## APPENDIX A

## NOTICE OF VIOLATION

The University of Oklahoma
Health Sciences Center
Oklahoma City, Oklahoma

Docket No. 30-12750/90-01
License No. 35-03176-04MD

During an NRC inspection conducted on July 30 through August 3, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

License Condition 24 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures (including any enclosures) contained in the application dated June 28, 1988; and letter dated November 20, 1989.

1. Item 7 of the letter dated November 20, 1989, references the duties of the campus radiation safety officer as described in the radiation safety manual submitted with this letter. Item 16, of the subsection entitled, "Responsibilities," of the section entitled, "Radiation Safety Officer (RSO)," specifies that the RSO shall perform the monitoring (evaluation) of any special filter systems associated with the use, storage, or disposal of radioactive material.

   Contrary to the above, as of August 3, 1990, the RSO had failed to monitor (evaluate) two charcoal filters used in air exhaust pathways from Rooms 139, 139C, and 139D in the nuclear pharmacy to ensure that they maintained the specified 99 percent efficiency. These filters were used in exhaust systems from fume hoods where millicurie quantities of volatile iodine-131 had been used and stored during this period and had initially been installed during the third quarter of 1989.

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

2. Item 10.11 of the application dated June 28, 1988, specifies that procedures described in the Guide for the Preparation of Applications for Nuclear Pharmacy Licenses (Guide), dated August 1985, Appendix J, will be adopted for area (radiation) surveys.

   Items 4 and 5 of Appendix J require, in part, that: (1) surveys consist of a series of wipe tests conducted with a method sufficiently sensitive to detect 220 disintegrations per minute (dpm) per 100 square centimeters for the contaminant involved; and (2) records of survey results include detected contamination levels in units of dpm or microcuries.

Contrary to the above, from May 1989 through July 1990, the licensee had failed to ensure that: (1) the method used for removable contamination surveys was capable of detecting 220 dpm per 100 square centimeters, and (2) records of wipe sample results were maintained in units of dpm or microcuries as required.

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

3. Item 10.4 of the letter dated November 20, 1989, specifies that procedures described in Appendix C of Regulatory Guide 10.8, Revision 2, August 1987, (RG 10.8) will be followed for calibration of dose calibrators.

   Appendix C requires, in part, that: (1) linearity test results be graphed on semilog graph paper, and (2) if the measured activity deviates by greater than 5 percent of the predicted assay value, that the instrument be either repaired or adjusted, or alternatively, that a correction table or graph be made to convert the activity indicated by the dose calibrator to "true activity."

   Contrary to the above; (1) during the first and third quarters of 1989, linearity test results for a dose calibrator (Serial No. 11056) deviated from -15 percent to +10 percent from the predicted assay value for certain activities within the ranges tested, and the licensee failed to adjust the calibrator or to make a correction table or graph for use in converting dose calibrator measurements to the "true activity"; and (2) results for those linearity tests conducted during the period January 1989 through August 1990 had not been graphed on semilog graph paper as required.

   This is Severity Level IV violation (Supplement VI).

4. Item 6(a) of the letter dated November 20, 1989, specifies, in part, that reagent kits will be redistributed as received from the manufacturer in the "kit sleeve" (original packaging) and that the manufacturer-supplied package insert, leaflet, brochure, or other document describing the procedure to be followed (in reconstituting and using the material) will be with the reagent kit.

   Contrary to the above, during the period February 1990 through August 1990, the licensee had distributed reagent kits in packaging other than the manufacturer's original packaging and without the required package insert.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Oklahoma is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, and if applicable, a copy to the NRC Resident Inspector, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for

each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 8th day of November 1990