APPENDIX A

NOTICE OF VIOLATION

St. John's Mercy Medical Center
St. Louis, Missouri

License No. 24-00794-03

As a result of the inspection conducted on September 27 and 28, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989) (Enforcement Policy) the following violations were identified:

1. 10 CFR 35.59(b)(2) requires any sealed source or brachytherapy source be tested for leakage at intervals not to exceed six months.

   Contrary to the above, a nominal 10 millicurie strontium-90 calibration standard with Serial No. 0183 has not been tested for leakage since March 1978; two nominal 13.8 millicurie strontium-90 eye applicators with Serial Nos. 1574 and 1562 have not been tested for leakage since April, 1974; and several cesium-137 brachytherapy sources model 6H6E were not tested for leakage between December 1987 and December 1988.

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

2. License Condition No. 18 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated February 21, 1986, states in item 10.15(8) that any patient who has received a temporary implant will not be released from the hospital until a radiation survey of the patient confirms that all sources have been removed from the patient.

   Contrary to the above, post implant surveys of patients were not always performed as required. For example, patients released from the hospital were not surveyed when brachytherapy sources were removed on May 4, 1989, April 28, 1989, April 27, 1989, and April 23, 1989.

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

3. License Condition No. 18 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced letter dated March 13, 1986, states in Item 10.4 that exhaust hoods and exhaust vents where iodine-131 therapeutic oral solutions are vented will be checked for airflow quarterly to assure negative pressure.

Contrary to the above, the exhaust hood located in the radiopharmacy where iodine-131 therapeutic oral solutions are used was not checked for proper air flow the second and third quarters of 1989.

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

4. License Condition No. 18 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

Item 10.4(8) of the referenced application dated February 21, 1986, states in part that finger exposure monitors will be worn during injection of radiopharmaceuticals. Item 10.4(2) of the referenced application dated February 21, 1986, states disposable gloves will be worn at all times while handling radioactive materials.

Contrary to the above, on September 27, 1989, the NRC inspector observed a nuclear medicine technologist injecting a radiopharmaceutical and not wearing disposable gloves or the required finger exposure monitor. In addition, a technologist handled millicurie amounts of iodine-125 in January and February 1989, while not wearing disposable gloves.

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

5. License Condition No. 18 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

Item 10.12 of the referenced application dated February 21, 1986, states laboratory areas where only small quantities of gamma emitting radioactive materials are processed will be surveyed and checked for contamination at least monthly.

Contrary to the above, the RIA laboratory has not been routinely surveyed or checked for contamination every month as required. For example, this area was not checked in January or February, 1989.

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

6. Item 9.I. of License No. 24-00794-03 authorizes up to 300 millicuries of iodine-125 for In-vitro studies only.

Contrary to the above, on January 10, and February 10, 1989, iodine-125 was used for purposes other than In-vitro studies when on those occasions a total of 20 millicuries of iodine-125 was diluted and used for the purpose of calibrating three robotic pipetters.

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

7. 10 CFR 20.401(b) requires each licensee to maintain records in the same units used in this part, of disposals made under 10 CFR 20.303.

Contrary to the above, as of September 28, 1989, records were not maintained of the disposals of licensed material made to the sanitary sewerage system.

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

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

November 2, 1989
Dated

Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch

APPENDIX B

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

a. Delineation of duties and responsibilities of all persons involved in licensed activities.

b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.

c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety-related procedures.

d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.