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

February 20, 2008

Docket No. 03036473 License No. 37-30868-01
Control No. 140325

David N. Culp
President and CEO
Nuclear Imaging Group, Inc.
27 Carey Lane
Jenkins Township, PA 18640-3225

SUBJECT: NUCLEAR IMAGING GROUP, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 140325

Dear Mr. Culp:

This is in reference to your application dated March 28, 2007 requesting to amend Nuclear Regulatory Commission License No. 37-30868-01. Your amendment request for a mobile veterinary medical service is new to NRC and required additional review of the regulations and existing guidance to establish any new policy considerations. From that review additional questions have been identified with regard to your application as follows:

1. The individual requested to be named as the Authorized User (AU) has not demonstrated that he has the training to meet the requirements of 10 CFR 30.33(a)(3). NRC's normal policy is that the AU should be a veterinarian.

   With regard to veterinary medical use, it is NRC's policy that the individual identified as the authorized user be an individual that has sufficient radiation safety training to safely use byproduct material, as well as being qualified to prescribe, order, and use drugs for veterinary medical use, protect public health and safety by determining which animals need the radionuclide procedure, determining the dosage to be administered for the individual patients and authority to release the radioactive animal from medical control. To ensure that this will be the case, the NRC has a longstanding policy that the AU should be a veterinarian.

2. You have proposed greatly expanding the scope of your licensed activities without increasing the expected time commitment from the Radiation Safety Officer (RSO). Please provide additional details of expected effort that will be needed from the RSO.

   a. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

b. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence

3. In accordance with 10 CFR 20.1301, the veterinary patients administered Technetium-99m (Tc-99m) radioactive drugs may not be released and would need to remain under your control until you can assure that no member of the public receives in excess of 100 millirem per year. Your release criterion of a radiation measurement of 0.5 milliRoentgen per hour (mR/hr) at one meter may not be adequate to assure that the dose to members of general public will be within the public dose limit. You currently are authorized only for medical uses permitted by 10 CFR 35.100 and 35.200 which means the isotopes and quantities used in patient dosages ensures that the patients may be released. Your mobile veterinary application indicates the licensee will release dogs and cats when the radiation measurement at 1 meter is 0.5 milliRoentgen per hour(mR/hr). Your application does not describe the facilities for holding veterinary patients until they reach this level and does not demonstrate that this release criterion is appropriate for all veterinary patients.

   The application indicates the horses will be injected, scanned, and held in their stalls. Your proposed release criteria for a horse is a 24 hour quarantine period and a radiation measurement of 2 mR/hr at the skin. You have indicated the stall will be posted, but have not indicated how you will secure and control the area during this period or longer if the maximum radiation reading at the skin exceeds 2 mR/hr after 24 hours.

   10 CFR 20.1301 requires that each licensee conduct activities such that exposure to a member of the public does not exceed 100 millirem in a year. In the case of veterinary treatment regardless of whether the treatment is provided at a clinic or a stable, the areas where the licensed materials are administered and veterinary radioactive patients are housed should be isolated from routine patient examination and treatment areas and other horse stalls to prevent contamination of unrestricted areas, other veterinary patients, other boarded horses, veterinary clinic staff, and the other members of the public. You have not addressed how this will be achieved in the veterinary clinic or the horse treatment area. You have not indicated that you have facilities for holding veterinary patients that cannot be released when you leave the site at the end of the day.

4. In accordance with 10 CFR 20.1301, you must develop and implement your mobile veterinary radiation safety program to assure that no member of the public, which includes the staff of the non-licensed veterinary clinics and stables, receives in excess of 100 millirem per year while the dogs and cats are in the clinic. You have not described how you will isolate your radioactive materials administering, imaging, and patient holding use areas from the rest of the veterinary clinic and the rest of the stable.

5. Only a licensee and its workers can perform licensed activities such as handling radioactive material, which includes the animals containing radioactive material and their waste. You have not demonstrated that you will take responsibility for all the tasks that cannot be performed by a non-licensed entity and you can not delegate responsibilities and tasks to the non-licensed veterinary clinic and stables.

