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

June 25, 2008

Docket No. 03035774 License No. 47-25570-01
Control No. 142278

Mark Ashworth
Director of Operations
Alliance Imaging, Inc.
330 Harper Park Drive
Suite C
Beckley, WV 25801

SUBJECT: ALLIANCE IMAGING, INC., VOIDANCE OF APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 142278

Dear Mr. Ashworth:

This is in reference to the letters dated March 25, 2008, March 29, 2008, June 4, 2008, and shielding documentation dated May 7, 2004 (submitted in an email on May 7, 2008), requesting to amend Nuclear Regulatory Commission License No. 47-25570-01 to include medical use of Fluorine-18, add sealed sources, and add medical authorized users. As a result of NRC's jurisdiction over NARM material and the recent waiver termination for users of NARM in several NRC States, you have requested that NARM be added to your license, to allow continued use at several temporary job sites and within a mobile van. This request is timely, i.e., the request was submitted to the NRC before the deadline date of May 30, 2008. Because you are upgrading your license from possession and use of sealed sources for the purpose of calibrating instrumentation to a full 10 CFR Part 35 medical license, we request a revised application to address all of the elements described in NUREG-1556, Volume 9, Rev. 2, with particular emphasis on the elements described in Appendix V for Mobile Service licenses. As discussed with Ms. Sharon Long on June 20, 2008, your current application will be voided to allow your staff the necessary time to collect the additional information necessary to support re-application in accordance with Volume 9, Rev. 2. Additionally, as discussed with Ms. Long, the original submittal dated March 25, 2008 to add NARM to your NRC license is deemed timely filed, i.e., within 6 months of November 30, 2007. Therefore, even though this action is being voided and the resubmittal will occur after May 30, 2008, Alliance will be considered to be in compliance with NRC requirements regarding submission of a license amendment to add NARM to your NRC license.

Please note that the germanium/gallium-68 transmission sources, the cesium-137 check and dose calibrator sources, the barium-133 check and dose calibrator sources, and the technetium-99m used for calibration are included in 10 CFR 35.65 for medical licensees, and will not be specifically listed on your NRC license.

The following additional information is requested to support resubmittal of your application to add NARM:

1. Please submit a letter signed by a management representative indicating that management has reviewed the shielding analysis submitted in the letter dated May 7, 2004 and concurs with the statements and representations contained therein. In addition, please provide:

   a. additional justification to support the use of a 0.025 occupancy factor for areas adjacent to the van;

   b. the gamma constant used for Fluorine-18;

   c. the maximum number of patients treated per day and per year at a client site;

   d. the estimated patient waiting time in the quiet room after injection and the maximum number of patients awaiting scanning in the quiet room;

   e. the maximum imaging time per patient; and

   f. the estimated time spent by the patient in a waiting area while awaiting scan results.

2. Describe your current scope of activities (e.g., 3 vans operating at the following 15 client sites with administration/scanning occurring on the van and patient waiting in “quiet rooms” located at the client facilities). In addition, clarify your type of use. As described in Appendix V of NUREG-1556, Volume 9, there are two types of mobile medical service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van use). A second type is transportation of byproduct material to a client’s facility for use within a client’s facility by the mobile medical service’s employees (i.e., transport and use). Whether a PET mobile medical service provider that uses a “quiet room” in the client’s facility is authorized for “in-van use” or “ transport and use” depends on whether the PET patients meet the criteria for release in 10 CFR 35.75 while they are in the “quiet room.” If they do not, then the “quiet room” in the client facility is an area of use for the mobile service licensee and must be described in the application.

3. As described in Appendix V of NUREG-1556, Volume 9, the locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. Please specify all base location(s). The base facility may be located in a medical institution, noninstitutional medical practice, commercial facility, or mobile van. A mobile licensee cannot provide a service to a private practice (nonlicensee) located within a licensed medical institution (e.g., hospital).

4. As required by 10 CFR 30.33 and 10 CFR 35.12, please submit a description and diagram(s) of all proposed base facilities and associated equipment in accordance with Items 8.14 through 8.19 of NUREG-1556, Volume 9. The description and diagram of the proposed facilities should demonstrate that the buildings (or vans) are of adequate construction and design to protect their contents from the elements (e.g., high winds,

rain), ensure security of licensed material to prevent unauthorized access (e.g., control of keys), and ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the licensed material receipt and use areas (e.g., hot lab, injection area, quiet room, scan room, and waste cabinet), and describe areas normally adjacent to restricted areas. For storage locations within a van, the description of the van should also address radiation levels in the van driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults." In addition, describe the type, dimension, and thickness of shielding that you will use for:

a. storage of NARM radiopharmaceuticals (e.g., stored in transport shielding from radiopharmacy);

b. preparation and dispensing of NARM radiopharmaceuticals (e.g., 2 inch lead glass L-block, tungsten syringe shields, flush counter mounted dose calibrator, shielded well counter, etc.);

c. patient quiet rooms for patients awaiting scanning (e.g., 1/4 to ½ inch lead shielding in walls, floor, and ceiling);

d. dedicated patient bathrooms;

e. scan rooms (e.g., 1/4 to ½ inch lead shielding in walls, floor, and ceiling);

f. storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste; and

g. storage of sealed sources.

5. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered. Please describe all delivery locations and procedures for delivery. When the base facility is in the mobile van, and there is no permanent structure for the licensed material storage, describe the following:

a. Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;

b. Secured storage facilities available for storage of licensed material and radioactive waste if the van is disabled;

c. Procedures for delivery directly to the van only if the van is occupied by licensee personnel at the time of delivery. As described in Appendix V to NUREG-1556, Volume 9, delivery of byproduct material to a van that is not occupied by the mobile medical service personnel will not be permitted. Alternatively, licensees may pick up the licensed material from the supplier (e.g., nuclear pharmacy) en route to client facilities; and

d. Additional security measures for storage of licensed material overnight in the van, when licensee personnel are not in attendance (e.g., locked cabinet in locked trailer with key control).

6. Submit an example of a signed agreement, as required by 10 CFR 35.80(a), that the location of the van will be on client-owned or controlled property. If a base facility is located in a residential area, provide the following additional information:

a. Justification of the need for a private residence location rather than for a commercial location;

b. 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) must be included;

c. A description of the program demonstrating compliance with 10 CFR 20.1301, "Dose limits for individual members of the public;" and

d. Verification that restricted areas do not contain residential quarters.

7. Of the physicians requested, only Drs. Kohatsu, Lauderman, Sherigar, Naseem, Valiveti, and Cappiello were confirmed to be listed on an NRC license for the uses requested within the last 7 years. In support of your request to authorize Drs. Burke, Estrada, Weaver, Yoo, Tatum, Jarmukli, Coleman, Hanson, Borges-Neto, Wong, and Chin for materials permitted under 10 CFR 35.200, please provide one of the following, as applicable:

a. Previous license number or permit (if issued by NRC or VA Medical Center) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an authorized user for the uses requested; or

b. Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35 for the use requested; or

c. Description of the training and experience identified in 10 CFR Part 35 Subpart D demonstrating that the proposed authorized user is qualified by training and experience for the use requested; and

d. Written certification, signed by a preceptor physician authorized user, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an authorized user for the medical uses authorized has been achieved; and

e. If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

NRC Form 313A may be used to document this information. Please note that if the board certification, or training and experience, was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

8. It appears that the list of authorized users provided are client physicians. Please describe how these physicians supervise the use of licensed material by Alliance Imaging staff pursuant to 10 CFR 35.27. In addition, please describe how Alliance Imaging will ensure that the supervised individual (e.g., technologist, nurse): (I) is notified of the supervising authorized user list for each client site for ease of contact during use of licensed material; (ii) will follow the instructions of the supervising authorized user (i.e., client physician) for medical uses of licensed material and preparation of licensed material for medical use;(iii) will follow the written radiation protection procedures established by Alliance Imaging; and (iv) will follow the applicable regulations (e.g., 10 CFR Parts 19, 20, 35, and 71), and the license conditions with respect to the medical use of licensed material. Finally, please describe how client physicians are notified of their responsibilities as supervising authorized users while licensed material is in use at their site.

9. Your application dated April 1, 2006, committed to following various criteria from NUREG-1556, Volume 7. With the upgrade of your license to a medical use license, please provide the following statements or alternatives to the statements:

   a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

   b. "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

   c. "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

   d. "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

   e. "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

f. "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and 10 CFR 35.92."

10. Confirm that drivers 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 should include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

11. In accordance with 10 CFR 35.80, confirm that survey instruments will be checked for proper operation before use at each address of use and dosage measurement instruments will be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

12. Submit your emergency procedures, in accordance with the Radiation Protection Program required by 10 CFR 20.1101. Indicate typical response times of the RSO and AU (e.g., less than 3 hours) in the event of an incident and describe response during an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire, that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material (HAZMAT)-trained personnel, and it should be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

a. A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel;

b. The emergency contact numbers for NRC's Operation Center and all appropriate State radiological protection agencies;

c. Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;

d. Procedures for retrieving and securing any byproduct material;

e. Predetermined (calculated) exposure rates for an unshielded source as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios;

f. Preplanned decontamination procedures, including ready access to all necessary materials;

g. A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;

h. Security of the transport vehicle against unauthorized access, including the driver's compartment; and

i. Procedures to provide a copy of the report, generated in accordance with 10 CFR 30.50, to clients following any accident in which there is actual or possible damage to the client's facility.

13. Describe transportation procedures to assure the following:

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

b. Procedures will include:

i. Use of approved packages,
ii. Use of approved labeling,
iii. Conduct of proper surveys,
iv. Complete and accurate shipping papers,
v. Bracing of packages,
vi. Security provisions, and
vii. Written emergency instructions.

c. Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities;

d. Licensed material is secured during transport and use at the client's facilities;

e. Radioactive waste is handled properly during transport. Describe the method of storage and final disposal; and

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

14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewer system, in accordance with 10 CFR 20.2003. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van for patient use, submit the following information for NRC review:

a. A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; and a description of procedures to assess the tank for possible leakage.

b. A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 10 CFR 20.1201 and 20.1301, that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

c. A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

15. In the shielding analysis dated May 7, 2004, you indicated that the radiation levels 1 meter from a patient awaiting scanning 45 minutes after injection is 7.8 mR/hour. For a single patient awaiting scanning on the coach, this appears to equate to approximately 10 mR/hour immediately after injection and 8 mR/hour outside of the coach shielded with 1/16 inch of lead and including scatter buildup. Please describe additional procedures for complying with 10 CFR 20.1301. These may include:

a. Roping off and posting the adjacent area with "Caution Radiation Area" signs;

b. Instructing staff to ensure that no member of the public has access to the radiation area adjacent to the coach;

c. A description of the limitations (if necessary) that will be used in the coach to minimize radiation around the coach; or

d. Procedures for periodic surveillance of the adjacent areas by coach staff.

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

17. 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 1-866-512-1800. 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. 142278 when resubmitting your application. If you have any technical questions regarding this letter, please call me at (610) 337-5169.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Sharon L. Long, Radiation Safety Officer

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