UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 23, 2008

Docket No. 03037877 License No. 09-31351-01
Control No. 143053

Lee Ann Farmer
Director Regulatory Compliance
RCOA Imaging Services, Inc.
7900 Glades Road, Suite 400
Boca Raton, FL 33434

SUBJECT: RCOA IMAGING SERVICES, INC.; REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE; CONTROL NO. 143053

Dear Ms. Farmer:

This is in reference to your application dated November 26, 2008 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. More contact information is needed for our records. Please include the telephone number for Lee Ann Farmer and the telephone number, facsimile number, and electronic mail address for Frank T. Bloe.

2. You have requested for use of materials in New Jersey. It appears from your application that you only use accelerator produced materials for medical use. Section 651(e) of the Energy Policy Act of 2005 authorized the NRC to issue a time-limited waiver (70 FR 51581; August 31, 2005) to allow continued use and possession of naturally-occurring and accelerator-produced radioactive materials (NARM) while the Commission developed a regulatory framework for regulation of the new byproduct material. New Jersey is currently being waived and we do not regulate accelerator-produced radioactive materials in that state. Please state that you plan to use NRC regulated materials for medical use (10 CFR 35.100 or 10 CFR 35.200) in New Jersey or alternatively, you may request for a new license to perform calibration of your equipment utilizing NRC regulated materials in New Jersey. Please see NUREG-1556, Volume 7, for guidance on applying for this limited scope program.

3. Please describe your anticipated scope of activities under this license (e.g., 3 vans operating at the following 15 clients sites). Please describe where the patient would be injected and what you would use as a “quiet room.” Describe the maximum number of patients that would be handled at a time within the van.

4. You state in item #3 of your application that you may receive radiopharmaceuticals at the Hot Lab at the licensed facilities. In accordance with 10 CFR 35.80 (b), “A mobile medical service may not have byproduct material delivered from the manufacturer or the

distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license." Please state that if you receive radiopharmaceuticals at the hot lab of the licensed facility, that you will receive and handle the byproduct material in conformance with the client's material license or state that you will not receive materials at the hot lab of your client's facilities.

5. You state in item #3 that you might inject the patient in the hospital.

   a. 10 CFR 35.80 (a) (1) states, "Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client." Please confirm that you will obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client before injecting a patient at that client's address. Please include an example of that letter.

   b. In Appendix V of NUREG-1556, Volume 9, Revision 2, "Program-Specific Guidance About Medical Use Licenses," if transportable services will be provide to the client's site for use within the client's facility by mobile medical service's employees, A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas. Please provide this information for each are you plan to use.

   c. Please note that a mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital).

6. In item 5 and 6, you requested the use of a germanium 68 source for Transmission and Attenuation source for a PET scanner. Please state if you expose this source to patients. If this source is exposed to patients then it needs to be listed as a medical use under 10 CFR 35.500. Additionally, you will need to submit information that demonstrates the qualification of proposed authorized users. 10 CFR 35.590 states the training and experience requirements for authorized users.

7. In item 7.2 you listed Edward J. Goldstein, M.D. as an authorized user and submitted the State of Delaware's radioactive material license as evidence of training and experience. However, Dr. Goldstein was not listed on the copy of the license that you submitted. Please submit Dr. Goldstein's evidence of training and experience to be an authorized user.

8. In item 7.2, you listed many physicians to be authorized users. You submitted a State of Delaware license of evidence of training and experience. However, in 10 CFR 35.57(b)(3) states, “Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses.” Please confirm that these physicians only used accelerator produced materials or please provide the NRC license number they may be listed as authorized users, a copy of an agreement state license identifying them as an authorized user, or documentation of other training and experience to meet subpart D of 10 CFR 35 requirements. NRC form 313A (aud) is recommended for this documentation.

9. In item 9.2, you submitted the type of portable radiation instrument you will use along with commitments of calibration. 10 CFR 35.80 (a)(3) states, “Check survey instruments for proper operation with a dedicated check source before use at each client's address.” Please state that you will perform this check and state how you will comply with this requirement.

10. In item 10, you did not discuss the safe use of unsealed licensed material. As written in NUREG-1556, Volume 9, Revision 2, “Program-Specific Guidance About Medical Use Licenses,” make the following statement, “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.”

11. In item 11.1, you made a statement of the RSO/Authorized user report to the facility if the incident is required to be reported to the state by regulations or if requested by officials of the state responding to the incident. As the NRC is not a state and the personnel responding are not normally state employees, the term “state” should be replaced by NRC in the first use and agency in the second. Please restate this commitment.

12. In item 11.1, you discussed use of your mobile nuclear medicine services. According to NUREG-1556, Volume 9, Revision 2, “Program-Specific Guidance About Medical Use Licenses,” Appendix V, when the base facility is in the van, and there is no permanent structure for the byproduct material storage, secured off-street parking under licensee control is needed. Please describe your secured off street parking under licensee control. Public rights-of-way are not considered part of the address of the client. Describe secured storage facilities availability for storage of byproduct material and radioactive waste if the van is disabled.

    In addition, if a base facility is located in a residential area, provide the following information, justification of the need for a private residence location rather than for a commercial location and documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service, van, etc., on the client property (if necessary) will be included. ' Documentation from both parties will illustrate the agreement between the client and the mobile medical

service. A description of the program demonstrating compliance with 10 CFR 20.1301, - "Dose limits for individual members of the public." - Verification that restricted areas does not contain residential quarters.

13. In Appendix X of your application, you list a procedure to return generators to the manufacturer. Please include Sr-82/Rb-82 generators to this procedure or state that you will not use Sr-82/Rb-82 generators.

14. Please provide documentation demonstrating that the mobile lab will be in compliance with 10 CFR 20.1301 during period of peak patient usage. Documentation could be in the form of a survey or shielding calculations.

15. Please submit your patient release criteria in detail as required by 10 CFR 35.75. Appendix U of NUREG-1556, Volume 9, Revision 2, may be used in developing your procedure. Please note that Fluorine-18 is not included in the current Appendix.

16. Since your activities are mobile, please indicate the location of record storage to facilitate review of records during an inspection.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 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. 143053. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

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.

Sincerely,

Original signed by Dennis R. Lawyer

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

cc:
Frank T. Bloe, Radiation Safety Officer

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SUNSI Review Complete: DLawyer
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