APPENDIX A

NOTICE OF VIOLATION

Veterans Administration Medical Center
Prescott, Arizona 86313

License No. 02-12726-01

As a result of the inspection conducted on March 26, 1981, and in accordance with the Interim Enforcement Policy, 45FR 66754 (October 7, 1980), the following violations were identified:

A. 10 CFR 20.101(a) states that no licensee shall possess, use, or transfer licensed material in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from radioactive material and other sources of radiation a total occupational dose in excess of 1.25 rems whole body exposure. The licensee may permit an individual in a restricted area to receive whole body exposures not exceeding 3 rems per calendar quarter provided the individual's accumulated occupational dose has been determined and recorded on a Form NRC-4 (or an equivalent record) as authorized by 10 CFR 20.101(b).

Contrary to this requirement, an individual in a restricted area received a whole body exposure of 1.50 rems during the period of June 24, 1980 to September 29, 1980. There was no Form NRC-4 (or equivalent record) on file for this individual.

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

B. 10 CFR 20.405(a) states that each licensee shall make a report in writing within 30 days to the appropriate NRC Regional Office with a copy to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555 of each exposure of an individual in excess of the applicable limits in 20.101.

Contrary to this requirement, no 30 day report was filed concerning the 1.5 rem exposure of one individual during the period of June 24, 1980 to September 29, 1980.

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

C. 10 CFR 20.409(b) requires that when a licensee is required pursuant to 10 CFR 20.405 to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also notify the individual in writing in accordance with 10 CFR 19.13.

Contrary to this requirement, no written report was submitted to an individual who received an exposure of 1.5 rems during the period of June 24, 1980 to September 29, 1980.

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

D. License Condition 14. states that visiting physicians may be authorized to use licensed material for human use at the licensee's facility provided that: (1) written permission is obtained from the hospital's Administrator and its Medical Isotope Committee, and (2) the physician is named as a user on an NRC license authorizing human use, and (3) the visiting physician performs only those procedures for which he is specifically authorized on his own license.

Contrary to this requirement, during the absence of the licensed physician on June 25-29, 1979; November 13-16 and 19-23, 1979; June 16-20, 1980; August 21-22, 1980; October 8-10, 1980; and November 6-7, 10-14, and 17-19, 1980, a visiting physician who was not named on an NRC license and did not have written permission from the hospital Administrator and the Medical Isotopes Committee, authorized the administration of licensed material to patients.

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

E. License Condition 15. requires the licensee to conduct certain tests, follow certain procedures, provide training, and maintain records relating to molybdenum-99 breakthrough tests associated with the use of molybdenum-99/technetium-99m generators.

1. License Condition 15.B. states that the licensee shall not administer to patients technetium-99m containing more than one microcurie of molybdenum-99 per millicurie of technetium-99m.

   Contrary to this requirement, on August 27, 1980, licensee tests and data of a sample of technetium-99m indicated 1.7 microcuries of molybdenum-99 per millicurie of technetium-99m. According to a licensee representative, quantities of this material had been administered to patients.

2. License Condition 15.D requires that personnel performing tests to detect and qualify molybdenum-99 breakthrough contamination shall be given specific training in performing these tests prior to conducting such tests.

   Contrary to this requirement, one technician who conducted molybdenum-99 contamination breakthrough tests between 4/1/80 and 3/26/81 had not received specific training in performing such tests until August 7 and 15, 1980.

3. License Condition 15.E.1. states that the licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the training given to personnel performing tests to detect and qualify molybdenum-99 breakthrough contamination.

Contrary to this requirement, there were no records of the on-the-job training given to a second technician who started working in the Nuclear Medicine Department on March 18, 1980. A licensee representative stated that the new technician had conducted molybdenum-99 breakthrough contamination checks when the senior technician was not available.

These items constitute a Severity Level IV violation (Supplement VII).

F. License Condition 16. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in applications dated February 22, 1978 and May 16, 1978, and letter dated April 13, 1979.

1. Item 10. of the application dated May 16, 1978 states that the procedures described in Appendix D, Section 2, of NUREG-0338, Revision 1 would be followed. Appendix D, Section 2, requires quarterly dose calibrator linearity tests.

   Contrary to this requirement, no dose calibrator linearity tests were conducted in accordance with the above NUREG-0338 procedures between April 1, 1980 and March 26, 1981.

2. Item 17. of the application dated May 16, 1978 states that wipe tests to measure contamination levels will be conducted on a weekly and monthly basis.

   Contrary to this requirement, no wipe tests to measure contamination levels were conducted in the Nuclear Medicine Department during the period of April 1, 1980 through March 26, 1981.

3. Item 7. of the application dated May 16, 1978 states that the responsibilities and duties of the Medical Isotope Committee are as described in Appendix B of NUREG-0338, Revision 1. Appendix B requires that: (a) the Committee review the training and experience of any individual who uses radioactive material and determine that the qualifications are sufficient to perform their duties safely and in accordance with NRC regulations and the conditions of the license; (b) the Committee review the entire radiation safety program at least annually and recommend remedial action to correct any deficiencies identified in the radiation safety program.

   Contrary to this requirement, during the April 7, July 1, September 18, and December 17, 1980 meetings of the radiation safety committee, there were no reviews of the training and experience of the Nuclear Medicine technicians to determine that their qualifications are sufficient to perform their duties safely and in accordance with the NRC regulations and the conditions of the license. The use of a visiting physician,

as stated by License Condition 14., was not reviewed or authorized by the Medical Isotopes Committee. Also, during reviews of the radiation safety program on September 18, 1980 and December 17, 1980, there were no discussions of the administration to patients of technetium-99m containing more than one microcurie of molybdenum-99 on August 27, 1980; nor was there a discussion of a whole body exposure of 1.50 rems received by one individual for the third quarter of 1980. It appears the Medical Isotope Committee is not carrying out its duties as described in the application.

These items constitute a Severity Level IV violation (Supplement VII).

G. 10 CFR 20.401(b) requires that records of (1) surveys required by 20.201(b), and (2) discharges of radioactive material into a sanitary sewer system pursuant to 20.303 be maintained for review.

1. Contrary to this requirement, survey records were not maintained of surveys conducted between April 1, 1980 and March 26, 1981 involving solid waste, including decayed technetium generators, vials and syringes used in nuclear medicine tests and evaluations, which had been released to normal trash.

2. Contrary to this requirement, disposal records of periodic releases to the sanitary sewer system of microcurie amounts of chromium-51 which were made between December 1980 and March 26, 1981, had not been maintained.

These items constitute a Severity Level V violation (Supplement IV).

H. 10 CFR 35.14(e)(1)(i) states that any licensee who possesses sealed sources as calibration sources shall conduct six month leakage tests on all sources containing byproduct material with a half-life greater than thirty days and in a form other than gas.

Contrary to this requirement, no leakage tests were conducted between August 7, 1980 and March 26, 1981 on a 241 microcurie cesium-137 source and a 276 microcurie barium-133 source, which are used on a daily basis for calibration purposes.

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

Pursuant to the provisions of 10 CFR 2.201, the Veterans Administration Medical Center, Prescott, Arizona is 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) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation. We anticipate that your response will be completed by not later than JUN 14 1981. Consideration may be given to extending your response time for good cause shown.

dated MAY 14 1981

B. A. Riedlinger

B. A. Riedlinger, Radiation Specialist