

APPENDIX A

NOTICE OF VIOLATION

The Montefiore Hospital Association
of Western Pennsylvania
Pittsburgh, Pennsylvania 15213

Dockets No. 030-15085
License No. 37-00865-10

As a result of the inspection conducted on October 2 and 3, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area to which access is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, as of October 3, 1985, the Nuclear Medicine Hot Lab and Radioimmunoassay (RIA) laboratories which contained millicurie quantities of licensed material, were unlocked when they were not under constant surveillance and immediate control.

This is a Severity Level IV violation. (Supplement VI)

- B. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of October 3, 1985, Nuclear Medicine Personnel were unaware of certain health and safety procedures as evidenced by:

1. Their failure to always wear gloves while handling radioactive materials as required on page III A-5 of the Radiation Safety Manual.
2. Their failure to use remote handling tools even though readily available.
3. Their unfamiliarity with the usually prescribed dose ranges as listed in Page 2 of the Nuclear Medicine Procedures Manual. They were unaware of the correct allowable range and, at the time of the inspection, assayed and administered a radiopharmaceutical in excess of the prescribed dose by greater than 25%.

This is a Severity Level IV Violation (Supplement VI).

- C. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on October 3, 1985, inadequate surveys were made to assure compliance with 10 CFR 20.105(b), which limits radiation levels in unrestricted areas. Specifically, inadequate surveys were made of the radiation levels in the room adjacent to a room recently vacated by a patient who had received a therapeutic dose of approximately 150 mCi of iodine-131. The inspectors identified radiation levels of 3 millirem per hour at the wall surface and 2.5 millirem per hour at 18 inches from the wall which were not identified by the licensee's surveys.

This is a Severity Level IV violation. (Supplement VI)

- D. Condition 25 of License No. 37-00865-10 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated July 26, 1984, and letters dated March 21, 1985, April 3, 1985, and May 14, 1985.

1. Item 10 of the application July 26, 1984 requires that you follow procedures listed in section III. E of the Radiation Safety Manual.

Section C-D of this section requires that survey instruments be calibrated at least biannually.

Contrary to the above, On October 3, 1985, several survey instruments had not been calibrated as required.

This is a Severity Level IV violation. (Supplement VI)

2. Section III A.2.1, page III A-5 of the Radiation Safety Manual, entitled, "Laboratory Rules and Procedures in the Use of Radioactive Material", submitted with this application requires that personnel wear a lab coat and rubber gloves when working with radioactive materials; that gloves and coat be removed before leaving the area and that hands, feet and clothing be monitored with a G-M meter to avoid the spread of contamination.

Contrary to the above, on October 3, 1985, Technologists in the Nuclear Medicine Department failed to wear gloves at all times while handling radioactive material and failed to monitor their hands and clothing before leaving the area.

This is a Severity Level IV Violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, the Montifiore Hospital Association of Western Pennsylvania is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.