

APPENDIX A

NOTICE OF VIOLATION

Sewickley Valley Hospital  
Sewickley, Pennsylvania 15143

Docket No. 030-03131  
License No. 37-11079-01

During an NRC inspection conducted on March 22, 1994, 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, the violations are listed below:

- A. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised user to follow the written quality management procedures established by the licensee.

The licensee's quality management procedure dated November 16, 1993, Section III, Item 1, requires that prior to the performance of either diagnostic or therapeutic procedures involving iodine-131 or iodine-125 in excess of 30 microcuries or any therapeutic administration of radiopharmaceuticals other than iodine-131 or iodine-125, a written directive will be made by the authorized user. Item 2 of Section III requires that the written directive include the procedure to be performed along with information on isotope name and chemical form, amount of radioactivity, the route of administration, and the signature of the authorized user.

Contrary to the above, on March 7, 1994, the licensee's Chief Nuclear Medicine Technologist, an individual under the supervision of the licensee's authorized user, did not follow the written quality management procedures established by the licensee in that a therapeutic dose of strontium-89 radiopharmaceutical was administered to a patient and the written directive did not include the signature of the authorized user.

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

- B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for the safe use of radiopharmaceuticals are described in the application dated March 27, 1991, and were approved by License Condition No. 18.

Item 10.4 of the application states that rules for the safe use of radiopharmaceuticals are appended as Attachment 10.4. Item 5 of Attachment 10.4 requires that individuals do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

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Contrary to the above, on March 22, 1994, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, on March 22, 1994, the Radiation Safety Officer carried a cup of coffee into the Nuclear Medicine Hot Lab, an area where radioactive material is used and stored.

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

Pursuant to the provisions of 10 CFR 2.201, Sewickley Valley Hospital 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 I, 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 or a Demand for Information 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.