FEB 2 3 2012

Positron Corporation
License No. 13-32765-01
Docket No. 030-38150

Mr. Ronald Hinton,

I have reviewed your requests received December 20, 2011, and February 14, 2012, and require responses to the following before I can complete my review:

1. Describe the facilities and equipment to be made available at the location where indium-111 Oxyquinoline will be processed.

2. Provide a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive material. You submitted diagrams for both facilities which did not show dimensions. Please resubmit your diagrams with dimensions and enlarge the writing so that it can be read.

3. Based on the information that you provided, Mr. Pitt, the proposed Radiation Safety Officer, is located in the State of Texas. Please explain/confirm that Mr. Pitt will be available to provide advice and assistance on radiological safety matters in a timely manner at your facilities in the State of Indiana.

4. Please submit a description of your training program including topics covered, groups of workers, and frequency of training for each group.

5. Please submit your audit program. It should be noted in the program whether or not operating procedures which can potentially affect the use of radioactive material or occupational dose have been developed, documented, implemented and maintained to demonstrate compliance with 10 CFR 20.1101(a).

6. Describe the instrumentation that will be used to perform required radiation surveys.

7. For occupational dose you indicate that Positron has done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 % of the allowable Part 20 limits. Please confirm that your prospective evaluation for occupational dose included a review of the In-111 Oxyquinoline production extremity/whole body monitoring.

8. Please provide the maximum activity of indium-111 intended per vial, syringe or other container of radioactive material. On page 6 of 6 of your letter received December 20, 2011, you show "shielding specifications". Please clarify exactly what the drawings represent. Also indicate the type of material the shields are made from. Please confirm that your proposed shielding is appropriate for the safe handling, shipping and storage of radioactive material.

9 Please review 10 CFR 32.72(c) and provide the method(s) by which Positron staff will measure the activity of radiochemical indium-111 prior to transfer for commercial distribution.

10. Please confirm that the labels affixed to each vial and or shipping container will identify the quantity of radioactivity at a specific time and date.

11. Your labels indicate that the radiochemical indium-111 Oxyquinoline is not for human use. Page one of your letter received February 14, 2012, states that you will distribute the radiochemical to licensed pharmacists and research laboratories. Please explain how this radiochemical will ultimately be used.

12. There has been a high turnover in a very short time of Radiation Safety Officers at Positron Corporation and NRC is concerned about the stability of your radiation safety program. Please tell us how you will ensure that your radiation safety program will meet NRC expectations in the future, particularly in view of your request to manufacture and distribute a radiochemical.

After reviewing the training and experience of Mr. Lane and Mr. Overman, they will not be added to your license at this time. If you wish to add them as authorized users in the future, please provide the training and experience described in Section 8.7.2 of NUREG-1556 Volume 12. However, they may continue to use radioactive material under the supervision of Ronald Bailey.

Please respond to each item above in writing including a viable signature and a date. Please reference the control number **576574.** You may pdf your response and send it to me by email (toye.simmons@nrc.gov). Or you may fax your response to 630-515-1078. Please submit your response by March 7, 2012. Should I not receive your response by that date your request will be voided without prejudice for re-submittal. If you have any questions feel free to contact me at 630-829-9842.

Toye L. Simmons
NRC Region III License Reviewer

February 23, 2012
Date