APPENDIX A

NOTICE OF VIOLATION

Salem Hospital
Salem, Massachusetts 01970

License No. 20-00083-02
Docket No. 030-01803

As a result of the inspection conducted on July 6, 1988, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violations were identified:

A. 10 CFR 35.14(b)(4) (superseded) requires that each licensee using molybdenum-99/technetium-99m generators shall test each elution of technetium-99m to determine either the total molybdenum-99 activity or the concentration of molybdenum-99 before administration to patients.

Contrary to this requirement, elutions of technetium-99m were not assayed for molybdenum-99 on the following dates: August 6, 1987; November 11, 1987; November 21, 1987; December 26, 1987; January 16, 1988; March 13, 1988; March 14, 1988; March 20, 1988; April 17, 1988; and May 2, 1988.

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

B. Condition 20 of License No. 20-00083-02 requires that licensed radioactive material be possessed and used in accordance with the representations, statements, and procedures contained in the radioactive material license applications dated May 14, 1979 and December 6, 1985 and in the letters dated October 11, 1980; January 10, 1981; and September 22, 1986.

1. Item 16.a. of Attachment 1 to the letter dated October 11, 1980 states that millicurie quantities of iodine-131 will be opened and dispensed in a fume hood.

Contrary to this requirement, as of July 6, 1988, therapeutic iodine-131 doses drawn from multiple-dose vials containing up to 70 millicuries of activity were not handled in a fume hood.

2. Item 16.b. of attachment 1 to the letter dated October 11, 1980 states that thyroid bioassays will be performed on nuclear medicine technologists 24 hours after the administration of iodine-131 therapy doses.

Contrary to this requirement, as July 6, 1988, thyroid bioassays were not performed on nuclear medicine technologists 24 hours after the administration of iodine-131 therapy doses. Specifically, thyroid bioassays were performed on the nuclear medicine department staff on an annual basis and without consideration of the date they last handled millicurie quantities of iodine-131.

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3. Item 9.b on page 3 of the attachment to the application dated December 6, 1985 states that dose calibrators will be tested for constancy on a daily basis.

   Contrary to this requirement, the nuclear medicine department's dose calibrator was not tested for constancy on a daily basis. Specifically, the dose calibrator was not tested for constancy on the following dates of use: August 6, 1987; August 22, 1987; October 3, 1987; November 21, 1987; December 26, 1987; January 16, 1988; February 13, 1988; February 14, 1988; March 18, 1988; March 20, 1988; April 9, 1988; April 10, 1988; April 17, 1988; and May 8, 1988.

   This finding is a repeat violation which was also documented during the NRC inspection on August 7, 1987.

4. Item 9.b on page 3 of the attachment to the application dated December 6, 1985 states that dose calibrators will be tested in accordance with the procedures described in Appendix D of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs". Section A.3 of Appendix D states that dose calibrator linearity will be tested on a quarterly basis. Section E.4 states that the results of the measured activity versus the calculated activity should be plotted on log-log paper. Section E.4 states that the results of such linearity tests should then be evaluated to ensure that the dose calibrator is linear throughout its operational range and is functioning properly.

   Contrary to these requirements, as of July 6, 1988, the nuclear medicine department dose calibrator was not tested in accordance with the procedures described in Appendix D of Regulatory Guide 10.8. Specifically, a complete evaluation of dose calibrator linearity had not been performed since July 31, 1987. Linearity test data collected subsequent to that date had not been plotted or evaluated to ensure that the dose calibrator was linear throughout its operational range and was functioning properly.

5. Item 9.b on page 3 of the attachment to the application dated December 6, 1985 states that dose calibrators will be tested in accordance with the procedures described in Appendix D of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs". Section A.2 of Appendix D states that the dose calibrator accuracy should be evaluated on an annual basis. Section G.5 requires records be maintained of dose calibrator accuracy tests.

Contrary to these requirements, as of July 6, 1988, the results of the annual dose calibrator accuracy test performed in February 1988 had not been evaluated. In addition, no record of the February 1988 annual dose calibrator accuracy test was available.

These are Severity Level IV violations. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Salem 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.