MAR 2 1983

APPENDIX A

NOTICE OF VIOLATION

Geisinger Medical Center
Danville, Pennsylvania 17821

Docket Nos. 30-02984
30-00465
License Nos. 37-01421-01
37-01421-04

As a result of the inspection conducted on January 20-21, 1983, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. 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 January 20-21, 1982, technologists working in the Nuclear Medicine Laboratory, a restricted area, had not been instructed in the required procedures for safely opening packages containing radioisotopes, for performing daily contamination checks in the Nuclear Cardiology Laboratory, and for performing weekly contamination wipe tests in the Nuclear Medicine Laboratory.

B. 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.

1. Contrary to the above, as of January 20-21, 1983, inadequate surveys (evaluations) were made to assure compliance with 10 CFR 20.101, a regulation which limits the radiation dose to the extremities of individuals in restricted areas. Specifically, no evaluation was made of the dose to the extremities of physicians who routinely do not wear a TLD finger badge while performing brachytherapy procedures and for individual who lost their TLD finger badges in June 1981 and March 1982.

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

2. Contrary to the above, as of January 20-21, 1983, inadequate surveys were made to determine that individuals who handled millicurie quantities of iodine-131 was not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103. Specifically, the thyroid bioassay procedure used to evaluate personnel exposure was not sufficiently sensitive and no thyroid bioassay was performed on a physician who administered 100 millicuries of iodine-131 in liquid form on February 24, 1982.

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

C. Condition 12 of License No. 37-01421-01 limits the use, or supervision of use, of licensed material to a named physician.

Contrary to the above, on January 20, 1983, a physician not authorized by this license condition used licensed material without an authorized user's direct supervision. Specifically, a physician on the obstetrics-gynecological service removed 65 milligrams radium-equivalent of cesium-137 as brachytherapy sources from a patient and returned them to the storage room without the direct supervision of a named physician.

D. Condition 20 of License No. 37-01421-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated March 31, 1978.

1. Item 14 (Appendix F) of this application, requires that when opening packages in which licensed material has been received, the exposure rate 3 feet from the surface of the package and at the surface be measured, and that the external surface of the final source container be wiped with a moistened cotton swab.

Contrary to the above, as of January 20-21, 1983, the required procedures were not routinely used on all incoming packages.

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

2. Item 17 (Appendix I) of this application, requires that all elution, preparation and injection areas be surveyed daily. This Appendix also requires that weekly surveys include wipe tests.

Contrary to the above, as of January 20-21, 1983, injection areas in the Nuclear Cardiology Laboratory was not surveyed for contamination on a daily basis and wipe tests were performed only in the sinks in the Nuclear Medicine Department and not all areas where licensed material is routinely prepared and handled.

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

3. Item 11 of this application, and the attached floor plan describes the hot laboratory facilities and areas where licensed material is to be stored, prepared, and handled.

Contrary to the above, as of January 20-21, 1983 facilities not described in this application was being used to store, and handle licensed material.

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

E. 10 CFR 20.203(e) requires that rooms in which specified amounts of licensed material are used or stored by conspicuously posted "Caution Radioactive Material."

Contrary to the above, as of January 20-21, 1983, the Nuclear Medicine Hot Laboratory which contained licensed materials in excess of 10 times the amount specified in Appendix C of 10 CFR 20, was not posted, as required.

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

F. 10 CFR 20.401(b) requires that each licensee maintain records showing the results of surveys required by 10 CFR 20.201(b).

Contrary to the above, as of January 20-21, 1983, records were not maintained of the final contamination and radiation surveys that were performed on patient rooms that had housed individuals treated with therapeutic quantities of iodine-131.

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

G. Condition 18 of License No. 37-01421-04 requires that, following any change in the teletherapy machine or treatment room, a radiation survey be performed and a report of the results of the survey be submitted to the Commission within 30 days.

Contrary to the above, as of January 20-21, 1983, a radiation survey report had not been submitted to the Commission following change of the teletherapy machine room location in 1981, a period of more than 30 days.

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

Pursuant to the provisions of 10 CFR 2.201, Geisinger Medical Center 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.