From: Frank Tran
To: kimberly.prescott@coxhealth.com
Subject: Request additional information for NRC Materials License No. 24-01143-06
Date: Tuesday, January 30, 2024 2:41:00 PM

Dear Kimberly B. Prescott,

This refers to the renewal license application for Lester E. Cox Medical Center, NRC Materials License No. 24-01143-06. We reviewed the application in accordance with the licensing guidance in NUREG-1556, Volume 9, Revision 3, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses”. Based on the review, we will need the following.

1. We could not read the low-resolution facility diagram for Martin Center for Diagnostic Imaging at 3901 S Fremont, Springfield, Missouri. Please resubmit a readable facility diagram showing the scan room, injection room, waiting room, hot lab, etc., as applicable, associated with the use of licensed materials at this location. If patients will only be injected with PET isotopes, waited, and scanned in the PET/CT room, please state. If not, provide the facility diagram with the injection room and/or uptake (waiting) room and the radiation shielding evaluation, if applicable.

2. 10 CFR 35.300 material is authorized for use by the license at Lester E. Cox Medical Center – South at 3801 S National Ave., Springfield, Missouri; however, there is no description of the areas of use related to the material. Please resubmit the diagram with information discussed in NUREG-1556, Vol. 9, Rev. 3, Section 8.9.1, “Facility Diagram” or Appendix C, Item 9 (drawings should be to scale, and the scale used should be indicated; the direction of north should be indicated; location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored; principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; doors should be indicated, and specify which doors are access controlled (i.e., locked).)

3. For the PET/CT suite in the East Campus Nuclear Medicine Department at 3801 S National Ave., Springfield, Missouri, provide the dimension of the PET/CT room. If patients will only be injected with PET isotopes, waited, and scanned in the PET/CT Room, please state. If not, provide the facility diagram with the injection room and/or uptake (waiting) room and the radiation shielding evaluation, if applicable.

4. Confirm that there are no changes for the sealed source manufacturer and model for use in the HDR as permitted by 10 CFR 35.600 which is currently authorized in the license.

5. Your license is authorized for 3M Health Physics Service Model 6500 Series, Amersham Health or Medi-Physics, Inc. Model 6711 (OncoSeed) containing I-125 and Theragenics Corporation Model TheraSeed 200 containing Pd-103, for use as permitted by 10 CFR 35.400; however, there were no information about them in the

application. If you have never possessed them, please state. If they were possessed but disposed, please provide records for the disposal.

6. Provide a description of any additional equipment which will be used in handling PET isotopes as permitted by 10 CFR 35.200 (e.g., vial shielding, syringe tungsten shielding, tong).

7. Item 9 of the application discussed the commitments from the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated June 2012. This licensing guidance is outdated. The current version is Revision 10.2 dated April 20, 2021. Provide a statement that the licensee will, for using Y-90 microspheres as permitted by 10 CFR 35.1000, meet the general requirements in 10 CFR Part 35, Subpart A, "General Information;" Subpart B, "General Administrative Requirements;" Subpart C, "General Technical requirements;" Subpart L, "Records;" and Subpart M, "Reports," except as specified in Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated April 20, 2021, Revision 10.2.

8. Provide a statement that the licensee will provide training in the licensee's procedures related to the use of Y-90 microspheres to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed; and this training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

9. Provide the following statement:

   "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 action by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration of Y-90 microspheres. 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 of the Y-90 licensing guidance when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.)

Additionally, the licensee will comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g)."

10. Provide a statement that the licensee will use only yttrium-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for TheraSphere® and SIR-spheres®, including maximum activity per vial limit.

11. Provide the following statement: "The licensees will survey, with an appropriate radiation detection survey instrument, all areas that the Y-90 microspheres are prepared for use or administered. The survey will be conducted immediately following each preparation and administration in unrestricted areas and by the end of the day for restricted areas. The licensee will retain a record of each survey for three years and the record will include the date of the survey, the results of the survey, the instrument used to perform the survey, and the name of the individual who performed the survey. The licensee does not need to perform surveys in an area(s) where patients or human research subjects are confined when they cannot be released under 10 CFR 35.75."

12. Item 10, "Occupational Dose", of your application referenced NUREG-1556, Vol. 9, Rev. 2. This revision is outdated. Please provide the following statement: "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 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.'"

13. In your application, you provided a copy of the checklist (Appendix C to NUREG-1556, Vol. 9, Rev. 3) and marked "Yes" for Item 10, "Material Receipt and Accountability". However, we could not locate the commitments as stated. Please provide the following:

"We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded;
- licensed material in storage is secured from unauthorized access or removal;
- licensed material not in storage is maintained under constant surveillance and control; and
- records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

14. Item 10, “Safe Use of Unsealed Licensed Material” of the application cited the requirement in 10 CFR 20.1301 (public dose limits), instead of 10 CFR 20.1201 (occupational dose limits). Please provide the following statement: “We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201.”

15. As a part of the license renewal review process, we would like a copy of the delegation of authority for the Radiation Safety Officer.

16. We also received and reviewed your letters dated December 11, 2023, January 2, 2024, and January 5, 2024. Based on the reviewed of the request for authorization for using of Y-90 TheraSphere in medical by Arshan Dehbozorgi, M.D., we need additional information for the proposed authorized user (AU). It appeared the pathway in Section 5.1(A)(3) of the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated April 20, 2021, Revision 10.2, was used in the application for Arshan Dehbozorgi, M.D. Please provide the following for Dr. Dehbozorgi: a) current medical permit/license number and name of the issuing entity (U.S. state or territory); b) training and experience as discussed in Section 5.1(A)(3)(i)(a) (a copy of the recognized board certificate is sufficient); c) name and radioactive materials license number (including the issuing entity: name of Agreement State or NRC) for the Y-90 TheraSphere AUs who provided the training in Section 5.1(A)(3)(ii), (iii), and (iv), and 5.1(B); d) information that Dr. Dehbozorgi has completed at least three unsupervised hands-on patient cases with Y-90 TheraSphere, conducted in the physical presence of a Y-90 TheraSphere AU; and e) a confirmation that the residency training program where Dr. Dehbozorgi obtained the training and experience above was approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and the residency training included training and experience as specified in criteria A and B of the Y-90 microsphere licensing guidance.

To continue the review of your application, we request that you submit your response under a dated and signed cover letter by February 29, 2024. In the cover letter, please reference the license number, docket number and Mail Control No. 637180. If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Best regards,

Frank Tran
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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

References:

NRC Regulations: https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html
NUREG-1556 Series: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html
NRC Forms: https://www.nrc.gov/reading-rm/doc-collections/forms/index.html
NRC License Fees: https://www.nrc.gov/about-nrc/regulatory/licensing/fees.html
Materials Licensees Toolkits: https://www.nrc.gov/materials/miau/mat-toolkits.html