

K & K Diagnostic and Imaging, LLC  
Iftexhar Kadri, M.D.  
81 Northfield Ave, Suite 102  
West Orange, NJ 07052  
Telephone: 973-736-2600

M516

February 9, 2007

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Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Material Safety  
United States Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

03036783

Re: License Number: 29-30982-01  
Control Number: 139823

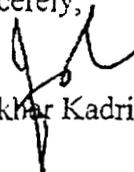
Dear Mr. Thompson:

In reference to the telephone call dated February 9, 2007, with Mr. Lawyer of the NRC, I am providing the additional information (attached) concerning the original application, for your appropriate actions concerning the license number 29-30982-01, mail control number 139823.

Please call me at 973-736-2600, or Mr. Venkata Lanka, Consulting Physicist at 908-788-4931/201-725-4899, if any additional information is required.

We request that you execute an expedited review of this amendment.

Sincerely,

  
Iftexhar Kadri, M.D.

139823

NMSS/RGN MATERIALS-002



### **Type of Mobile Service:**

Mobile Medical services: We will transport byproduct material from base location, trained personnel, and gamma camera to a client's facility and administer radioactive materials for diagnostic purposes at the client's facility. We are responsible for all aspects of by product material use and authorized patient administrations. All scans will be performed in the client's facility.

When providing services, the van will be located on the client's property that is under client's control.

This is to confirm that we do not provide scan-in-van service. We will move our mobile gamma camera into the client's facility and perform scans within the client's facility. The client's facility will have the temporary hot lab, waiting, examining, imaging, reading, office, file storage area, fresh material storage area, toilets, closet, etc. Since we perform all activities in client's facility and only transport gamma camera and radioactive materials to the client's facility, the patients use sink and toilet facilities located at the client's facility. We will dispose all radioactive waste accordance with 10 CFR 20 Subpart K-Waste Disposal.

### **Client's Site(s) and Address:**

Amjad Najeer, M.D., P.C.  
22 Howard Blvd., Suite 103  
Mt. Arlington, NJ 07856

Keshava M. Shivashankar, M.D.  
50 Newark Ave, Suite 305  
Belleville, NJ 07109

Hamant Patel, M.D.  
2083 Millburn Ave  
Maplewood, NJ 07040

Hamant Patel, M.D.  
59 Main Street  
West Orange, NJ 07052

Joaquim Correia, M.D.  
243 Chestnut Street, Suite 2.L  
Newark, NJ 07015

Dr. John P. Smith  
15-01 Broadway  
Fairlawn, NJ 07410

Advance Cardiology, LLC  
4a - Doctor Park  
Hackettstown, NJ 07048

### **Licensed Activities:**

Licensed activities will be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a).

We will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of our clients for which services are rendered. The letter will permit the use of byproduct material at the client's address and clearly delineate the authority and responsibility of each entity. This agreement shall be applicable for the entire period of time over which the service is to be provided. The letter will be retained for three years after the last provision of service.

we will develop and implement survey procedures to ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed before leaving each location of use as required by 10 CFR 35.80(d).

Applicants who will provide transportable services to the client's site and use within the client's facility (i.e., Class 2) must provide the following facility information and commitment:

#### 1. Building Construction

This building is constructed of noncombustible materials, with exterior walls designed to withstand the effects of fire and prevent its spread. Early detection and warning of fire is provided by automatic fire detection systems designed to detect the incipient stages of a fire. There are fire extinguishers through out the building.

The lab is utilized as patient imaging area and store the transported radioactive material in a secured area. Lead shielded storage containers will be brought to the lab to protect personnel. The room has a single access which is locked whenever the room is unoccupied.

- i. All generated waste will be brought to one of the base locations and will be decayed for 10 half lives and disposed as non-radioactive waste after surveying with the calibrated GM counters to ensure that it is at background levels.
- ii. The lab door is lockable.
- iii. A treadmill for stress testing is located in the room.

#### 2. Fire Protection

- a. The building described in this application is constructed of noncombustible materials with exterior walls designed to withstand the effects of fire and prevent its spread.

- b. There are fire extinguishers throughout the building.

