UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

April 6, 2021

Laura T. Speer Smith, M.S.
Radiation Safety Officer
Bronson Methodist Hospital
601 John St.
Kalamazoo, MI 49007

Dear Mrs. Speer Smith:

We have reviewed the licensee's renewal application dated January 15, 2021, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 21-13125-01 for Bronson Methodist Hospital and letter dated March 3, 2021 to name a new Radiation Safety Officer (RSO) and an Associate Radiation Safety Officer (ARSO).

Based on our review of the information, we have identified that additional information is needed to proceed with the renewal process. Please refer to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses," which is accessible at https://nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html for guidance when preparing your response.

In a signed by senior management and dated letter (or NRC Form 313), please provide the following information by May 6, 2021:

1. Appointment of a new RSO:

    a. Please provide an NRC/Agreement license number/copy where Mr. Ray Carlson is listed as the RSO for Title 10 *Code of Federal Regulations* (CFR) 35.300 and 35.1000 (yttrium-90) material use or provide the additional training in accordance with 10 CFR 35.57(a). Specifically, please provide an attestation that Mr. Carlson received training in radiation safety, regulatory issues and emergency procedures for the use of 10 CFR 35.300 and 35.1000 material including Y-90 SirSpheres and TheraSpheres delivery systems (provide date/s and location/s).

    b. Because the proposed RSO is responsible for overseeing multiple facilities where radioactive material is used, please provide additional information, signed by senior management and Mr. Carlson, regarding the proposed RSO's ability to perform RSO duties (letter dated March 3, 2021 was not signed by management or the proposed RSO):

        - Confirm that the proposed RSO will allocate adequate time at the facility to permit the performance of the duties of the RSO as described in the regulations (you may state the minimum amount of onsite time, hours per week or days per quarter, as appropriate for the program, if desired).

- Identify an in-house representative who will serve as the point of contact during the RSO's absence.
- 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.
- 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.

c. Please resubmit the Delegation of Authority letter for the RSO with new dates and signatures of the proposed RSO and senior management.

2. Appointment of an ARSO:

   Please provide attestation that Ms. Ritchlin received additional training in radiation safety, regulatory issues and emergency procedures for the use of the Y-90 TheraSphere delivery system.

3. Confirm Positron Emission Tomography (PET) material is not used at your facilities.

4. Provide medical license numbers for each Authorized User to be named on the license.

5. Resubmit the diagram for a location of use at 601 John St., Kalamazoo, Michigan to include:

   a. the scale or dimensions of each room where radioactive material is used,
   b. the storage cabinet/area for radioactive material inside the hot lab.

6. Please resubmit the diagram for a location of use 408 Hazen St., Paw Paw, Michigan to include:

   a. the storage cabinet/area for radioactive material inside the hot lab,
   b. clarify the need for a thyroid uptake probe at this location since only the use of 10 CFR 35.100 and 35.200 material is allowed at this location.

7. Location of use at 352 E Lovell St., Kalamazoo, Michigan:

   Please clarify whether you will use material at 352 E Lovell St. Kalamazoo, Michigan, which is currently a location of use listed on the license. If so, please specify the material to be used at this location, purpose, and provide the facility diagrams in accordance with guidance in NUREG 1556, Volume 9, Revision 3. If the location of use is to be removed from the license, please provide the history of use (radioisotopes used and dates the material was used), and the final status survey maps.

8. Please provide additional information regarding the location of use referred to as the radiopharmacy on page 8 of your application dated January 15, 2021. Specifically, provide the following:

   a. the type of material and radioisotopes used,

b. the facility diagrams in accordance with guidance in NUREG 1556, Volume 9, Revision 3, including address, direction of north, dimension/scale, description of rooms and adjacent areas including above and below, detailed description of the hot lab and the equipment, and security measures to prevent unauthorized access.

9. Please provide the final status surveys for the area of the hospital at 955 S Bailey St, South Haven, Michigan to be decommissioned. If the information cannot be provided by May 6, 2021, please resubmit the diagram for the area and include scale/dimensions, description of areas above and below, and describe security measures (i.e. locked door).

10. Please provide a 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."

11. Please provide a complete commitment for medical event reporting in yttrium-90 administrations:

“In place of 10 CFR 35.3045(a), the licensee shall 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:

• 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 ○ an administration of the wrong radionuclide or type of microsphere; or
○ an administration to the wrong individual or human research subject; or
○ an administration by the wrong route of administration; or
○ an administration by the wrong mode of treatment; or

• 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

• 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).”

12. If you wish to make changes to your yttrium-90 radiation safety program, please provide a commitment: “We will follow the following conditions before making revisions to the radiation safety program:

a. the revision is in compliance with the regulations; and

b. the revision is based upon NRC’s current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC’s Medical Uses Licensee Toolkit Web site; and

c. the revision has been reviewed and approved by the licensee's RSO and licensee's management; and

d. the affected individuals are instructed on the revised program before the change is implemented; and

e. the licensee will retain a record of each change for five years; and

f. the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Magdalena R. Gryglak

Digitally signed by Magdalena R. Gryglak
Date: 2021.04.06 11:44:13 -05'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 21-13125-01
Docket No. 030-02146