APPENDIX A

NOTICE OF VIOLATION

Veterans Administration Medical Center
Batavia, New York 14020

Docket No. 030-09204
License No. 31-08946-02
EA 90-184

As a result of the inspection conducted on September 18, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990), the following violations were identified:

Condition 17 of License No. 31-08946-02 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in the application dated June 9, 1978; letters dated March 28, 1979, February 8, 1982 and February 11, 1982; ALARA Program dated February 10, 1982; and letters dated March 27, 1984 and December 10, 1985 and also in accordance with 10 CFR Parts 20 and 35.

A. Item 12 of the application dated June 9, 1978, (Personnel Training Program and Frequency) states, in part, that all trainees are licensed and registered radiological technologists and that each trainee is given 40 hours of didactic lectures on subjects related to radiation safety before being allowed to participate in the handling and preparation of isotopes and patient studies.

Contrary to the above, between June 1988 and July 1989, a licensee trainee was not a licensed and registered radiologic technologist, nor did the trainee receive 40 hours of didactic lectures on subjects related to radiation safety before being allowed to participate in the handling and preparation of isotopes and patient studies.

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

B. The licensee's letter dated March 28, 1979 states, in part, that ancillary medical center employees, (nursing, clerical, housekeeping, security, etc.) will be included in the radiation safety training program which includes annual refresher training.

Contrary to the above, as of September 18, 1990, the licensee clerical staff had never received the annual radiation safety refresher training.

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

C. Item 2 of the licensee's letter dated December 10, 1985 states, in part, that the procedures described in Appendix D of Regulatory Guide 10.8, Revision I (dated October 1980) will be followed. Appendix D, Section 1, Paragraph A.2 of this Regulatory Guide requires that survey meters shall be calibrated at least annually and after servicing.

Contrary to the above, two survey meters (a Victoreen 491 survey meter and a Keith 36100 survey meter) were not calibrated annually in that neither meter was calibrated in 1989.

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

D. Item 2 of the licensee's letter dated December 10, 1985 states, in part, that the procedures described in Appendix B of Regulatory Guide 10.8, Revision 1, will be followed. Appendix B (Medical Isotopes Committee), Section 9 (Duties), requires that the Medical Isotopes Committee ensure that the byproduct materials license is amended, when necessary, prior to any changes in facilities or personnel as specified in the license.

Contrary to the above, the Medical Isotopes Committee did not ensure that the byproduct material license was amended when necessary, prior to any changes in facilities or personnel as specified in the license, as evidenced by the following examples:

1. the licensee changed radiation safety officers in 1980 and 1988; however the Medical Isotopes Committee did not ensure that the license was amended to reflect the change in personnel; and

2. In the latter part of 1988 through June 1989, the Nuclear Medicine scan room and Hot Lab were relocated from the location described in the license application dated June 9, 1978; however, the Medical Isotopes Committee did not ensure that the license was amended to reflect the changes in the facility.

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

E. The Model ALARA Program dated February 10, 1982, paragraph B states, in part, that licensee management will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections and consultations with the radiation protection staff and outside consultants.

Contrary to the above, as of September 18, 1990 the formal annual reviews of the radiation safety program including ALARA considerations, were inadequate in that the licensee failed to identify numerous violations of their license commitments.

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

F. Item 2 of the licensee's letter dated December 10, 1985 states, in part, that the procedures described in Appendix I of Regulatory Guide 10.8, Revision 1 will be followed. Appendix I, (Area Survey Procedures), Section 5 requires that a permanent record be kept of all survey results including an identification of the survey equipment used, with the serial number and pertinent counting efficiencies and the name of the person performing the survey.

Contrary to the above, as of September 18, 1990, area survey records did not contain all of the required information. Specifically, the survey records did not include an identification of the survey equipment used including the serial number and pertinent counting efficiencies, and the name of the person performing the survey.

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

G. Item 2 of the licensee's letter dated December 10, 1985 states, in part, that the procedures described in Appendix D of Regulatory Guide 10.8, Revision 1 will be followed for calibration of the dose calibrator.

1. Appendix D, Section A.4 requires that a geometrical variation test be performed at the time of installation of the dose calibrator.

   Contrary to the above, a geometrical variation test was not performed at the time the dose calibrator was installed.

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

2. Appendix D, Section C.6 requires that for dose calibrator constancy testing, a graph will be plotted to indicate the predicted activity of each source based on decay calculations and the ±5 percent limit on the graph.

   Contrary to the above, as of September 18, 1990, the dose calibrator constancy test did not include a graph indicating the predicted activity of each source based on decay calculations and the ±5 percent limits on the graph.

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

3. Appendix D, Section B.4 requires, that for dose calibrator linearity testing, a graph of the measured net activity versus the calculated activity will be plotted.

   Contrary to the above, as of September 18, 1990, a graph of the measured net activity versus the calculated activity was not plotted for the dose calibrator linearity test.

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

H. 10 CFR 35.59(d) requires, in part, that a licensee in possession of any sealed source shall retain leakage test records which contain the model number and serial number (if assigned), of each source tested, the estimated activity, the measured activity expressed in microcuries and a description of the method used to measure each test sample.

Contrary to the above, the sealed source leakage test records did not include all the required information. Specifically, the records did not include:

1. the model number and serial number of each source tested;

2. the estimated activity of the sealed source;

3. the measured activity of the sealed source expressed in microcuries; and

4. a description of the method used to measure each test sample.

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

I. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, as of September 18, 1990, the physical inventory of sealed sources in the licensee's possession was not being conducted quarterly. Specifically, the sealed source inventories were conducted annually.

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

J. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which 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 conditions.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, as of September 18, 1990, the licensee did not survey a rest room wall (an unrestricted area) adjacent to the hot lab waste storage closet.

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center 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, and if applicable, a copy to the NRC Resident Inspector, 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 may be issued to show case 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.

Dated at King of Prussia, Pennsylvania
This 27th day of December, 1990