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

March 3, 2022

Kenneth L. Miller, M.D.
Radiation Safety Officer
Washington County Memorial Hospital
300 Health Way Dr.
Potosi, MO 63664

Dear Dr. Miller:

I am reviewing the application dated October 28, 2021, signed by Randy Dunn, Director of Radiology, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 24-32317-01.

The NRC's guidance document for your type of license, which I refer to below as "the guidance", is NUREG-1556, Volume 9, Rev. 3, dated September 2019, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Medical Use Licenses." This guidance is available on the NRC Web site at: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf

Upon review of your application, I identified the following areas requiring additional or clarifying information:

1. NRC Form 313, "Application for Materials License," indicates that the license application should be prepared following the instructions provided in the current volume of NUREG-1556, "Consolidated Guidance About Materials Licenses."

   Your application was not prepared in accordance with the guidance and did not include all supporting documentation. Please understand that each renewal application is evaluated independently of any previously approved radioactive materials license.

   Therefore, please resubmit your application providing all supporting documentation as indicated in the guidance. You may use Appendix B, "Suggested Format for Providing Information Requested in Items 5 through 11, of the U.S. NRC Nuclear Regulatory Commission Form 313," to prepare your revised application.

   Additional items in this letter address the specific areas in which additional or clarifying information is requested. Further information regarding completion of the license application may be found in Section 8, "Contents of an Application," of the guidance.

2. Section 8.5.1, "Byproduct Material and Depleted Uranium," specifies that the licensee should indicate the byproduct material requested.

   Your request is unclear and appears to be incomplete.

   Please refer to Table C-1 of Appendix C of the guidance for an acceptable format for describing the radioactive material and resubmit your request. Specifically, please identify the radionuclides, possession limit, physical form, and the intended use. Also, please clarify if you intended to omit iodine-131 as sodium iodide permitted by Title 10 Code of Federal Regulations (10 CFR) §35.300, in quantities less than or equal to 33 millicuries. If applicable, please confirm that patients will be released under the provisions of 10 CFR §35.75.

3. Section 8.7.1, “Radiation Safety Officer,” of the guidance identifies that the Radiation Safety Officer (RSO) is responsible for the oversight of licensed operations. The RSO must have sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices.

   Submit an updated delegation of authority supporting your continued appointment as the RSO. A model Delegation of Authority is provided in Appendix I, “Radiation Safety Officer Duties, Responsibilities, and Delegation,” of the guidance. The completed Delegation of Authority should be signed by the RSO and a management representative. Include the printed name, title and date for each individual signing.

4. Section 8.7.2., “Authorized Users (AUs),” of the guidance, specifies that applicants should provide the name of each proposed authorized user and the uses requested.

   Your license previously identified Kenneth D. Smith, M.D., as an authorized user. Though, your application for license renewal did not include a reference to this authorized user.

   Please clarify if it is your intention to have this authorized user removed from the license upon issuance of the renewed license. Otherwise, please provide supporting information (e.g., medical license number) to permit his continued identification on the license.

5. Section 8.7.2., “Authorized Users (AUs),” of the guidance, specifies that applicants should provide the medical license number and the issuing entity (e.g., state or territory) for each requested authorized user.

   Your application did not include the medical license number for the requested authorized user, Kenneth L. Miller, M.D.

   Please provide the medical license number and the issuing entity for the requested authorized user.

6. Section 8.8, “Item 8: Training for Individuals Working in or Frequenting Restricted Areas,” of the guidance, states that individuals working with or in the vicinity of licensed material must have adequate safety instructions, as required by 10 CFR Part 19 and 10 CFR Part 35.

   Your application did not address the provision of radiation safety instructions for individuals working with or in the vicinity of licensed material.

   The “Response from Applicant,” section of the guidance, indicates that the following may be provided:

   - the statement, “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.”

   Please submit an acceptable response. For additional information, please refer to Section 8.8, “Item 8: Training for Individuals Working in or Frequenting Restricted Areas,” of the guidance.

7. Section 8.9.1, “Facility Diagram,” of the guidance identifies that facilities and equipment must be adequate to protect health and minimize danger to life or property. The facility design and safety equipment must minimize the possibility of contamination and keep exposures to workers and the public as low as reasonably achievable (ALARA), as required by 10 CFR §30.33(a)(2), 10 CFR §35.12(b)(1), and 10 CFR §35.18(a).

   Your application did not include a facility diagram and description.

