

APPENDIX A
NOTICE OF VIOLATION

Yale - New Haven Hospital
New Haven, Connecticut 06504

Docket No. 03C-01244
License No. 06-00819-03

As a result of the inspection conducted on August 1 and 2, 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 20.301 requires that no licensee dispose of licensed material except by certain specified method.

Contrary to the above, on April 14, 1990, vials containing residual xenon-133 were included in the normal medical waste sent for disposal by a contractor who is not licensed to handle radioactive material, a method not authorized by 10 CFR 20.301.

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

- B. Condition 27 of License No. 06-00819-03 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in an application dated December 13, 1986.

1. Item No. 17 of this application requires that elution, preparation, and injection areas be surveyed daily and that waste storage areas and imaging rooms be surveyed weekly.

Contrary to the above, daily surveys were not performed on weekend work days including July 14, 15, 21, and 22, 1990, and weekly surveys were not performed for the weeks of January 22 and 29, 1990, nor in the month of February.

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

2. Item 15.D of this application requires that patient doses not be used if the activity is greater than $\pm 10\%$ of the standard prescribed amount, and that each dose be checked with the dose calibrator prior to its administration.

Contrary to the above, as of August 2, 1990, patient doses were not checked in the dose calibrator to determine if the activity was greater than $\pm 10\%$ of the prescribed dose prior to administration.

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

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- C. 10 CFR 35.53(c) requires, in part, that records of the measurement of radiopharmaceutical dosage contain the activity of the dosage at the time of measurement and the initials of the individual who made the records.

Contrary to the above, as of August 2, 1990, the labels used as records of the measurement of radiopharmaceutical dosage contained neither the activity of the dosage at the time of measurement nor the initials of the individual who made the record.

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

- D. 10 CFR 35.204 requires, in part, that the record of molybdenum-99 concentration in each eluate include, for each elution of technetium-99m, the measured activity of technetium expressed in millicuries, and the measured activity of molybdenum-99 expressed in microcuries.

Contrary to the above, as of August 2, 1990, record of molybdenum-99 concentration in each eluate contained neither the measured activity of molybdenum-99 nor the measured activity of technetium-99m.

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

Pursuant to the provisions of 10 CFR 2.201, Yale - New Haven Hospital 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.