

APPENDIX A

NOTICE OF VIOLATION

Veteran Administration Medical Center
Brockton/West Roxbury, Massachusetts 02132

Docket No. 030-01902
License No. 20-08551-01

As a result of the inspection conducted on September 10 and 11, 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 35.59(b)(2) requires that each sealed source or brachytherapy source be tested for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, as of September 11, 1990, leak tests were not performed on sealed calibration sources at your Brockton location from January 1989 until August 1990, a interval in excess of six months.

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

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

Contrary to the above, as of September 11, 1990, annual reviews of the radiation safety program have not been performed by the Radiation Safety Committee.

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

- C. 10 CFR 35.51(a)(3) requires that licensees conspicuously note on each survey instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration and the date of the calibration. 10 CFR 35.51(d) requires that licensees retain a record of each survey instrument calibration for two years and that the record include a description of the calibration procedure, the date of calibration and a description of the source used and the certified exposure rates from the source, the rates indicated by the instrument being calibrated, the correction deduced from the calibration data and the signature of the individual performing the calibration.

Contrary to the above, as of September 11, 1990, the apparent exposure rate from a dedicated check source was not conspicuously noted on each survey instrument and the record of survey instrument calibration did not contain the required information.

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

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- D. 10 CFR 35.50(1, 2, and 3 requires that records of dose calibrator accuracy, linearity, constancy and geometry testing be maintained by the licensee which contain the model and serial number of the dose calibrator. The signature of the Radiation Safety Officer is required on accuracy, linearity and geometry test records.

Contrary to the above, as of September 11, 1990, records of dose calibrator accuracy and linearity were not signed by the Radiation Safety Officer and the constancy records did not contain the model and serial number of the dose calibrator. Furthermore, records of dose calibrator geometry testing were not available.

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

- E. 10 CFR 35.53(c) requires that records of the measurement of radiopharmaceutical dosage contain the:
- (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number and the expiration dates and the radionuclide;
 - (2) Patient's name, and identification number if one has been assigned;
 - (3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;
 - (4) Date and time of the measurement; and
 - (5) Initials of the individual who made the record.

Contrary to the above, as of September 11, 1990, the records of the measurement of radiopharmaceutical dosages did not contain the prescribed dosages and the lot number and expiration date of the radionuclide.

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

- F. 10 CFR 35.204(c) requires that records of the permissible concentration of molybdenum-99 in the generator eluate contain:
- (1) The measured activity of the technetium-99m expressed in millicuries,
 - (2) The measured activity of molybdenum expressed in microcuries,
 - (3) The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium,
 - (4) The time and date of the measurement, and
 - (5) The initials of the individual who made the measurement.

Contrary to the above, as of September 11, 1990, the records of the permissible level of molybdenum-99 did not contain the activity of technetium expressed in millicuries and the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium.

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

- G. 10 CFR 20.401(b) requires that each licensee maintain records of disposals made under 10 CFR 20.303.

Contrary to the above, as of September 11, 1990, records were not maintained of the disposals of licensed materials made to the sanitary sewerage system from the research and development facility for 1989 and the first two quarters of 1990.

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

- H. 10 CFR 35.59(d) requires that records of leak tests of sealed 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, as of September 11, 1990, the records of leak test results did not 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 source tested expressed in microcuries, and a description of the method used to measure each test sample.

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.