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

January 10, 2007

Docket No. 03036783 License No. 29-30982-01
Control No. 139823

Iftekhar Kadri, M.D.
Administrator
K & K Diagnostic and Imaging, LLC
81 Northfield Avenue, Suite 102
West Orange, NJ 07052

SUBJECT: K & K DIAGNOSTIC AND IMAGING, LLC, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 139823

Dear Dr. Kadri:

This is in reference to your letter dated December 4, 2006 requesting to amend Nuclear Regulatory Commission License No. 29-30982-01. In order to continue our review, we need the following additional information:

1. It appears from your letter that a possible change of ownership (control) has occurred. Licensees must provide full information and obtain NRC's ***prior written consent*** before transferring control of the license. Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license. A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation. A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

    a. Provide a complete description of the transaction (transfer of stocks or assets, or merger).

    b. Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

    c. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for any new personnel.

    d. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

e. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

f. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

g. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

h. If your license requires financial assurance for decommissioning, you will need to address changes to financial assurance for name changes and/or change in ownership (control). If your company's name is changing and there is no change of ownership, you will need to amend your financial assurance instruments and supporting documents to address the change in name. If there has been a change of ownership (control), the transferee must submit new financial assurance in accordance with Chapter 4 to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance."

2. You have proposed Dr. Iftekhar Kadri, who is a current authorized user on the license, to be the Radiation Safety Officer. In accordance with 10 CFR 35.50(d), please submit a written attestation , signed by a preceptor Radiation Safety Officer, that Dr. Itfekhar Kadri has training in the radiation safety, regulatory issues, and emergency procedures for the types of use approved on the license, meets 10 CFR 35.50(c)(1), and has achieved a level of knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

3. On page 20 of your letter there appears to be a typographical error that states you will use Table P.1 as general guidance. The letter then list Table N.1. Please confirm that you will use Table N.1 instead of table P.1.

4. On page 43 of your letter there appears to be a typographical error that states you will develop and implement survey procedures and all associated wastes have been removed as required by 10 CFR 35.80(d). The requirement is 10 CFR 35.80(a)(4). Please confirm you will commit to following 10 CFR 35.80(a)(4).

5. On page 46 of your letter there appears to be a typographical error that states you will will check dose measurement instruments as described in 10 CFR 35.60 or 10 CFR 35.62. 10 CFR 35.62 no longer exists. Please confirm you will follow 10 CFR 35.60 or 10 CFR 35.63.

6. On page 47 of your letter, Emergency Procedure, you did not specify what the typical response times of the Radiation Safety Officer and the Authorized User will be in an event of an incident.

7. In the Emergency Procedure section of your letter, you did not commit to including the following in your emergency procedures as listed in Appendix V of NUREG 1556 Volume 9:

   Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached an/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers.

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

8. No commitment was made as described in the Transportation section of Appendix V of NUREG 1556 Volume 9. Please commit to developing, documenting, and implementing procedures to assure that the following takes place:

   Radioactive material is transported in accordance with 49 CFR Parts 170–189. Procedures will include:
   – Use of approved packages;
   – Use of approved labeling;
   – Conduct of proper surveys;
   – Complete and accurate shipping papers;
   – Bracing of packages;
   – Security provisions; and
   – Written emergency instructions.

   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.

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

   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.

9. For scan-in-van service, provide the following information:

   a. Submit a diagram of the mobile van including principal use of each area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway), any shielding available, and additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

   b. Demonstrate 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).

c. If the van will have sink or toilet facilities, it is not a sanitary sewer for disposal as allowed in 10 CFR 20.2003. Please state that the van does not have a sink or toilet facility or describe how you will either not allow materials into the van's disposal system or dispose of the material in accordance with 10 CFR 20 Subpart K- Waste Disposal.

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 **Toolkit Index Page.** Or you may 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. 139823. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer 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 Thomas K. Thompson

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

cc:
Sang O. Lee, M.D., Radiation Safety Officer

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SUNSI Review Complete: DLawyer
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