WASHINGTON
HOSPITAL
CENTER

MARK H. MERRILL
VICE PRESIDENT
OPERATIONS & ADMINISTRATIVE SERVICES

202/877-5566

3001325

May 25, 1994

Director, Office of Enforcement
U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D. C., 20555

SUBJECT: REPLY TO NOTICE OF VIOLATION OF APRIL 28, 1994

Dear Director:

The following outlines our response to the violations described in the letter of April 28, 1994.

A. Failure to limit the whole body radiation dose of a researcher working in the old radiopharmacy, a restricted area, to one and one quarter rems per calendar quarter.

1. Admission. The licensee did not limit the whole body radiation dose of an independent researcher who gained access to the old radiopharmacy, a restricted area. Thus, the conditions of 10 CFR 20.101(b) were not met.

2. Reason for violation. The licensee did not check the worker's previous months radiation records nor the environment to insure that the worker's activities would not exceed the whole body limit. The licensee inappropriately assumed that the research workers activities were under the supervision of the Medlantic Research Institute.

3. Corrective steps. The radiopharmacy, the restricted area in question, has been secured and access can only be gained through the Manager of the Nuclear Medicine Department. The Radiation Safety Officer will be notified of any requests for use of radioactive materials by the Manager of Nuclear Medicine so that the RSO can insure proper use and monitoring of the room.

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WASHINGTON, D.C. 20010-2975

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4. Corrective steps to avoid further violations. Again, security of the restricted area is to be controlled by the Manager of the Nuclear Medicine Department. A memo will be distributed to the Department Heads and Department Chairpersons of the Washington Hospital Center detailing that all requests for use of radioactive materials must be submitted and approved by the Radiation Safety Committee and the Hospital's IRB (as appropriate).

5. Compliance with this was achieved in January 1994, immediately following the discovery of this violation.

B. Failure to provide appropriate personnel monitoring equipment.

1. Admission. The licensee did not supply appropriate personnel monitoring equipment to a research associate working in the old pharmacy, a restricted area at the facility.

2. Reason for violation. The licensee inappropriately assumed that the Medlantic Research Institute had supplied the necessary monitoring equipment to the research associate and that he was an employee of and conducted his work in the Research Institute.

3. Corrective steps. The restricted area in question has been secured and is controlled by the Manager of Nuclear Medicine. The Radiation Safety Office will be notified of any request of intended use of radioactive material by the Manager of Nuclear Medicine so that the RSO can insure proper use and monitoring of the room and so that appropriate personnel monitoring equipment can be provided.

4. Corrective steps to avoid further violations. In accordance with the procedures outlined in the attached Standard Practice, "Procurement, Receipt and Inventory of Radioactive Materials," the RSO will be notified of any request of intended use of radioactive material by the Manager of Nuclear Medicine so that the RSO can insure proper use and monitoring of the room and so that appropriate personnel monitoring equipment can be provided.

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive and final approval expected by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

C. Failure to instruct an individual to follow established radiation safety procedures.

1. Admission. The licensee did not instruct or require an individual who was supervised by an authorized user and working in the old radiopharmacy to follow the established and written radiation safety and quality management procedures and did not periodically review the supervised individual's use of byproduct material.

2. Reason for violation. The licensee inappropriately assumed that the Medlantic Research Institute had provided the proper instructions to follow the established and written radiation safety and quality management procedures and was periodically reviewing the supervised individual's use of byproduct materials.

3. Corrective steps. All requests for the use of radioactive materials will be handled in accordance with the Hospital's Standard Practice, "Procurement, Receipt and Inventory of Radioactive Materials". Thereby, the RSO will be notified to provide the required instruction to those individuals authorized to use the radioactive materials.

4. Corrective steps to avoid further violations. The suppliers/vendors of radioactive materials will be provided with updated lists of authorized individuals who alone can order radioactive materials in accordance with Hospital's Standard Practice.

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive approval to follow by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

D. Failure to ensure that radiation safety procedures were being performed in accordance with our license.

1. Admission. Radioactive materials (technetium-99m) were ordered by a research associate who is not a designee of the supervising Nuclear Medicine technologist.

2. Reason for violation. The research worker in question was not authorized to order radiopharmaceuticals. While the vendor (Syncor) did have a current list of individuals authorized to order radiopharmaceuticals, they nonetheless, and inappropriately honored the request of the research worker.

