From:	Elliott, Robin
To:	Bruce Morton
Cc:	Gallaghar, Robert
Subject:	Request for Additional Information, License No. 47-35564-01, CN 613864
Date:	Thursday, September 12, 2019 7:21:00 AM

Licensee Name: Beckley Cardiology, PLLC
License No.: 47-35564-01
Docket No.: 030-39191
Mail Control No.: 613864

Dear Mr. Morton,

As per our phone conversation September 9, 2019, additional information is needed to process the application for a new license for Beckley Cardiology, PLLC.

- Please confirm that you do not possess or intend to use PET radiopharmaceuticals.
- NUREG 1556 Vol. 9 Rev. 2 https://www.nrc.gov/docs/ML0734/ML073400289.pdf Section 8.5 Radioactive Material, provides guidance to licensees regarding information to include in their applications for the byproduct material requested. On the second page of your application you list sealed sources not associated with 10 CFR Part 35. Calibration, Transmission and Reference sources are not required to be listed on the license provided they are covered under 10 CFR Part 35.65. Confirm that the sealed sources listed on your application will be used under 10 CFR 35.65 and provide the manufacturer and model number for any sealed sources that do not meet the criteria in 10 CFR 35.65 (e.g. greater than 30 millicuries).
- NUREG 1556 Vol. 9 Rev. 2 Section 8.11 Radiation Safety Officer, provides guidance to licensees regarding information to include in their applications to support the naming of a Radiation Safety Officer. The 313A RSO form submitted with the application did not have Section 3.C. completed to document the training in radiation safety, regulatory issues, and emergency procedures for the type of medical use requested as required by 10 CFR 35.51(e). Provide this information.
- NUREG 1556 Vol. 9 Rev. 2 Section 8.15 Facilities and Equipment and Section 8.16 Facility Diagram provides guidance to licensees regarding information to include in their application regarding the facility design and equipment used to protect health and safety. Further additional information is needed for the current facility diagrams submitted as outlined in NUREG 1556 Volume 9 Revision 2 and can be found in section 8.16: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final.pdf#08-16

  It can also be found in NUREG Volume 9 Revision 2 Appendix E Figure E.1.: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final.pdf#app-e

  The additional information we are requesting is as follows:
  - Provide room numbers for the restricted areas as applicable.
  - Show adjacent rooms, what exists above and below the use areas and their relation to the exterior of the building as applicable.
  - Indicate what shielding will be used to reduce occupational exposure, such as L-block and syringe shields.

- Drawings and diagrams that provide exact locations of materials or depict specific locations of safety or security equipment should be marked as "Security-related information – withhold under 10 CFR 2.390."

- NUREG 1556 Vol. 9 Rev. 2 Section 8.17 Radiation Monitoring Instruments provides guidance to licensees regarding information to include in their application regarding calibration of radiation detection and measuring equipment.
  - In your application you state, "Survey Meter calibrations are performed, other than in-house, by individuals identified on a radioactive materials license, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform these services." Clarify if you are requesting survey meter calibrations to be conducted "in-house." If so, provide the following commitment: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements in 10 CFR 35.61."
  - In addition, you may wish to also make the following statement: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

- The following sections of NUREG 1556 Vol. 9 Rev. 2: 8.23, 8.24, 8.25, 8.26 and 8.29 suggest that the licensee may make statements committing to the development, maintenance and implementation of applicable procedures. You have submitted specific procedures to address these sections of the NUREG. You may choose to replace these procedures with the designated commitments if you choose to obtain flexibility in the revision of the applicable procedures. However; if you do you not replace the procedures with the commitment statements, the procedures, as submitted, will become part of the license and will require an amendment to modify them in the future. In addition, please provide a statement that you will implement and maintain the procedures submitted.

When submitting your response, management must sign the letter transmitting the information. Once we receive the additional information requested, we should be able to finalize the processing of your application, pending the successful pre-licensing visit that will occur the week of September 23, 2019. Mr. Robert Gallaghar will perform this visit. You may respond to my attention in writing by letter, email with an attached scanned letter, or fax (610-337-5269), referencing mail control 613864. 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.

Regards,

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