

GE Healthcare

4 August 2005

NM502

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Nellam Bhalla
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
King of Prussia, PA 19406

03031990

RE: Radioactive Material License 37-27830-02MD

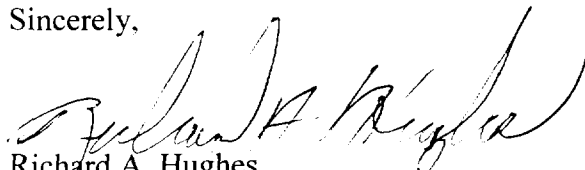
Dear Ms. Bhalla,

Please allow this letter to serve as notice that Medi-Physics, Inc., dba GE Healthcare wishes to make the following changes to the above referenced license:

1. Please replace Item 11 Instrument Calibration of the current application with Attachment 1.
2. Please remove the following individuals from Condition 11B; Frank Smith; Lawrence Rush, Jr.; James Mantel; Steven Petner; they are no longer under the employee of GE Healthcare.

Should you have any additional questions or are in need of additional information, please feel free to contact me at 609-514-6647.

Sincerely,


Richard A. Hughes
Corporate Radiation Safety Officer

General Electric Company
Amersham plc
101 Carnegie Center
Princeton, NJ 08540
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137505
NMCC/RONI MATERIALS-002



ATTACHMENT 1

10.4 Calibration of Dose Calibrator

Accuracy. The dose calibrator will be checked for accuracy at annual intervals, installation, and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. At least two (2) of the sources listed below shall be used during this evaluation.

The accuracy of the sealed source standards will be traceable to National Institute of Standard and Technology (NIST). They will consist of:

<u>Nuclide</u>	<u>Activity</u>	<u>Accuracy</u>
Co-57	50 μ Ci or more	Within $\pm 5\%$
Ba-133	50 μ Ci or more	Within $\pm 5\%$
Cs-137	50 μ Ci or more	Within $\pm 5\%$

The net activity displayed by the dose calibrator must be within $\pm 10\%$ of the standard's calibrated activity. If the unit displays readings with an error greater than $\pm 10\%$, arrangements will be made for immediate repair or adjustment.

Constancy. The dose calibrator shall be checked for constancy for each day of use. Measurements will be completed in accordance with nationally recognized standards or the manufacturer's instructions against NIST traceable standards for commonly used nuclides.

If variations greater than $\pm 10\%$ are noted, arrangements will be made for immediate repair or adjustment

Linearity. The dose calibrator will be checked for activity linearity at installation, quarterly intervals, and following repair. This test will be performed using the maximum activity measured in a dose calibrator (i.e., reagent kit preparation or the maximum activity used to fill a dose; whichever is greater). The linearity test will be continued by repeating the assay several times a day over a multiple day period. The linearity test shall be continued until the activity displayed is less than 30 microcuries.

The above linearity test will be plotted or calculated as a function of activity versus time and compared to predicted activities versus the same time. The acceptable range of error will be $\pm 10\%$. If test result error exceeds $\pm 10\%$, arrangements will be made for immediate repair or mathematical correction. The unit may be used in the interim using the correction factors identified.

As an alternative procedure, the linearity test will be performed by a sleeve attenuation method, such as Calicheck Kit or Lineator system. The manufacturer's instructions for use will be followed. The range of linearity, the limits of acceptability, and any corrective actions described above shall be followed.

Geometry. The dose calibrator will be checked for geometrical variation upon installation and after chamber repair. The test will be performed using approximately 1-10 mCi of Tc-99m in a geometrical configuration approximating that of a point source. Geometry testing shall be completed to include all vial and syringe configurations routinely used for patient doses.

The source geometry will be changed by dilution, with assays performed after each dilution step. The data will be analyzed relating the various readings to a defined standard. Correction factors will be used for assays when a geometry-induced error exceeds a $\pm 2\%$ tolerance.

This is to acknowledge the receipt of your letter/application dated

8/4/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amended. 37-27830-02MD
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 137505.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.