   Therefore, please submit a facility diagram and/or drawing providing all of the following:

   - Complete dimensions or the scale of the facility. Also, please identify the direction of north on the facility diagram and/or drawing.
   - Identify the locations, room numbers, and principal use of each room, including patient treatment rooms or areas where radioactive material is prepared, used, and/or stored.
   - Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway).
   - Doors should be indicated, and specify which doors are access controlled (i.e., locked).

8. Section 8.9.2., “Radiation Monitoring Instruments,” of the guidance, identifies that your application must describe the radiation detection instruments available for measuring radiation levels, radioactive contamination, and radioactivity, as applicable.

   Your application identifies that you maintain Ludlum Model 14C survey meters for the performance of radiation measurements. Your application also commits to using Mid-America Calibrations, Inc., to perform annual calibration and repair of your survey meters.

   Your Ludlum Model 14C survey meters should be equipped with an external probe for measuring the typical radiation levels in your facility and for detecting and assessing radioactivity and radioactive contamination at your facility.

   With your response, please identify the compatible external probes to be used with your Ludlum Model 14C survey meters.

   Also note that your commitment to use Mid-America Calibrations, Inc., may be overly restrictive. The guidance specifies that the following is an acceptable response:

   - the statement, “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”

   You may modify your commitment to align with the less restrictive commitment suggested in the guidance.

9. Section 8.9.3., “Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material,” of the guidance, identifies that equipment used to measure dosages must be calibrated in accordance with nationally recognized standards [e.g., American National Standards Institute (ANSI)] or the manufacturer’s instructions.

   Your application indicates that your Dose Calibrator will be calibrated by a qualified person. Your statement is not an acceptable response.

   The “Response from Applicant,” section of the guidance, indicates that the following may be provided:

   - the statement, “Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions.”

   Please submit an acceptable response. For additional information, please refer to Section 8.9.3., “Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material.”

10. Section 8.10.2, “Occupational Dose,” of the guidance, identifies that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

    Your application stated that occupational radiation exposure will be done by Mirion Technologies on a monthly basis.

    Your response appears to indicate that you will obtain dosimetry for your monitored workers from Mirion Technologies, Inc., with processing performed monthly. Though, your response does not identify which occupational workers will be included in your personnel monitoring program. Your response does not provide all required information.

    The “Response from Applicant,” section of the guidance, indicates that one of the following may be provided:

    - the 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
    - the statement, “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.”

    Please submit an acceptable response. For additional information, please refer to Section 8.10.2, “Occupational Dose,” of the guidance.

11. Section 8.10.10, “Material Receipt and Accountability,” of the guidance, identifies that licensees must establish procedures for securing licensed material, maintaining records of the receipt, transfer and disposal of licensed material and conducting physical inventories of licensed material.

    Your application does not identify how you will maintain accountability of licensed material.

The “Response from Applicant,” section of the guidance, indicates that the following may be provided:

- the statement, “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.”

Please submit an acceptable response. For additional information, please refer to Section 8.10.10, “Material Receipt and Accountability,” of the guidance.

12. Section 8.10.11, “Leak Tests, of the guidance, identifies that licensees must perform leak testing of sealed sources possessed under 10 CFR Part 35 (e.g., calibration, transmission, reference, or brachytherapy sources), in accordance with 10 CFR §35.67, “Requirements for possession of sealed sources and brachytherapy sources.”

    Your application does not address the performance of leak testing of your sealed sources.

    If a contractor is used to perform leak testing, the “Response from Applicant,” section of the guidance, indicates that the following may be provided:

    - the statement, “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.”

    Please submit an acceptable response. For additional information, particularly regarding the establishment of an in-house leak testing program, please refer to Section 8.10.11, “Leak Tests,” and Appendix Q, “Model Leak Test Program,” of the guidance.

13. Section 8.10.14, “Safe Use of Unsealed Licensed Material,” of the guidance, identifies that licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material, from the time it arrives at their facilities until it is used, transferred, and disposed of.

    Your application included the following statement: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.”

    It appears that a typographical error was made. Rather that the reference to 10 CFR §20.1301, “Dose limits for individual members of the public,” it appears that the intended reference is to 10 CFR §20.1201, “Occupational dose limits for adults.”

Please revise your commitment to match that suggested in the guidance, which should include the statement: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter 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.

To continue review of your application, I request that you submit your response to this letter within 20 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or need clarification on any of the information stated above, I encourage you to contact me at Jason.Kelly@nrc.gov or at (630) 829-9737.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2022.03.03 08:02:04 -06'00'
Adobe Acrobat version: 2021.007.20099

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-35711
License No.: 24-32317-01
Control No.: 629060