NOTICE OF VIOLATION

The Medical Center of Delaware, Inc.
Wilmington and Newark, Delaware

Docket Nos. 030-01303
030-17578
030-30420
License Nos. 07-12153-02
07-12153-03
07-12153-04
EA No. 90-034

During an NRC inspection conducted on January 29-31, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1989), the violations are set forth below:

A. 10 CFR 20.301 prohibits disposal of licensed material, except by certain procedures specified in 10 CFR 20.301(a) or (b).

Contrary to the above, on April 25, 1989, a urine sample containing approximately 900 microcuries of iodine-131 was obtained from a radioiodine therapy patient and was disposed of in the normal trash, a method of disposal not specified in 10 CFR 20.301(a) or (b).

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

B. 10 CFR 20.203(f) requires that each container of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, on April 25, 1989, a container which held 15 milliliters (ml) of patient urine containing approximately 60 uCi per ml of iodine-131 did not bear a clearly visible label identifying the radioactive contents when it was removed from the patient's room and subsequently analyzed in the hospital pathology laboratory.

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

C. 10 CFR 35.92(a)(2) requires that byproduct material held for decay-in-storage before disposal in ordinary trash be monitored before disposal to determine that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

Contrary to the above, as of January 30, 1990, certain byproduct material held for decay-in-storage was routinely sent for disposal in the ordinary trash without the required monitoring. Specifically, radioimmunoassay waste containing iodine-125 had not been surveyed prior to the disposal in the ordinary trash.

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

D. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy, the patient's room and private sanitary facility be surveyed for removable contamination with a radiation detection survey instrument before assigning another patient to the room and that the room not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, as of January 31, 1990, radiopharmaceutical therapy patient rooms were reassigned before removable contamination was less than 200 disintegrations per minute per 100 square centimeters.

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

E. 10 CFR 20.101(a) limits the whole body radiation dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). 10 CFR 20.101(b) allows a whole body radiation dose of three rems per calendar quarter, provided conditions specified therein are met, including a prior determination of the individual's accumulated occupational dose to the whole body on NRC Form 4, or on a clear and legible record containing all of the information contained on that form.

Contrary to the above, an individual working in a restricted area received a whole body radiation dose of 1.890 rems during the fourth calendar quarter of 1989, and the conditions set forth in 10 CFR 20.101(b) were not met, in that a prior determination of the individual's accumulated occupational dose to the whole body was not provided on a NRC Form 4, or a suitable alternative record.

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

F. 10 CFR 35.634(c) requires that licensees have the teletherapy physicist review the results of each monthly spot-check of the teletherapy unit within 15 days.

Contrary to the above, the teletherapy physicist did not review, within 15 days, the results of the spot-checks of the teletherapy unit for those checks performed in August 1989, June 1989, April 1989, and January 1989.

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

G. 10 CFR 35.204(b) requires that a licensee using molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum-99 concentration in each elute or extract.

Contrary to the above, as of January 31, 1990, when the molybdenum-99/technetium-99m generators were used to prepare a technetium-99m radiopharmaceutical, the technetium-99m eluted from the generator had not been adequately evaluated for molybdenum-99 concentration in that the correction factor required by the manufacturer was not applied.

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

H. 10 CFR 35.59(d) requires that records of leak test results of sealed sources or brachytherapy sources contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, records of results of leak test conducted on June 15, 1988, December 15, 1988, June 8, 1989, and December 21, 1989 for brachytherapy sources, as well as strontium-90 and cobalt-60 sources, did not contain the model number, estimated activity or the Radiation Safety Officer's signature.

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

Pursuant to the provisions of 10 CFR 2.201, The Medical Center of Delaware, Inc. is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to this office, within 30 days of the date of this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Consideration may be given to extending the response time for good cause shown.

FOR THE NUCLEAR REGULATORY COMMISSION

(SIGNED) MALCOLM R. KNAPP

Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards

Dated at King of Prussia, Pennsylvania
this 9th day of March 1990