APPENDIX A

DRAFT

NOTICE OF VIOLATION

Veterans Administration Medical Center
Albany, New York 12208

Docket No. 030-10026
License No. 31-02755-05

As a result of the inspection conducted on November 20 and 21, 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:

A. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radioactive materials.

Contrary to the above, on August 3, 1990, a shipment of radioactive material (1 millicurie of tritium) was left unsecured in an unrestricted area (hallway) and not under the constant surveillance and immediate control of the licensee.

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

B. 10 CFR 35.315(a)(8) requires that licensees, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage.

Contrary to the above, as of November 21, 1990, an individual who prepared and administered a dosage of iodine-131 on July 13, 1990 did not have the required bioassay, within 3 days after administering the dosage.

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

C. 10 CFR 35.22(b)(6) requires that Radiation Safety Committee review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, as of November 21, 1990, the Radiation Safety Committee, with the assistance of the Radiation Safety Officer have failed to review the radiation safety program for 1989.

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

D. 10 CFR 35.205(c) requires that before receiving, using or storing a radioactive gas, licensees calculate the amount of time needed after a spill to reduce the concentration in the room to the limit listed in 10 CFR 20, Appendix B, Table I, that a record of these calculations be made, and that licensees post the calculated time and safety measures to be instituted in case of a spill at the area of use.

Contrary to the above, as of November 21, 1990, no calculation (or posting) of the time needed after a spill of xenon-133 to reduce the concentration in the imaging room (Room 626D) to the applicable limit has been performed.

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

E. 10 CFR 20.303 describes requirements for the disposal of radioactive materials by release into the sanitary sewerage system. 10 CFR 20.401 requires that each licensee maintain records of disposals made under 10 CFR 20.303.

Contrary to the above, as of November 21, 1990, adequate records of disposals of radioactive material by release into the sanitary sewerage system, for 1988 and 1989, were not maintained as required under 10 CFR 20.401.

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

F. 10 CFR 35.70(d) requires that a licensee shall establish radiation dose rate trigger levels for areas surveys required by paragraphs (a) and (b) of 10 CFR 35.70.

Contrary to the above, as of November 21, 1990, the licensee has not established radiation dose rate trigger levels for area surveys required under 10 CFR 35.70.

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

G. 10 CFR 35.59(b)(2) requires that each sealed source or brachytherapy source be tested for leakage at intervals not to exceed 6 months or at intervals approved by the Commission or an Agreement State.

Contrary to the above, sealed sources containing licensed material with a required leak test frequency not to exceed every 6 months were not tested for leakage from October 14, 1989 to November 21, 1990 a period in excess of every 6 months.

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

H. 10 CFR 35.205(e) requires that licensees check the operation of collection systems for radioactive gases each month and measure the ventilation rates available in areas of use of radioactive gases each 6 months.

Contrary to the above, as of November 21, 1990, the ventilation rates available in the imaging room (Room 626D) used for radioactive xenon gas were not being measured each 6 months.

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

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

Contrary to the above, on July 16, 1990, a radiopharmaceutical therapy patient's room was reassigned before removable contamination was less than 200 disintegrations per minute per 100 square centimeters.

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

J. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions and procedures to minimize exposure and the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials.

Contrary to the above, as of November 21, 1990 the licensee failed to adequately instruct all individuals working in or frequenting any portion of a restricted area in the health problems associated with exposure to radioactive materials, in precautions and procedures to minimize exposure and the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radioactive materials.

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

K. 10 CFR 35.50(b)(2) requires that the licensee check the dose calibrator for accuracy upon installation and at least annually thereafter.

Contrary to the above, as of November 21, 1990, dose calibrator accuracy tests are not being performed.

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

L. 10 CFR 35.25 requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11 shall require the supervised individual to follow the instructions of the supervisory authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the regulations of 10 CFR 35 and license conditions with respect to the use of byproduct material. 10 CFR 35.25 further states that a licensee who supervises an individual is responsible for the acts and omissions of the supervised individual.

1) The licensee's procedures described in Appendix 20 of the license application require that individuals do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

Contrary to the above, on November 20, 1900 evidence of eating and drinking was observed in five research laboratories (Rooms A607, A625, A629, B607 and B630) where radioactive material is stored or used.

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

2) The licensee's procedures described in item 2 of letter dated March 16, 1987 require that individuals survey their hands, shoes, body and clothing for radioactive contamination prior to leaving an area where radioactive materials are used.

Contrary to the above, on November 20 and 21, 1990 numerous individuals were observed leaving research areas where radioactive materials are used without surveying their hands, shoes, body and clothing for radioactive contamination.

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

3) The licensee's procedures described in Section 3.1.4 of license application require that authorized users notify the Radiation Safety Officer whenever there is a change in laboratory personnel or location.

Contrary to the above, as of November 21, 1990 two authorized users failed to notify the Radiation Safety Officer of prior changes in laboratory personnel and location.

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

4) The licensee's procedures described in item 2(J) of letter dated March 16, 1987 state that whole body personnel monitoring devices (film badges and/or TLD) shall be worn at all times while in areas where radioactive materials are stored or used.

Contrary to the above, on November 20 and 21, 1990 individuals were observed not wearing whole body personnel monitoring devices while in areas where radioactive materials are used or stored.

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

5) The licensee's procedures described in Section 3.1.4 of the license application require authorized users maintain on file, up-to-date records of the use, disposition, storage and disposal of all radionuclides including the amount of radioactivity, isotope, chemical form, volume or weight, date of analysis, company and location of isotope.

Contrary to the above, as of November 21, 1990 up-to-date records of radioactive waste disposal were not maintained by the authorized user for radioactive waste generated in Room A607.

