NOTICE OF VIOLATION

University of Minnesota
Minneapolis, Minnesota

License No. 22-00187-46
Docket No. 030-00842
License No. 22-00187-49
Docket No. 030-13175

During an NRC inspection conducted from November 18 through 21, 1996 and December 6, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

License No. 22-00187-46

1. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that it not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

   Contrary to the above, on at least November 20, 1996, the licensee did not secure from unauthorized removal or limit access to packages containing approximately 2.0 millicuries of chromium-51, 14.6 millicuries of sulfur-35, 18 millicuries of phosphorous-32, and 0.2 millicuries of iodine-125, located in a closet in the Boynton Health Services Building, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material.

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

2. 10 CFR 35.32(a)(1)(iii) requires, in part, that the licensee establish and maintain a quality management program (QMP) which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose.

   10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information including for brachytherapy the radioisotope, number of sources, and source strengths.

   Contrary to the above, since at least April 1996, written directives were not dated prior to administering brachytherapy treatments involving iridium-192 and cesium-137 implants.

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

3. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

   Contrary to the above, from August 13, 1996 through December 6, 1996, the licensee had not surveyed areas where radiopharmaceuticals or radiopharmaceutical waste, comprised of millicurie quantities of technetium-99m, was stored at its authorized location of use at 3M Center, St. Paul, Minnesota, Building 270, Rooms SC344 and SC348.

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

4. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

   Contrary to the above, from August 13, 1996 through December 6, 1996, the licensee had not surveyed for removable contamination areas where technetium-99m radiopharmaceuticals were routinely prepared for use, administered, or stored at its authorized location of use at 3M Center, St. Paul, Minnesota, Building 270, Rooms SC344 and SC348.

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

License No 22-000187-49

License Condition No. 18. requires, except as specifically provided otherwise in the license, the licensee to conduct its program in accordance with the statements, representations, and procedures contained in the documents listed on the license.

Items 1.b. and 2 of the letter dated November 7, 1994, listed in License Condition No. 18.B, were excepted as procedures which included radioactive waste compaction at the licensee's Integrated Waste Management Facility.

Contrary to the above, on numerous occasions since November 7, 1994, the licensee has compacted radioactive waste at the Integrated Waste Management Facility.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Minnesota 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 III, 801 Warrenville Road, Lisle, Illinois 60532-4351

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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to 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.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 20 day of December 1996