3. Corrective steps. Syncor and all other vendors were immediately notified that the Washington Hospital Center's instructions were that only those on the list were authorized to order radioactive material.

4. Corrective steps to avoid further violations. All ordering of radioactive material will be conducted in accordance with the Hospital's Standard Practice, "Procurement, Receipt and Inventory of Radioactive Materials."

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive approval to follow by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

E. Failure to survey with a radiation detection instrument at your old radiopharmacy.

1. Admission. The licensee did not survey with a radiation detection instrument at the end of each day the old radiopharmacy used by this research worker.

2. Reason for violation. The licensee inappropriately assumed that the Medlantic Research Institute was properly surveying the radiopharmacy being used by one of their research associates.

3. Corrective steps. The research project that the research associate was conducting was terminated by the respective Chairpersons of the Medlantic Research Institute and the Washington Hospital Center's Radiation Safety Committees.

4. Corrective steps to avoid further violations. Radiation survey equipment will be available for all authorized users of this restricted area. Again, all users of radioactive materials must access use of this restricted area through the Manager of the Nuclear Medicine Department who, in turn, will notify the Radiation Safety Officer to insure proper compliance with use and room monitoring and personnel monitoring.

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive approval to follow by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

F. Failure to maintain records of the receipt of certain byproduct material.

1. Admission. Detailed records were not kept for the receipt in September and October, 1993 of the technetium-99m.

2. Reason for violation. Proper identification for the use of the technetium-99m in the Nuclear Medicine Department was not handled appropriately.

3. Corrective steps. The Nuclear Medicine Department has taken steps to identify the intended use and user of all radioactive materials, materials are wipe-tested and monitored for contamination, and documented in the "In and Out Log" in accordance with the Hospital's Standard Practice, "Procurement, Receipt and Inventory of Radioactive Materials."

4. Corrective steps to avoid further violations. Proper compliance with the Hospital's Standard Practice, "Procurement, Receipt and Inventory of Radioactive Materials."

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive approval to follow by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

G. Failure to maintain records of the measurement of radiopharmaceutical dosages.

1. Admission. The licensee did not maintain records as of January 10, 1994 of the measurement of radiopharmaceutical dosages administered to patients included in a technetium-99m labelled monoclonal antibody research study prior to that date.

2. Reason for violation. These records were maintained by the research associate in question.

3. Corrective steps. A copy of these records has been retrieved from the research associate and are now on file in the Nuclear Medicine Department.

4. Corrective steps to avoid further violations. All records of measurements of radiopharmaceutical dosages are to be kept in the Nuclear Medicine Department. All radiopharmaceutical dosages administered to patients must be assayed in Nuclear Medicine prior to patient administration. A record of this activity is also kept in the Nuclear Medicine Department.

5. The attached Standard Practice was approved at the May 18, 1994 meeting of the Radiation Safety Committee and will be reviewed by the Hospital's Investigational Review Board on June 14, 1994 with Hospital Executive approval to follow by June 16. The procedures and safeguards outlined in this Standard Practice have nonetheless been in effect since January of 1994 following the unfortunate incident in question.

Additionally, with respect to your request for clarification of the information in the letter dated January 12, 1994 from Barbara Howard, President of the Mediantic Research Institute, we will accept the extremity exposure to the research worker as reported by Landauer for September and October of 1993.

As you will note in the attached Standard Practice we have taken this opportunity to add additional controls and documentation to improve the manner in which radioactive materials are handled and used at the Washington Hospital Center. Additionally, we have initiated discussions with the administration of the Mediantic Research Institute to incorporate the activities of the Research Institute under the license of the Washington Hospital Center. Radiation safety activities for both the Research Institute and the Hospital Center will then fall under the authority of the Hospital Center's Radiation Safety Committee. This action is taken to minimize the possibility of future situations like the one which resulted in these violations.

Finally, we would like to thank you and the staff of the NRC for their participation in the improvement of our Radiation Safety Program.

Please find enclosed a check in the amount of $2,500 to satisfy the civil penalty levied in the letter dated April 28, 1994. I am available at 202-877-5566 if you have any questions regarding the foregoing or if I can provide you with any additional information.

Sincerely,

Mark H. Merrill

Mark H. Merrill
Vice President, Operations and Administrative Services

COPY: Regional Administrator
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Gerald Johnston, M.D.
Barbara Howard, PhD.
Ken Williams
Kevin Harlen
John Zurita

ENCLOSURE: Check for $2,500 - Civil Penalty