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January 23, 1995

Francis M. Costello, Chief  
U.S. Nuclear Regulatory Commission  
Region I  
Medical Licensing Section  
475 Allendale Road  
King of Prussia, PA 19406-1415

Medi-Physics, Inc.  
2636 S. Clearbrook Drive  
Arlington Heights, IL 60005  
tel (708) 593-6300

Amersham  
HEALTHCARE

RE: Docket No. 030-31972  
License No. 29-28341-02MD  
Application for renewal dated October 28, 1994

Dear Mr. Costello,

On January 11, 1995, Theresa Dardin contacted me and requested additional information regarding the above referenced license which is currently in the process of renewal. Below please find the requested information. The questions have been restated for ease of review.

1. *Confirm that your operations do not conflict with local codes and zoning laws.*

Medi-Physics confirms that operations at the pharmacy located at 1 Naylon Place, in Livingston, New Jersey do not conflict with local codes and zoning laws.

2. *Provide a copy of arrangements made with the local fire department which include locations where radioactive material is stored and location of survey instrumentation.*

Please find enclosed a copy of the letter which has been sent to the local fire department containing the required information.

3. *Regarding calibration of survey instruments, please provide the name of at least one NRC or Agreement State calibration service that you may use.*

Medi-Physics may use, but will not be limited to the calibration services offered by Ludlum Measurements, Inc. in Sweetwater, Texas.

4. *Confirm that the application will be revised to change all references to 10 CFR 20.1 through 20.602 to the corresponding sections of 10 CFR 20.1001 through 20.2402.*

We have modified the statements in Attachment B of the license application to correspond to Sections 20.1001 through 20.2402 of 10 CFR Part 20. Please find Section 10.1.2 enclosed as it should appear in the license application. We also confirm that all

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other references made to 10 CFR 20 in the license application refer to sections 20.1002 through 20.2402.

5. *Please confirm that you will comply with the requirements of Appendix E of Regulatory Guide FC 410-4 for constancy and linearity tests without exception.*

We confirm that we will comply with the requirements of Appendix E of Draft Regulatory Guide FC 410-4 without exception.

6. *Please confirm that you will perform a physical inventory of all sealed sources in your possession every six months and maintain a record of the results for inspection by the Commission.*

For sealed source inventory requirements, Medi-Physics shall comply with the regulations in Section 35.59 (g) of 10 CFR Part 35.

7. *Submit a copy of your New Jersey State Board of Pharmacy License.*

Please find a copy of the New Jersey State Board of Pharmacy license enclosed.

8. *Revise and resubmit a copy of Item 10.12 to describe the geographical areas within which radiopharmaceuticals will be delivered.*

Radiopharmaceuticals will be delivered by prescription to local physicians and may also be distributed to any licensed recipient authorized by the NRC or an Agreement State to receive licensed material.

9. *Revise and resubmit your "Instructions in Case of Vehicular Emergencies". These instructions should include a space for the name and telephone number of your Nuclear Pharmacy as well as the telephone number of the individual to contact in case of an emergency during non regular hours. Also, include the name and telephone number of the NRC Operations Center for notification (301)816-5100.*

Written instructions in case of vehicular emergencies found in Item 10.15 C of the license application are printed on the back of the bill of lading. The name and telephone number of the pharmacy as well as the telephone number for after hour emergencies will be printed on the front of the bill of lading. Individuals, listed on the bill of lading, when contacted about vehicular emergencies, will in turn notify the NRC Operations Center if necessary.

Please find the enclosed sample bill of lading for review. Please be advised that the bills of lading shall always comply with all regulatory and license requirements but may be subject to administrative changes.

10. *Please provide minimum qualifications of the auditors.*

Audits will be performed by individuals with the following qualifications:

- a. have previously been approved by NRC or an Agreement State as a Radiation Safety Officer,
- b. have a minimum of a baccalaureate degree in Radiological Sciences, Health Physics or a related field, or
- c. have a minimum of four years technical experience in radiological health.

11. *Confirm you will meet all labeling requirements specified in the regulations.*

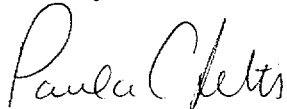
We confirm that product labeling will meet the requirements of all applicable regulations.

*The following information is provided as explanation for Item 6.b of the license application:*

In the renewal application we requested to provide this information in the form of a booklet because a customer may order just one vial from a package of ten. Since there is only one package insert per box of ten, there would always be a shortage. Additionally, we are not allowed to reproduce the manufacturer's package insert or brochure for redistribution to customers. Medi-Physics shall, however, redistribute reagent kits in accordance with board of pharmacy regulations.

If you any questions or require further clarification, please do not hesitate to contact me at (708)593-6300, extension 381.

Sincerely,



Paula C. Jeter  
Sr. Health Physicist  
Regulatory Affairs