APPENDIX A

NOTICE OF VIOLATION

Howard University
Washington, D.C.

Docket No. 030-01321
License No. 08-03075-07

During an NRC inspection conducted on February 16 and 17, 1994, 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, the violations are listed below:

A. 10 CFR 35.60(b) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, or the clinical procedure to be performed, or the patient's name.

Contrary to the above, on February 17, 1993, the licensee did not label a syringe containing a technetium-99m labeled radiopharmaceutical (sulphur colloid) to show the radiopharmaceutical name or its abbreviation, or the clinical procedure to be performed, or the patient's name.

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

B. 10 CFR 35.22(a)(1) requires that the membership of the Radiation Safety Committee consist of at least three individuals and include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, as of February 17, 1994, the membership of the licensee's Radiation Safety Committee did not include an authorized user of materials identified in 10 CFR 35.400 and the licensee is authorized to use these materials.

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

C. 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on December 19, 1992, the licensee's Radiation Safety

Committee met and conducted business and a quorum was not established because the representative of the management did not attend the meeting.

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

D. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

(i) The licensee's procedures for spills are described in the application dated February 19, 1988, and were approved by License Condition No. 13.

The application dated February 19, 1988 states in Item No. 10.5 that the Model Spill Procedures published in Appendix J to Regulatory Guide 10.8, Revision 2 will be followed.

Item (1) of the Model Spill Procedures of Appendix J to Regulatory Guide 10.8, Revision 2, requires that the persons in the area be notified of the spill, and Item (5) of the same document requires that the incident be reported to the Radiation Safety Officer.

Contrary to the above, on , the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, a spill of radioactive materials occurred on February 17, 1994 and neither the persons in the area nor the Radiation Safety Officer were notified of the spill.

(ii) The licensee's procedures for safe use of radiopharmaceuticals are described in the application dated February 19, 1988, and were approved by License Condition No. 13.

The application dated February 19, 1988 states in Item No. 10.4 that the Model Safety Rules published in Appendix I to Regulatory Guide 10.8, Revision 2 will be followed.

Item (9) of the Model Rules for Safe Use of Radiopharmaceuticals of Appendix I to Regulatory Guide 10.8, Revision 2, requires that the radioactive waste be disposed of only in designated, labeled and properly shielded receptacles.

Contrary to the above, on February 16, 1994, radioactive waste from the pulmonex unit was disposed of in a receptacle that was not designated, labeled or properly shielded.

These are Severity Level IV violations (Supplement VI)

E. 10 CFR 35.25(a)(3) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user, review the supervised individual's use of byproduct material and the records kept to reflect this use.

Contrary to the above, the licensee did not periodically review the supervised individual's use of byproduct material and the records kept to reflect this use. Specifically, nuclear medicine technologists, working under the supervision of an authorized user, used sealed source to check the survey instruments and the records of this use, which contained several discrepancies were not reviewed periodically by the licensee.

This is a Severity Level IV violation (Supplement VI)

F. 10 CFR 19.12 requires, in part, 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 February 17, 1994, individuals who were working in the hot lab of the Nuclear Medicine department, a restricted area, had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, the nuclear medicine technologists were not instructed in the procedures of measuring molybdenum concentration, and in the proper procedures of checking survey instruments for proper operation.

This is a Severity Level IV violatior (Supplement VI)

G. 10 CFR 35.50(e) and 35.50(e)(3) require, in part, that a licensee retain records of quarterly dose calibrator linearity tests for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, as of February 17, 1994, the licensee's record of the quarterly linearity test of its dose calibrator performed between August 31, 992 and December 13, 1993 did not include the signature of the Radiation Safety Officer.

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

H. 10 CFR 35.59(g) requires, in part, that a licensee retain for five years records of quarterly physical inventories of sealed sources and brachytherapy sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

Contrary to the above, as of February 17, 1994, the licensee's records of physical inventories of its sealed sources did not contain the signature of the Radiation Safety Officer.

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

Pursuant to the provisions of 10 CFR 2.201, Howard University is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.