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

July 2, 2024

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

Dear Dr. Kestin:

A request for additional information was sent to you on June 14, 2024, in reference to your request to renew your U.S. NRC Materials License No. 21-26488-01. A copy of this request is enclosed for your reference. A response was requested by July 1, 2024. To date, your response has not been received.

To continue the review of your request, please submit a written response to this letter by July 12, 2024. Failure to respond by this date may result in your request being considered abandoned and appropriate administrative actions may be initiated.

To expedite the licensing process, you may fax your response to (630) 515-1078. If you have any questions, you may contact me at (630) 829-9737 or Jason.Kelly@nrc.gov.

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the U.S. Nuclear Regulatory Commission's (NRC) "Rules of Practice," a copy of this letter and enclosure will be 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 http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Digitally signed by JASON KELLY
Date: 2024.07.02 08:37:58 -05'00'
Adobe Acrobat version: 2024.002.20759

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

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

Enclosure(s): As stated

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

June 14, 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, and your letter dated June 13, 2024, requesting 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. Section 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)," identifies that a licensee may choose to identify one or more individuals as ARSOs to support the RSO in accordance with 10 CFR §35.24(b). The ARSOs may be assigned duties and tasks in the oversight of the radiation safety operations of designated sections of the licensed program, but the RSO retains responsibility for all sections of the program.

   It appears that you would like to identify Tim Nurushev, Ph.D., as an Associate Radiation Safety Officer, on the license. Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation," of the guidance includes a "Model Appointment of ARSO," on page I-5. Note that this appointment document should be signed by the RSO and a management representative. Include the printed name, title, and date for each individual signing.

   If applicable, please complete and submit the above Model Appointment of ARSO or otherwise include documentation affirming that the appointed ARSO will report to you as the RSO.

2. 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 (including the address on each facility diagram or drawing), 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.

3. 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 Radiation Survey Physics Report dated August 23, 2018, for your facility in Pontiac, Michigan, was performed with a source less than the maximum activity authorized. At that time, a commitment was made to repeat the survey evaluation using a source equaling or closely approximating the maximum activity authorized for use.

   Please confirm that a follow-up survey was performed as stated above and provide applicable documentation of the survey, including the date of the survey, identification of the individual performing the survey, instrumentation used and the survey results.

4. 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 in Madison Heights, Michigan.

   Submit 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 available for the performance of required surveys at your facility in Madison Heights, Michigan.

   Further, please clarify if your facilities have specialized instrumentation available for assessing alpha-emitting radionuclides and performance of full calibration measurements of the HDR remote afterloader unit per 10 CFR §35.630(a) and 10 CFR §35.633.

5. Section 8.9.4, “Manual Brachytherapy Sources and Sealed Sources in Therapy Unit – Calibration and Use,” of the guidance, identifies that licensees must 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 “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.

   The letter dated June 13, 2024, included your Daily Q/A procedure for the Flexitron HDR afterloader unit, which you identified as aligning with Appendix H, “Model Procedures for Remote Afterloader Spot-Checks,” from the guidance.

   Upon review of the submitted Daily Q/A Procedure for the Flexitron HDR afterloader unit, I identified that the procedure either does not address or does not include adequate detail for some of the topical areas specified in Appendix H (Model Procedure for Remote Afterloader Spot-Checks) of the guidance.

   Please respond by resubmitting the Spot Check Procedure ensuring that it addresses all topical areas included in Appendix H with equivalent detail. For example, this should include:

   - ensuring that source activity displayed in the control console matches to within 0.5 percent of the manufacturer’s provided decay table; and
   - verification of stopwatch measured time to the irradiation time indicated on the control console to within one percent.

6. Section 8.13, “Item 13: Certification,” specifies that a representative of the legal entity filing the application must sign and date the NRC Form 313, “Application for Materials License.” The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant (i.e., a certifying official).

   Tim Nurushev, Ph.D., Deputy RSO, signed the application for license renewal dated January 30, 2024. Though, his title is not recognized as that of a certifying official (i.e., President, Director or Branch Manager).

   Therefore, please confirm that you recognize his previous statements and commitments as legally binding, except as superseded by your statements and commitments included in your letter dated June 13, 2024. For additional information, you may refer to Chapter 3, “Management Responsibility,” of the guidance.

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 15 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: 2024.06.14 16:31:15 -05'00'
Adobe Acrobat version: 2024.002.20759

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

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