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

April 17, 2007

Docket No. 03031990 License No. 37-27830-02MD
Control No. 140333

Richard A. Hughes
Corporate Radiation Safety Officer
Medi-Physics, Inc.
D.b.a. GE Healthcare
3520 Progress Drive, Suite C
Bensalem, PA 19020

SUBJECT: MEDI-PHYSICS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 140333

Dear Mr. Hughes:

This is in reference to your letter dated April 1, 2007 requesting to amend Nuclear Regulatory Commission License No. 37-27830-02MD. In order to continue our review, we need the following additional information:

1. As stated in NUREG-1556, Volume 13, "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Commercial Radiopharmacy Licenses", the license must provide:

   Description of the facilities and equipment to be made available at each location where radioactive material will be used. A diagram should be submitted showing the applicant's entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.

   Include the following information:

   a. Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage;

   b. Sufficient detail in the diagram to indicate locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;

   c. general description of the ventilation system including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials with the

probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and

d. Verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, the ALARA contraints for air emissions established under 10 CFR 20.1101(d), and are ALARA.

2. Current licensing guidance does not allow for an "as needed" maximum amount that a licensee may possess at any one time under the license. Please request a specific maximum amount per radionuclide and total activity associated with item 6.L. of your current license. You may wish to review the amount of material which would require a security order for increased controls at http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic 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 9:00 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. 140333. 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:
Michael J. Hess, Radiation Safety Officer

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SUNSI Review Complete: DLawyer
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