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

M. 10 CFR 35.21 requires, in part, that the Radiation Safety Officer establish and implement written policy and procedures for performing periodic radiation surveys. The Radiation Safety Officer established procedures requires that the xenon airborne concentrations in restricted areas and releases to unrestricted areas be calculated to demonstrate compliance with 10 CFR 20.103 and 10 CFR 20.106 requirements, respectively.

Contrary to the above, as of November 21, 1990, the xenon airborne concentration in restricted areas (room 626D) and release to unrestricted areas were not calculated to demonstrate compliance with 10 CFR 20.103 and 10 CFR 20.106 requirements.

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

N. 10 CFR 35.13(e) requires that a licensee shall apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or in the license.

Contrary to the above, as of November 21, 1990, the licensee changed the location of radioactive xenon gas use from room 609D to 626D without applying for or receiving a license amendment.

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

O. 10 CFR 35.50(e)(3) requires that records be maintained of quarterly dose calibrator linearity tests for 3 years unless directed otherwise and that the record 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 November 21, 1990, records of quarterly linearity tests did not contain the serial number of the dose calibrator and the signature of the Radiation Safety Officer.

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

P. 10 CFR 35.50(e)(1) requires that records be maintained of daily constancy checks of dose calibrators for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured and the initials of the individual who performed the test.

Contrary to the above, as of November 21, 1990, records of daily constancy checks did not include the model and serial number of the dose calibrator.

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

Q. 10 CFR 35.50(e)(4) requires that records be maintained of tests for dose calibrator geometrical dependence for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 21, 1990, the records of tests for geometrical dependence did not include the serial number of the dose calibrator and signature of the Radiation Safety Officer.

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration 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.

Docket No. 030-10026 License No. 31-02755-05

Veterans Administration Medical Center, Albany, New York

Inspection History

Inspection	Results
90-001 (November 20 and 21, 1990)	Violation - 10 CFR 20.207(a) - Failure to secure licensed material against unauthorized removal. Violation - 10 CFR 35.315(a)(8) - Failure to perform bioassay on an individual who prepared an Iodine-131 therapy dose. Violation - 10 CFR 35.22(b)(6) - Failure to conduct an annual review of the radiation safety program. Violation - 10 CFR 35.21 - Failure to make surveys to demonstrate compliance with 10 CFR 20.103 and 20.106 in accordance with licensee's procedures. Violation - 10 CFR 35.205(c) - Failure to calculate and post spilled gas clearance times. Violation - 10 CFR 20.401 - Failure to maintain adequate records of disposals made under 10 CFR 20.303. Violation - 10 CFR 35.70(d) - Failure to establish dose rate trigger levels for area surveys. Violation - 10 CFR 35.59(b)(2) - Failure to perform sealed source leakage tests at the required frequency. Violation - 10 CFR 35.205(e) - Failure to measure imaging room ventilation rates.

Inspection	Results
90-001 (continued)	Violation - 10 CFR 35.315(a)(7) - Failure to assess limits of removable contamination before releasing a radiopharmaceutical therapy room for unrestricted use.
	Violation - 10 CFR 19.12 - Failure to adequately instruct all occupationally exposed individuals in the health protection problems associated with exposure to radioactive materials.
	Violations - 10 CFR 35.50(b)(2) - Failure to perform dose calibrator accuracy tests.
	Violation - 10 CFR 35.25 - Evidence of eating and drinking in areas where radioactive materials are used or stored.
	Violation - 10 CFR 35.25 - Failure to survey hands, shoes, body and clothing prior to leaving areas where radioactive materials are used.
	Violation - 10 CFR 35.25 - Failure to notify Radiation Safety Officer of changes in laboratory personnel and location.
	Violation - 10 CFR 35.25 - Failure to wear film badges.
	Violation - 10 CFR 35.25 - Failure of authorized user to maintain records of waste disposal.
	Violation - 10 CFR 35.13(e) - Failure to apply for and receive a license amendment before changing areas of radioactive material use.
	Violation - 10 CFR 35.50(e)(3) - Failure to maintain adequate dose calibrator linearity records.
	Violation - 10 CFR 35.50(e)(1) - Failure to maintain adequate dose calibrator constancy records.

Inspection	Results
90-001 (continued)	Violation - 10 CFR 35.50(e)(4) - Failure to maintain adequate dose calibrator geometry records.
89-001 (October 30, 1989)	Violation - 10 CFR 35.59(g) - Failure to conduct sealed source inventories at the required quarterly frequency.
	Violation - 10 CFR 35.204(c) - Molybdenum concentration records did not contain the time of the measurement.
88-001 (November 14 and 15, 1988)	Form 591
86-001 (October 23 and 24, 1986)	Form 591
84-001 (September 26, 1984)	Clear Letter
80-001 (May 1 and 2, 1980)	Violation - 10 CFR 20.207 - Licensed material not secured against unauthorized removal and not under an constant surveillance and immediate control of the licensee.
	Violation - License Condition 20 - Failure to use syringe shields while preparing and administering radiopharmaceuticals.
	Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be necessary to comply with all sections of Part 20. Specifically, failure to assure compliance with 10 CFR 20.106, "Concentrations in effluents to unrestricted areas".
78-001 (August 3 and 4, 1978)	Clear letter

Inspection	Results
76-001 (September 13, 1976)	Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be needed to comply with all Sections of Part 20. Specifically, failure to make surveys to determine that persons handling significant quantities of iodine-125 were not exposed to airborne concentrations in excess of the limits in 10 CFR 20.103.
73-001 (August 15 and 17, 1973)	Violation - 10 CFR 20.201(b) - Failure to make such surveys as may be necessary to comply with all sections of Part 20. Specifically, failure to adequately evaluate hand exposures incurred by technologists administering 15 millicurie doses of 99m technetium.