APPENDIX A

NOTICE OF VIOLATION

Massachusetts General Hospital
Boston, Massachusetts 02114

Docket Nos. 030-01867
030-00239
030-08948
030-15211
License Nos. 20-03814-80
20-03814-14
20-03814-81
20-03814-84

As a result of the inspection conducted on July 25-28, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violations were identified:

A. 10 CFR 19.12 requires that individuals working in or frequenting a restricted area be instructed in the precautions and procedures to minimize exposure to radiation and radioactive materials, in the purpose and function of protective devices employed, and in the applicable provisions of the Nuclear Regulatory Commission's regulations and licenses.

Contrary to this requirement, a research technologist working with licensed radioactive material in a research laboratory, a restricted area, had not been instructed in the precautions and procedures to minimize exposure to radiation and radioactive material, in the purpose and function of protective devices employed, and in the applicable provisions of the Nuclear Regulatory Commission's regulations and licenses. Specifically, the technologist had worked with licensed radioactive material for approximately one month before attending Massachusetts General Hospital's required radiation safety training for all users of radioactive material.

Also contrary to this requirement, as of July 28, 1989, a student teletherapy technologist working in the teletherapy treatment room, a restricted area, had not been instructed in the applicable provisions of the Commission's regulations and licenses.

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

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of 10 CFR 20 and are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 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 circumstances.

Contrary to this requirement, as of July 28, 1989, no surveys were made of radiation levels during brachytherapy procedures to assure compliance with 10 CFR 20.105 which establishes the maximum permissible levels of radiation in unrestricted areas. Specifically, during the first seven months of 1989, no surveys were made, during five cesium-137 and four iridium-192 brachytherapy procedures, of radiation levels in unrestricted areas adjacent to rooms in which brachytherapy patients were housed.

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

C. Condition No. 26 of Radioactive Materials License No. 20-03814-80 requires that licensed radioactive materials be possessed and used in accordance with the statements, representations, and procedures described in the radioactive materials license application dated June 29, 1983 and in the documents submitted in support of that application.

1. Item 19 of the application dated June 29, 1983 describes the procedures and precautions for the therapeutic use of radiopharmaceuticals. Section D.2 of Item 19 requires that the radiation safety staff perform surveys of rooms used to house iodine-131 therapy patients after the patient's discharge and prior to release of the room to unrestricted use.

   Contrary to this requirement, as of July 28, 1989, the radiation safety staff did not perform surveys of rooms used to house iodine-131 therapy patients after the patient's discharge and prior to release of the room to unrestricted use.

2. Item 17 of the application dated June 29, 1983 states that nuclear medicine area radiation surveys will be performed in accordance to the procedures described in Appendix I of Regulatory Guide 10.8. Section 1 of Appendix I states that radiopharmaceutical elution, preparation, and injection areas will be surveyed daily with an appropriate low-range survey meter and decontaminated if necessary. Section 3 of Appendix I states that nuclear medicine and radioactive waste storage areas will be surveyed weekly.

Contrary to this requirement, as of July 28, 1989, radiopharmaceutical elution, preparation, and injection areas were not surveyed on a daily basis and nuclear medicine and waste storage areas were not surveyed on a weekly basis. Specifically, no surveys of radiopharmaceutical handling areas were performed for 11 consecutive days in March 1989, 17 consecutive days in May 1989 and on weekends when nuclear medicine scans were performed on an "on-call" basis. In addition, weekly radiation surveys of nuclear medicine and radioactive storage areas were not performed during 13 weeks in 1988 and 13 of 29 weeks in 1989.

These are Severity Level IV violations. (Supplement VI)

D. Condition No. 20 of Radioactive Materials License No. 20-03814-14 requires that licensed radioactive materials be possessed and used in accordance with the statements, representations, and procedures described in the radioactive materials license application dated September 21, 1984 and in the documents submitted in support of that application.

Item 17 of the application dated September 21, 1989 states that teletherapy system operational checks of safety devices including emergency off buttons and treatment room door interlocks will be performed on a daily basis

Contrary to this requirement, as of July 28, 1989, daily teletherapy system operational checks of safety devices including emergency off buttons and treatment room door interlocks were not performed on weekends when the system was used.

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

Pursuant to the provisions of 10 CFR 2.201, Massachusetts General Hospital 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.