

APPENDIX A

NOTICE OF VIOLATION

West Virginia University

License Nos. 47-01163-20 and  
47-01163-22

As a result of the inspection conducted on May 19, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified.

- A. 10 CFR 35.21(a)(3) requires that any licensee authorized to use teletherapy units shall cause full calibration measurements to be performed on each teletherapy unit at intervals not exceeding one year.

Contrary to the above, full calibration measurements were last performed on your teletherapy unit on January 18, 1981, a period exceeding one year.

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

- B. License Condition 18 requires that licensed material be used in accordance with statements and procedures contained in your letter dated April 6, 1979, with enclosed application. One procedure in your application requires that the linearity of your dose calibrators be checked at quarterly intervals over the entire range of activities employed.

Contrary to the above, your dose calibrators have been checked on an annual basis using an amount of technetium-99m that is not sufficient to ascertain linearity over the entire range of activities employed.

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

- C. 10 CFR 35.14(b)(6) requires that any licensee using byproduct material in Groups I, II, and III for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding: (i) chemical and physical form; (ii) route of administration; and (iii) dosage range.

Contrary to the above, ten to fifteen radioactive cystography studies were performed in your Nuclear Medicine Department. These studies were performed by administering byproduct material to patients via catheter, a route of administration not listed on the product labeling.

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

- D. License Condition 18 requires that licensed material be used in accordance with statements and procedures contained in your letter dated April 6, 1979, with enclosed application. One procedure in your application requires that

radiation level surveys in your Nuclear Medicine Department be performed weekly.

Contrary to the above, radiation level surveys in your Nuclear Medicine Department are being performed on a monthly basis.

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

Pursuant to the provisions of 10 CFR 2.201, you are hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) admission or denial of the alleged violations; (2) the reasons for the violations if admitted; (3) the corrective steps which have been taken and the results achieved; (4) corrective steps which will be taken to avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Date: JUN 30 1982