

APPENDIX A
NOTICE OF VIOLATION

Veterans Administration Medical Center
Syracuse, New York 13210

Docket No. 030-02619
License No. 31-00845-01

As a result of the inspection conducted on January 31 and February 1, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated June 24, 1983.

1. Item 7. of this application requires that the duties of the Medical Isotopes Committee are to be the same as those in Appendix B of Regulatory Guide 10.8, Rev. 1., October, 1980.

Contrary to this requirement, the Medical Isotopes Committee had not met at the required frequency. Meetings were only held during July and November of 1981; May, October, and December of 1982; and December of 1983; and on May 10 and October 3, 1984, not at the required quarterly frequency.

This a Severity Level V violation. (Supplement VI)

2. Item 12 of this application requires that personnel will be properly instructed: before assuming duties with radioactive materials; during annual refresher training; and whenever there is a significant change in duties, regulations or the terms of the NRC license.

Contrary to this requirement, as of the dates of this inspection, according to statements made, a technologist in Research Services received no training since initial employment in April, 1984. In addition, no record of training provided to this individual was available.

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

3. Item 17 of this application requires weekly wipe tests be performed in accordance with Appendix I of Regulatory Guide 10.8, Rev. 1, October, 1980.

Contrary to this requirement, as of the dates of this inspection, these surveys were not always performed at the required frequencies, a repeat violation, and data was not available to verify that the method for performing wipe tests was sufficiently sensitive to detect 200 dpm per 100 cm² for the contamination involved.

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Specifically, surveys had not been performed in a Hematology Laboratory since April, 1984, and the instrument used to measure wipe test samples had not been calibrated to determine disintegration rates or microcuries.

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

- B. License Condition No. 17 A. and B. require that sealed sources containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months, and that leak test results shall be kept in units of microcuries (uCi).

Contrary to these requirements, as of the dates of this inspection tests for leakage and/or contamination had not been performed at the specified frequency for sealed calibration sources containing more than 100 uCi of Cesium-137. Leakage and/or contamination tests were performed during July, 1981, April, 1982, March, 1983, March, 1984 and October, 1984, periods in excess of six months. These results were maintained in units other than uCi.

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

- C. 10 CFR 20.401(b) requires each licensee to maintain records in the same units used in this part for surveys (evaluation) performed in accordance with 10 CFR 20.201(b) to verify compliance with 10 CFR 20.103(a).

Contrary to this requirement, as of the dates of this inspection, bioassay results of measurements of thyroid burdens were not maintained in uCi units as used in this part.

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

- D. 10 CFR 19.11(a) and (b) require that current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures be posted, or that a notice describing these documents and where they may be examined, be posted.

Contrary to this requirement, on the dates of this inspection, neither the documentation nor the notice were posted.

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

- E. 10 CFR 35.43 requires that when a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office written 10 days after the end of the calendar quarter in which it occurred.

Contrary to this requirement, as of the dates of this inspection, the NRC Region I Office had not received written notices of diagnostic misadministrations that occurred during January and December 1983.

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

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