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

April 18, 2024

Larry Kestin, M.D.
Radiation Safety Officer
American Oncologic Associates of Michigan, P.C.
70 Fulton St.
Pontiac, MI 48341

Dear Dr. Kestin:

This letter is regarding the application dated January 30, 2024, signed by Tim Nurushev, Ph.D., Deputy RSO, for the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-26488-01.

The U.S. 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 U.S. NRC website at: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf

Upon review of the request, 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."

   The application was not prepared in accordance with the current guidance and did not adequately address all required items. Therefore, you may revise and resubmit your application using Appendix C, "Suggested Format for Providing Information Requested in Items 5 through 11, of the U.S. NRC Nuclear Regulatory Commission Form 313," from the guidance.

   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 8.7.1, "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 continuing appointment as RSO. Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation," of the guidance includes an example delegation of authority on page I-4. Note that the delegation of authority should be signed by the RSO and a management representative. Include the printed name, title, and date for each individual signing.

3. Section 8.7.1, “Authorized Users (AUs),” of the guidance, identifies that applicants must provide the medical license number and identify the issuing entity for each requested Authorized User.

   The application did not include the required information.

   A check with the Michigan Licensing and Regulatory Affairs’ Bureau of Professional Licensing website was not successful in locating the medical license number for Mihai Ghilezan, M.D.

   Please provide evidence that Mihai Ghilezan, M.D., has a valid medical license from the Michigan Licensing and Regulatory Affairs’ Bureau of Professional Licensing.

   Further, your application omitted Thomas P. Boike, M.D., who was previously identified on your license as an Authorized User. Please confirm that the Authorized User should be removed upon issuance of the renewed license.

4. Section 8.8, “Item 8: Training for Individuals Working in or Frequenting Restricted Areas,” of the guidance, identifies that individuals working with or in the vicinity of licensed material must have adequate safety instructions, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 19 and 10 CFR Part 35.

   The application does not identify how you will provide safety instructions to your workers.

   The “Response from Applicant” section of the guidance states that the following should 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 provide an acceptable and complete response.

5. Section 8.9.1, “Facility Diagrams,” of the guidance, identifies that the application must include a facility diagram and description of the rooms or rooms where radioactive material are prepared, used, administered and stored, with a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect public health and minimize danger to life or property.

   The application requests authorization to use licensed material described in 10 CFR §35.300 (limited to parenteral administration of unsealed byproduct material); however, the application does not include a diagram and description of the areas where this licensed material is received, prepared, used and disposed for each requested location of use.

Provide the following for each location of use:

- facility diagrams and/or drawings, identifying room dimensions and the direction of north;
- location, room numbers, and principal use of each room, including patient treatment rooms where radioactive material is prepared, used and stored;
- principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway);
- doors should be indicated, specifying which doors are access controlled (i.e., locked);
- specific hot lab detail, including the locations of available sink(s), shielded cave, L-block, dose calibrator and cabinets for storing radioactive waste as applicable; and
- label the boundary of the restricted area.

6. Section 8.9.1, “Facility Diagram,” of the guidance, specifies that your application should include shielding calculations for your HDR Remote Afterloading Brachytherapy facilities, including a description of the shielding materials (type, thickness and density) to be installed, distances to adjacent areas, workload assumptions (including the number of exposures per day, time per exposure in minutes and number of workdays per week) and should account for the maximum activity authorized for medical use.

   The submitted shielding evaluations do not account for the requested maximum activity authorized for medical use. Further, your facility diagrams do not clearly identify the type, thickness and density of the shielding materials installed, which is needed for independent verification of your shielding calculations.

   If applicable, please also identify the distances to adjacent areas from both primary and any secondary treatment locations within the HDR Remote Afterloading Brachytherapy vault.

7. 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.

   The application does not identify the radiation detection instruments that will be available at your facility and does not include all applicable commitments identified in the current guidance.

   The “Response from Applicant” section of the guidance states that the following should be provided:

   - a statement that: “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”; and/or
   - a statement that: “We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.”; and

- a description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys is attached.

Please provide an acceptable and complete response.

8. Section 8.9.3, "Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material," of the guidance, identifies the requirements for the use, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

The application does not identify your dose calibrator and other equipment used to measure dosages of unsealed byproduct material.

The "Response from Applicant" section of the guidance states that the following should be provided:

- a statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."; and
- a description of the equipment used to measure the dosages; and
- for measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

Please provide an acceptable and complete response.

9. Section 8.9.4, "Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use," of the guidance, specifies that licensees must perform full calibrations before first medical use and at intervals specified in 10 CFR §35.633. For additional information, the guidance refers to AAPM Report No. 41, "Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41)," 1993.

Additionally, licensees must also perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the Authorized Medical Physicist as specified in 10 CFR §35.643.

