

Appendix

NOTICE OF VIOLATION

St. Luke's Hospital

License No. 24-01570-03

As a result of the inspection conducted on March 19 and 20, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition No. 19 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 received October 12, 1978, states in Item No. 14 that Appendix F of NUREG 0338 will be followed for safely opening packages containing radioactive material. Appendix F requires, in part, tests of all packages received, including measurements of exposure rates at three feet and surface; performance of wipe tests on the external surface of the final source container; and that results of these tests will be maintained.

Contrary to the above, it was learned through statements of licensee representatives, and the absence of records, that these requirements were not being met. Specifically, various packages received at the Charter Hospital in January, February, and March of 1985 were not wipe tested.

This is a repeat item of noncompliance.

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

2. License Condition No. 19 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 February 14, 1979 states in Item No. 7 that diagnostic procedures utilizing xenon-133 gas at St. Luke's Hospital will be performed in a room located in the radiology department on the second level of the hospital. Included with this letter were air flow calculations upon which the Commission based authorization for the use of this room. In the event that a room other than the one designated is required to be used for procedures utilizing xenon-133 gas, a new set of air flow calculations, specific to that room, is required to be submitted to the Commission for prior review and approval.

Contrary to the above, as of the date of the inspection, diagnostic procedures utilizing xenon-133 gas were not being performed in the room authorized. Specifically, diagnostic procedures using xenon-133 gas were being performed in a room on the eighth floor of the hospital, for which no air flow calculations were submitted to the Commission for prior review and approval.

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

3. 10 CFR 35.14(e)(1)(i) requires that any licensee who possesses sealed sources as calibration sources shall cause each sealed source to be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, the licensee has failed to meet this requirement. Specifically, a 229 microcurie and 190 microcurie barium-133 and 795 microcurie cesium-137 sealed calibration sources, possessed by St. Luke's Hospital, were leak tested April 18, 1983, January 5, 1984, and November 2, 1984, intervals exceeding six months.

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

4. License Condition No. 19 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 received October 12, 1978 states in Item No. 17 that Appendix I of NUREG 0138 will be followed for area survey procedures. Appendix I requires daily surveys of all elution, preparation, and injection areas with a G-M survey meter and a series of weekly and monthly wipe tests to measure contamination levels.

Contrary to the above, the daily surveys and the weekly wipe tests were not being performed as required at St. Luke's Hospital. Specifically, surveys and wipe tests have been performed March 6 1985, January 22, 1985, and December 8, 1984.

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

5. License Condition No. 18 states that the licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of 10 CFR 71. 10 CFR 71.5 requires that no licensee shall transport licensed material outside of the confines of its place or use unless the licensee complies with the applicable requirements of the regulations of the Department of Transportation in 49 CFR Parts 170-189.

49 CFR 173.443(a) states that the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment shall be kept as low as practicable. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels.


Contrary to the above, the licensee has been shipping spent generators and used central pharmacy cases containing licensed materials without evaluating each package for non-fixed radioactive contamination.

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

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 item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

APR 4 - 1985

Dated \_\_\_\_\_

  
D. G. Wiedeman, Chief  
Nuclear Materials Safety  
Section 1