APPENDIX

NOTICE OF VIOLATION

Huron Regional Medical Center
Huron, South Dakota 57350

Docket No. 030-09603/90-01
License No. 40-15697-01

During an NRC inspection conducted on November 7, 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:

A. 10 CFR 35.27(a) states, in part, that a licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if the licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, and if that copy identifies the visiting authorized user by name as an authorized user for medical use.

Contrary to the above, on at least four occasions in 1989 and 1990, visiting authorized users used licensed material for medical use without the licensee first obtaining a copy of the license that identified the visiting authorized user by name.

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

B. 10 CFR 35.21(b)(2) requires the radiation safety officer to establish, collect in one binder or file, and implement specified written policy and procedures.

Contrary to the above, the radiation safety officer had neither established, collected in one binder or file, nor implemented the required written policies and procedures.

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

C. 10 CFR 35.22(a)(4) requires, in part, that the minutes of each radiation safety committee meeting include certain specified information. This includes members absent, summary of deliberations and discussions, recommended actions, and the numerical results of all ballots.

Contrary to the above, minutes of the licensee's radiation safety committee meetings for 1988, 1989, and 1990 did not contain the information required above.

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

D.1. 10 CFR 35.220 requires that a licensee authorized to use byproduct material for imaging and localization studies have in its possession a

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portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

Contrary to the above, from October 31, 1990, to November 7, 1990, the licensee did not possess a portable radiation detection survey meter.

2. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

   Contrary to the above, the licensee did not perform the required daily surveys between October 31, 1990, and November 6, 1990.

3. 10 CFR 35.70(h) requires that records of surveys for contamination and ambient radiation exposure rate contain specified information.

   Contrary to the above, the records of surveys performed by the license in accordance with 35.70(a) and (e) did not contain the required specified information.

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

E. 10 CFR 35.60(b) requires the licensee to conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

   Contrary to the above, syringes containing radiopharmaceuticals were not labeled during 1989 and 1990.

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

F. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

   Contrary to the above, no quarterly inventories of sealed sources used to test the dose calibrator were performed from February 23, 1988, to November 7, 1990.

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

Pursuant to the provisions of 10 CFR 2.201, Huron Regional Medical Center 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 4th day of December 1990