The application requests continuing authorization to possess and use the following device and medical use subject to the above requirements:

- Elekta, Inc. (formerly Nucletron Corporation) Model 136149A02 Flexitron HDR remote afterloader for medical use as permitted in 10 CFR §35.600;

The "Response from Applicant" section of the guidance states that the following should be provided:

- the applicant must provide the procedures required by 10 CFR §35.643, if applicable to the license application.

While the application included a Spot Check Procedure, the submitted procedure lacked adequate detail (e.g., timer accuracy within one percent). As an example of the level of detail needed, please refer to Appendix H (Model Procedure for Remote Afterloader Spot-Checks) of the guidance.

Please respond by resubmitting the Spot Check Procedure with additional detail.

10. Section 8.10.2, "Occupational Dose," of the guidance specifies that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure in accordance with 10 CFR §20.1502.

The application identifies that you will provide dosimetry that meets the requirements listed under "Criteria," in NUREG-1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

The response is not acceptable because it does not refer to the current revision of the guidance.

Therefore, you may revise your statement providing one of the responses identified in the "Response from Applicant," section of the guidance, as follows:

- 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."; and/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.'"; or, in lieu of these statements,
- provide a description of an alternative method for demonstrating compliance with the referenced regulations.

Please provide an acceptable and complete response. For additional information, you may refer to Section 8.10.2 and Appendix M, "Model Procedures for Occupational Dose Monitoring Program," of the guidance.

11. Section 8.10.6, "Emergency Procedures for Therapy Devices Containing Sealed Sources," of the guidance, identifies that you must develop, document, implement, and submit written emergency procedures in accordance with 10 CFR §35.610.

The Emergency Procedures must include:

- 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.

The application identified that a copy of the emergency procedures to be followed in case of failure of source retraction was enclosed. Upon review, I was not able to locate applicable Emergency Procedures for your HDR Remote Afterloading Brachytherapy Unit.

Therefore, please submit your HDR Remote Afterloading Brachytherapy Emergency Procedures ensuring that it addresses all of the above items.

12. Section 8.10.6, "Emergency Procedures for Therapy Devices Containing Sealed Sources," of the guidance identifies that a copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. The licensee must provide instructions, initially and annually, to include responding to an abnormal situation described in 10 CFR §35.610(a)(4). Practice drills, using nonradioactive (dummy) sources when possible, must be practiced at least annually and may be conducted more frequently, as needed. Team practice is important for adequate emergency coordination. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators, if applicable, and emergency procedures for removing the patient from the radiation field. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points:

- when the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation;
- the actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient;
- the step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions (procedures should clearly specify which steps are to be taken under different scenarios and should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event);
- location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios (emergency equipment should include 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);
- radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position);
- instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation;
- specifying who is to be notified; and
- requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Please confirm that your staff receive annual training in the above subjects, including practice drills addressing stuck or dislodged sources and applicators.

13. Sections 8.10.10, "Material Receipt and Accountability," of the guidance, describes that licensed materials must be tracked from "cradle to grave," from receipt to its eventual transfer/disposal; to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and ensure that the possession limits listed on the license are not exceeded.

The application does not describe how you will ensure that licensed radioactive materials are secured from unauthorized access or removal or maintain continuous surveillance of licensed radioactive material that is not in secure storage.

The "Response from Applicant" section of the guidance indicates that the following statement should be provided:

"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
- records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

Therefore, please respond by describing your Material Receipt and Accountability Procedures.

14. 10 CFR §30.32(i) and 10 CFR §30.35 identify applicable requirements for provision of financial assurance and submission of an emergency plan.

While provision of financial assurance and the submission of an emergency plan is not typically required for medical use licensees, the expanding use of alpha emitting therapeutic radiopharmaceuticals requires its consideration.

This is in part because certain alpha-emitting therapeutic radiopharmaceuticals, including accelerator produced actinium-225 may include long-lived impurities of actinium-227. While typically only a small percentage, some licensees may approach or exceed the 10 microcurie threshold for actinium-227 for which submission of financial assurance in the specified amounts identified in 10 CFR 30.35(d) is indicated.

Further, the threshold for submission of an emergency plan for a licensee possessing alpha-emitting therapeutic radiopharmaceuticals may also be approached or exceeded. For example, the threshold for submission of an emergency plan for a licensee possessing actinium-225 is 2 curies.

Licensees possessing multiple alpha-emitting therapeutic radiopharmaceuticals must also account for the combination of all unsealed radionuclides when determining the

applicability of the requirement for provision of financial assurance or submission of an emergency plan.

As this item is only advisory in nature, no specific response is required or necessary unless changes are made to your application to address it.

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 request, please submit your response to this letter within 30 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 require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by JASON KELLY
Date: 2024.04.18 15:32:47 -05'00'
Adobe Acrobat version: 2023.008.20533

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-33134
License No.: 21-26488-01
Control No.: 639062