From: Elliott, Robin
To: "Greg Madison"
Subject: Renewal of License No. 47-31304-02, CN 611096 Request for Additional Information
Date: Monday, March 04, 2019 12:27:55 PM

License No.: 47-31304-02

Docket No: 030-37863

Control No: 611096

Licensee Name: Beckley Oncology Associates, Inc.

This refers to your request to renew your license dated January 1, 2019. In order to continue our review of your request, the following additional information is needed:

1. Your current license lists Alan M. Lintala, M.D. and Shawn D. Reesman, M.D. as authorized users (AU) for Ra-223 and your application did not list them as AUs. Please confirm that they should be removed from the license.
2. NUREG 1556 Vol. 9 Rev. 2 https://www.nrc.gov/docs/ML0734/ML073400289.pdf Section 8.16 Facility Diagram provides guidance to licensees regarding information to include in their applications for facilities. Please indicate what lies above and below the facilities where licensed material will be used.
3. NUREG 1556 Vol. 9 Rev. 2 Section 8.20 Other Equipment and Facilities provides guidance to licensees regarding information to include in their applications for providing facilities and equipment that protect health and minimize danger to life or property. In your application you indicated that the keys to the HDR storage location are stored in a lockbox. Please indicate who has access to the lockbox and their training status.
4. NUREG 1556 Vol. 9 Rev. 2 Section 8.23 Occupational Dose provides guidance to licensees regarding information to include in their applications for addressing occupational dose. You provided information in your application regarding monitoring individuals working in and around the HDR facility. With regard to the use of Ra-233, please confirm that you will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licensees," dated October 2002 (enclosed). Otherwise, please describe an alternative method for demonstrating compliance with the referenced regulations. You may refer to Appendix M of the NUREG 1556 Vol. 9 Rev. 2 for guidance in preparing your response.
5. 10 CFR 35.610 requires that licensees develop written safety procedures for emergency response for remote afterloader units. The actions specified for emergency response should give primary consideration to minimizing exposure to the patient and healthcare personnel while maximizing patient safety. In your application, you provided a document entitled, “Safety Procedures and Instructions for the High Dose Rate Remote Afterloader.” Please submit written safety procedures that you will implement for emergency response for your remote afterloader unit including:
   a. the circumstances when emergency procedures are to be implemented (i.e., when the source cannot be returned to a fully shielded position with controls from outside the room, console indicates source is not retracted or shielding doors are not closed;
   b. step-by-step instructions/actions for responding to single and/or multiple equipment failures and the individual(s) responsible for implementing each action. Clearly specify which steps are to be taken under different scenarios (i.e., exposed source versus a detached source);
   c. the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
   d. the names and telephone numbers of authorized users, authorized medical physicists, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
   In addition, 10 CFR 35.610 requires, in part, that all device operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially

and at least annually. You may refer to Item 8.22 of NUREG 1556 Vol. 9 Rev. 2 for guidance in preparing your response.

1. NUREG 1556 Vol. 15 Rev. 1 Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses https://www.nrc.gov/docs/ML1618/ML16181A003.pdf provides licensees guidance related to change of control. It appears from your application, since you have included the designation dba Carl Larson Cancer Center, that a possible change of ownership (control) has occurred. Licensees must provide full information and obtain NRC's ***prior written consent*** before transferring control of the license. Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license. A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation. A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.
   a. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.
   b. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.
   c. Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.
   d. Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.
   e. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
   f. Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.
   g. Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Regards,

Robin L. Elliott
Health Physicist
Medical & Licensing Assistance Branch
Division of Nuclear Materials
U.S. NRC, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5076 voice
(610) 337-5269 fax
Robin.Elliott@nrc.gov