    vi. "In the event of stasis, we will prepare a record within 24 hours after the completion or termination of the administration and must 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."
    vii. "In the event of an emergent patient condition, the AU shall document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive shall include the reason for not administering the intended dose or activity, the signature of an AU for Y-90 microspheres, and the date signed."
    viii. "We commit to report any event, except for an event that is caused by shunting as described in the criteria below, or as a result of patient intervention, as defined in 10 CFR 35.2 as an actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration. The criteria for event reporting is:
        1. the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and

a. an administration of the wrong radionuclide or type of microsphere; or
b. an administration to the wrong individual or human research subject; or
c. an administration by the wrong route of administration; or
d. an administration by the wrong mode of treatment; or

2. the total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding shunting as defined in Section 6.1 when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

ix. "We commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:
1. Label vials and vial radiation shields with the radioactive device (i.e. SIR-spheres®, TheraSphere®); and
2. Label syringes and syringe radiation shields with the radioactive device."

x. "We commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75."

We will continue our review upon receipt of this information. Please reply to my attention with a signed letter attached to an email at Robin.Elliott@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 610-337-5076 or via electronic mail at robin.elliott@nrc.gov

Thank you for your cooperation.

Sincerely,

Robin L. Elliott

Digitally signed by Robin L. Elliott
Date: 2022.10.11 09:02:24 -04'00'

Robin L. Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-02388-01
Docket No. 030-01250
Mail Control No. 632335

cc: Mohammed Aljallad, Ph.D.
Radiation Safety Officer

THE HOSPITAL OF CENTRAL CONNECTICUT, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 632335 DATED OCTOBER 11, 2022

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