

From: [Shawn Seeley](#)
To: kim.lowe@camc.org
Subject: Request for Additional Information MC633365
Date: Monday, January 23, 2023 1:18:00 PM

Dr. Lowe,

This is a request for additional information with respect to the renewal application dated October 31, 2022, in support of NRC license number 47-15473-02MD. In order to complete our review, we need the following additional information.

1. Your application implies that you do not transfer sealed and unsealed materials to mobile medical licensees. Please confirm you will not be transferring materials to mobile medical licensees.
2. Your application on page B-9 states, among other things, that for the preparation of radiopharmaceuticals that you be compounding using a "Boxer Kit". Please confirm if you will be compounding any iodine-131 capsules.
3. Section 10.13, "Leak Testing" of your application, refers to attachment #7 as containing the description of the leak testing process. However, Attachment #7 appears to be absent on the leak testing procedure. Please provide the information noted in Appendix H of NUREG-1556, Volume 13, Revision 2 and either submit a statement that "The applicant will follow the model procedures in Appendix H of NUREG-1556, Volume 13, Revision 2, Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Commercial Radiopharmacy Licenses." Or submit alternate procedures.
4. Section 11, "Waste Management" of your application, requests extended interim storage of waste. However, your application appears absent on the required information as outlined in Section 8.11 of NUREG-1556, Volume 13, Revision 2. Please submit the information required in Section 8.11.
5. Please note the Attachment #7 that was submitted appears to reference several old attachments from a previous application. Specifically, Item 8 in this attachment references attachments 12, 13, 14, 15, 16 and 17. However, attachments 11 through 16 were submitted. Please revise the Attachment 7 and submit for our review.

Please let me know if you have any questions or require clarification. We will continue our review upon receipt of this documentation.

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