From: Weidner, Tara
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Subject: NRC-Request for additional information
Date: Friday, July 13, 2012 2:12:00 PM

Docket No. 03038552License No. 41-31476-01
Control No. 577686

D. Scott Holbrook
Diagnostic Laboratories, LLC
101 Dillon Court
Gray, TN 37615

SUBJECT: DIAGNOSTIC LABORATORIES, LLC, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR A MOBILE MEDICAL SERVICE LICENSE, CONTROL NO. 577686

PLEASE RESPOND BY RETURN E-MAIL TO CONFIRM RECEIPT OF THIS REQUEST

Dear Mr. Holbrook:

This is in reference to your application dated May 30, 2012 requesting a Nuclear Regulatory Commission License for a mobile medical service. In order to continue our review, we need the following additional information:

1. Your application failed to list any authorized users for the intended radioactive materials. In order for a license to be issued, qualified authorized users must be identified.

2. Based on the information provided, it is our understanding that you will provide "scan-in-van" services to your clients. For scan-in-van service, provide the following information:

   a. Please submit procedures for siting the mobile van at temporary job sites. Mobile vans should be sited on the client's property, preferably adjacent to the building (e.g., outpatient entrances, receiving docks, etc.) Siting the mobile van for scanning in public right-of-ways (e.g., streets, public parking areas, alleys, etc.) is not acceptable.

   b. Provide shielding calculations demonstrating how the scan-in-van operation shall remain in compliance with 10 CFR 20.1301 regarding radiation levels in unrestricted areas (i.e. outside of van).

3. Your application stated that, “You will develop, implement, and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.” If you will be performing your own calibrations, please identify the source that you will use by source manufacturer and model number, nuclide, activity, and calibration accuracy. Otherwise state that, “Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations”.

4. Describe the additional facilities and equipment that you will have available for use with PET radionuclides to receive, use, store, and dispose of these materials. Focus on the need for additional shielding and other remote handling devices that may be needed when handling and storing the higher energy emissions of these materials.

5. The Memorandum of Understanding (MOU) provided in your application states that, "It will be the responsibility of _____ to provide the sanitary facilities for patient use prior to/pursuant to imaging. Also, _____ will be responsible for the radiation protection aspects of this area and compliance with any and all applicable radiation or environmental regulations as prescribed by The U.S. Nuclear Regulatory Commission." Because the client is not an NRC licensee, they cannot be held accountable to the NRC regulations. Please revise the MOU to remove the requirement that the client is responsible for compliance with NRC regulations regarding the sanitary facilities.

6. Please confirm that a private sanitary facility will be provided for patient use and that surveys of the facilities will be performed by Diagnostic Laboratories personnel prior to leaving the client site. In addition, specify what would be done if contamination was identified in the sanitary facilities.

7. In the MOU, under the Authorized User heading, you stated that, "It will be the _____ responsibility to provide an AU for the ordering of all radiopharmaceuticals. Furthermore it will be responsibility of _____ to ensure that these physicians are properly licensed by an Agreement State, or the U.S. Nuclear Regulatory Commission." Even though the client may be providing the authorized users (AU), because Diagnostic Laboratories is the NRC licensee, it is ultimately their responsibility to verify that the physicians meet the requirements to be an AU.

8. Based on the diagrams provided, it is unclear how you will maintain security of the byproduct material stored inside the mobile van. Please describe your methods for securing the byproduct material from unauthorized access.

9. In the event that the van becomes disabled, confirm that you have a secure facility available for the storage of byproduct material and radioactive waste.

10. Confirm that the drives and technologists will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of 10 CFR 19.12, and 10 CFR 35.27. The training for these individuals must include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

11. Your application did not address emergency procedures. Please confirm that you have developed and will implement and maintain emergency procedures, in accordance with the Radiation Protection Program required by 10 CFR 20.1101. Appendix V of NUREG-1556, Volume 9 provides guidance that may be helpful in developing your procedures.

12. Please confirm that you will develop, document, and implement procedures to assure that:

a. Radioactive material is transported in accordance with 49 CFR Parts 170-189;

b. Management (or designee) will perform audits, at least annually, of the transportation documentation and activities at client sites;

c. Licensed material is secured during transport and use at the client's site;

d. Radioactive waste is handled properly during transport; and

e. The transport vehicle, including the driver's compartment, if separate, will be secured at all times from unauthorized access when the vehicle is unattended.

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. 577686. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Tara L. Weidner
Health Physicist
U.S. Nuclear Regulatory Commission