   The non-licensed client has no authority to possess, and no responsibility for, the licensed material and cannot perform tasks it is not authorized to perform. You have indicated that all temporary job sites for the dog and cat veterinary use encompassing the scanning room, examination room and holding cages would be wiped, surveyed, and released if readings were less than 2000 disintegrations per minute per 100 square centimeters and background. Areas above these levels are to be quarantined and put out of use for 24 hours until below these levels. There is no indication of how you will secure and maintain control of the area during the quarantine. Also, there is no indication how you will clean the holding cages or kennels before survey or how you will handle liquid excreta in kennels. You have committed to quarantining the radioactive equine patients for 24 hours after the administration. Because you do not have a fixed veterinary facility or stables and are required to remove all radioactive materials when you leave a site and you have not described adequate radioactive waste storage facilities, it is unclear how you would perform these tasks without leaving the non-licensed client in possession of the radioactive patient, which will entail handling contamination associated with the radioactive animal, and responsibility for holding the waste for decay in storage and proper disposal.

6. Your proposed instructions to dog and cat owners do not address key ALARA issues of minimizing time in public places, contamination of public areas, streets, sidewalks, lawns, and parks, or instructions for horses that will contaminate public spaces, streams, and waterways. Furthermore, your instructions do not address the potential exposure of children who may use an owner's yard that may be contaminated by released veterinary patients, or to potential contamination of neighboring fences, shrubs, and yards. You should revise your instructions to include instructions on preventing contamination of these areas and keeping exposure of the general public to radioactive materials used in its veterinary medical use ALARA.

7. You have not adequately described your waste storage sites and disposal of radioactive materials at unlicensed sites.

   A mobile human nuclear medical service is expected to generate minimal radioactive waste with respect to both amount of radioactivity and volume of material. Routine administration of the unit dosages is expected to result in few if any radioactive spills or contamination events. The veterinary use of radioactive materials for dogs and cats on the other hand is expected to result in frequent radioactive spills as the radioactive animals drool, urinate, and defecate in examination/treatment rooms, holding cages/pens, and when being transported between these locations. This will result in significant volumes of contaminated materials from bedding and cleaning up spills. Equine veterinary use of radioactive materials will result in a continuous "radioactive spill" environment with even larger volumes of contaminated materials and waste.

You have indicated that there will be a written agreement signed by management at each client site and the agreement will delineate responsibilities of each entity. In requesting mobile veterinary use, no client sites were identified to indicate you intend to maintain responsibility for permanent areas within any veterinary clinics for the small animal or equine use and no facility diagrams were provided of client sites to indicate where the licensed materials would be used. Further, you have not identified veterinary clients as NRC license holders. Non-licensed clients can provide space for the mobile veterinary service to use for Tc-99m licensed activities. However, under 10 CFR 30.3, the non-licensed client cannot possess licensed material which includes the radioactive veterinary patient and the radioactive waste associated with the radioactive animal. Therefore, you would be required to remove all radioactive material including the radioactive patients when you leave the site each day. In addition, it does not appear you have facilities to hold patients that cannot be released when you leave the site. You have indicated all waste from the dog and cat veterinary use would be contained in a locked cabinet in the Lackawanna Medical Group site. You also indicated in the event of an expired or euthanized animal, the animal would be held in storage for 60 hours before disposal but did not specify where this storage area was located. You have not demonstrated you have facilities to hold a dead animal in the medical suite for almost 3 days. No additional information was provided describing your abilities to store the increased contaminated waste, your engineering controls, equipment or facilities designed to minimize expected increases in contamination and control the spread of contamination between areas.

You indicated that at the veterinary nuclear medicine horse treatment locations, the animal waste (manure and urine) will be contained separately and posted as radioactive for the 60 hours, and stated: “After the 60 hours it shall routinely be disposed. If it is used for fertilizer, the area shall be recorded for future reference.” However, you did not describe how you will secure the waste during decay in storage or confirm that a radiation measurement would be made to assure the material could be disposed.

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. 140325. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

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 Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
John C. Ramsey, Radiation Safety Officer

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