### 3. Security

- a. All patients come through front of the building. Unless the employee opens the door no one can enter into the suite without any authorization.
- a. The lab is secured when staff is not present.
- b. We will secure from unauthorized removal or access those radioactive materials that are stored in controlled or unrestricted areas.

### Shielding:

We purchased leaded shielding (L-blocks, leaded waste containers, syringe shields, leaded syringe shield boxes, etc.) which will have sufficient thickness to maintain the exposure rate below 2 mR/hr at 3 feet from the surface of the shield.

### Lab:

- i. Walls - The walls have a low flame spread characteristic.
- ii. Floors - The floor covering is sealed with waxed floor tiles so that spills are contained and they are easily decontaminated.
- iii. Surfaces - Surfaces on benches are non-porous and smooth to facilitate cleanup should a spill occur.
- iv. Entrances to lab and storage areas are posted with radioactive signs when treating patients.
  - i. Protective Clothing - We insure that there are lab coats and an adequate supply of disposable rubber or plastic gloves available for individuals under my supervision.
  - ii. Bench Top Covering - we will have adequate supplies of absorbent plastic backed paper to cover bench tops where radioactive materials are handled.
  - iii. We use radiation detection and counting equipment for use in evaluating contamination levels.
- We will retain a record establishing that the mobile service licensee has full control of the treatment room during byproduct material use for each client. We will obtain in either the form of a signed agreement or a lease agreement with the client, establishing full control of the treatment room by the applicant during all periods of use.

**Base Location(s):**

Address: 81 Northfield Avenue, Suite 102  
West Orange, New Jersey, NJ 07052

Byproduct material will be delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.

**Training And Experience**

We will require the supervised individual to:

- follow the instructions of the supervising authorized user for medical uses of byproduct material;
- follow the written radiation established by the licensee; and
- comply with the regulations of 10 CFR 35.80, 10 CFR 35.647 (if applicable) and the license conditions with respect to the mobile use of byproduct material.

**Training for Individuals Working in or Frequenting Restricted Areas**

In addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable), drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures. The training records for these individuals will include (at a minimum) dates, topics discussed (e.g., DOT regulations, shielding, ALARA, basic radiation protection), attendees, and the instructor's name, and shall be maintained for 3 years for NRC review.

**Survey Instrument & Dose Measurement Instrument Checks**

We will check survey instruments for proper operation with a dedicated check source before use at each address of use. We will check dose measurement instruments (e.g., dose calibrator) as described in 10 CFR 35.60 or 10 CFR 35.62, as applicable, 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.

**Order and Receipt of Byproduct Material**

Byproduct material will be delivered by a supplier to the base location. Delivery of byproduct material to a van that is not occupied by the mobile service personnel will not be permitted.

**Emergency Procedures**

We will develop and implement emergency procedures, in accordance with 10 CFR 20.1101, that, in part, will indicate that the RSO, AU, or a responsible designee, can be physically present at the client's address in response to incidents (e.g., accidents, spills, medical events) that occur at client facilities. We will indicate typical response times of

the RSO and AU in the event of an incident. We will develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other events, such as, wind, water or fire damage that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile service. The transportation emergency response plan will cover both the actions to be taken by the mobile service provider's headquarters emergency response personnel and the "on scene" hazmat trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency response contacts. At a minimum, this plan will include:

- A 24-hour emergency contact telephone number for the mobile service provider's emergency response personnel.
- Emergency contact number for NRC's Operation Center and all appropriate state radiological protection agencies.
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Preplanned decontamination procedures including ready access to all necessary materials.
- A copy of the report, generated in accordance with 10 CFR 30.50, will be provided to any Class 2 clients following any accident in which there is actual or possible damage to the facility or device.
- A calibrated, operational survey meter should be maintained in the cab of the transporting vehicle. Such a survey meter may be used at an accident scene for conducting surveys.

*Note:* The type of response is consistent with the level of the incident. The response is ranging from phone contact for minor spills, to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

In summary we will perform the following:

- (1) We 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;
- (2) We will check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required

by this paragraph must include a constancy check;

(3) We will check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) We will before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(5) We will retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(1) of this section in accordance with § 35.2080(a) and (b), respectively.