

APPENDIX A

NOTICE OF VIOLATION

Okeon Associates, Inc.

License No. 47-16563-01

As a result of the investigation conducted on March 11 - April 1, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified.

- A. License Condition 12 requires that licensed material be used by Dr. Okeon or Dr. Strobl.

Contrary to the above, the requirement to use licensed material only by Dr. Okeon or Dr. Strobl was not met in that during 1979 and 1980 on several occasions, licensed material was used by two physicians who are not named on the license.

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

- B. License Condition 15 requires that licensed material shall be used in accordance with statements, representations and procedures contained in your application dated January 29, 1975 and your letter dated October 13, 1975. Your letter of October 13, 1975 states that a physician trained in nuclear medicine will be present at the time procedures are performed at Calhoun County General Hospital.

Contrary to the above, the requirement to have a physician trained in nuclear medicine present when procedures are performed at Calhoun County General Hospital was not met in that on numerous occasions during 1979 and 1980 procedures were performed at Calhoun County General Hospital by a technologist when no physician was present.

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

- C. License Condition 15 requires that licensed material be used in accordance with statements, representations and procedures contained in your application dated January 29, 1975. Your application states that all elutions, assaying and kit preparation will take place at St. Joseph's Hospital.

Contrary to the above, the requirement to perform all elution, assaying and kit preparation at St. Joseph's Hospital was not met in that these procedures were actually performed at Calhoun County General Hospital from March 1979 to December 1980.

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

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. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

Date: JUN 11 1981