UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

June 28, 2012

Docket No. 03018982 License No. 47-15473-02MD
Control No. 577682

George A. Farris
Associate Administrator
Charlestown Area Medical Center
P.O. Box 1547
Charleston, WV 25326

SUBJECT: CHARLESTOWN AREA MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 577682

Dear Mr. Farris:

This is in reference to your application dated May 28, 2012 requesting to renew Nuclear Regulatory Commission License No. 47-15473-02MD. In order to continue our review, we need the following additional information:

1. You did not fill in item 2 of your application which is the name and mailing address of the applicant. Please confirm that the current name and mailing address is accurate.

2. On item 5 of your application you did not request for yttrium 90 which is currently listed on your license. Please confirm that you wish to have that isotope removed from the license.

3. You did not list the sealed sources for any byproduct material authorized under 10 CFR 35.65. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; **or** contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed source(s) requested in your application or alternately state that the model numbers currently listed on your license are sufficient.

4. You provided few specifics about the distribution and redistribution of sealed and unsealed materials. Please see NUREG-1556, Volume 13, Rev. 1, “Consolidated Guidance About Material Licenses, Program-Specific Guidance About Commercial Radiopharmacy Licenses”, Section 8.6.1 as a reference for the needed information. Please confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32,72, or under equivalent Agreement State requirements; and describe all licensed material to be distributed or redistributed.

5. In your application, you supplied the procedures for repackaging used generators for distribution. NUREG-1556, Volume 13, Rev. 1, “Consolidated Guidance About Material Licenses, Program-Specific Guidance About Commercial Radiopharmacy Licenses”, Section 8.6.1 state to: confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; confirm that the generator will not be distributed beyond the expiration date shown on the generator label; confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and confirm that only generators used in accordance with the manufacturer’s instruction will be redistributed. These requirements were not in your application or procedure, please make the preceding confirmations.

6. You had requested an authorize use to distribute any byproduct material authorized under 10 CFR 35.65. NUREG-1556, Volume 13, Rev. 1, “Consolidated Guidance About Material Licenses, Program-Specific Guidance About Commercial Radiopharmacy Licenses”, Section 8.6.1 states to confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements, to initially distribute such sources, and confirm that the manufacturer’s labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing of sources. Please make the preceding confirmations.

7. You did not provide what types of radiopharmaceutical preparation activities you intend to perform. NUREG-1556, Volume 13, Rev. 1, “Consolidated Guidance About Material Licenses, Program-Specific Guidance About Commercial Radiopharmacy Licenses”, Section 8.6.2 states that the applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform (e.g., compounding of iodine 131 capsules, radioiodination, chemical synthesis of PET radiopharmaceuticals, and technetium-99m kit preparation). In particular, you requested I-123 as an additional material authorization. Please provide what types of radiopharmaceutical preparation activities you intend to perform.

8. Your application included a facility diagram and locations of some source storage locations. However, in accordance with the checklist in Appendix D, NUREG-1556, Volume 13, Revision 1, you did not provide a description of the facilities and equipment to be made available, identification of activities conducted in all contiguous areas surrounding the facility, descriptions of the areas assigned for production, receipt, storage, preparation, measurement, and distribution of radioactive materials and the location for radioactive waste storage. Shielding, the proximity of radiation sources to unrestricted areas and other items related to radiation safety like description of the ventilations system including airflow rates and monitoring systems if needed were not included. Please include the description as described in NUREG-1556, Volume 13, Revsion 1, section 8.9.2.

9. Your application did not include a description of the types of systems to be used for the measurement of alpha – beta – gamma- and photon –emitting radioactive drugs as listed

in section 10.8 of Appendix D. It also did not include a sample calculation for determining beta-correction factors for dose calibrators with ionization chamber or a means for ensuring the accuracy of beta-corrections factors supplied by the instrument manufacturer or other entity. Please include these descriptions.

10. Your application in section 10.11 did not describe all labels, indicating the colors to be used that will accompany the products and where each label is placed. Please include a description that describe all labels, indicating the colors to be used, that will accompany the products and where each label is placed. Please see section 8.10.11 of NUREG-1556, Volume 13, Revision 1 for background information.

11. Your application in section 10.12 did not provide the radionuclide and maximum activity for each type of container, describe the type and thickness of the "transport radiation shield" provide for each type of container, and did not indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity. Please provide this information. Please see section 8.10.12 of NUREG-1556, Volume 13, Revision 1 for background information.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 577682. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Steven Artz, M.D., Radiation Safety Officer

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