Woodlawn Hospital
1400 E. NINTH STREET
ROCHESTER, INDIANA 46975-8937
TELEPHONE 219/223-3141

DMB COPY

May 25, 1989

D. G. Wiedeman, Chief
Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Docket No. 030-18270
License No. 13-20338-01

Dear Mr. Wiedeman:

This is in reply to your letter of April 25, 1989, Notice of Violation (copy attached). The following action has been taken:

1. VIOLATION: Using higher bone scan doses than prescribed.

   CORRECTIVE ACTION: We are now injecting patient three hours before examination instead of six hours before examination.

   RESULTS ACHIEVED: Dose now reduced to correct level.

   CORRECTIVE ACTION TO AVOID FURTHER VIOLATIONS: Procedure to inject patient three hours before exam is now routine policy.

   DATE WHEN FULL COMPLIANCE ACHIEVED: May 1, 1989

2. VIOLATION: Wipe sample test results not reported in units of microcuries.

   CORRECTIVE ACTION: Convert counts per minute to units of microcuries.

   RESULTS ACHIEVED: Wipe sample test results now reported in units of microcuries.

   CORRECTIVE ACTION TO AVOID FURTHER VIOLATIONS: Conversion of counts per minute to units of microcuries now routine policy and procedure.

   DATE WHEN FULL COMPLIANCE ACHIEVED: May 11, 1989

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3. VIOLATION: Not using cobalt 57 source for checking accuracy of dose calibrator.

   CORRECTIVE ACTION: Adapt present equipment for cobalt 57.

   RESULTS ACHIEVED: None yet, but will be able to use cobalt 57 for checking accuracy of dose calibrator after revision of present equipment.

   CORRECTIVE ACTION TO AVOID FURTHER VIOLATION: Adapt present equipment for cobalt 57. Routinely order cobalt 57 annually and check dose calibrator for accuracy.

   DATE WHEN FULL COMPLIANCE ACHIEVED: Repairman is scheduled to be in by May 26, 1989, to adapt equipment for cobalt 57.

4. VIOLATION: Wipe samples being read with instrument not capable to detect 2000 disintegrations per minute.

   CORRECTIVE ACTION: Use clinical laboratory's Vicon 2000 to analyze wipe tests.

   RESULTS ACHIEVED: Wipe samples of 2000 disintegrations per minute are now detectable.

   CORRECTIVE ACTION TO AVOID FURTHER VIOLATIONS: The Vicon 2000 test instrument is now kept and used in the Nuclear Medicine Department.

   DATE WHEN FULL COMPLIANCE ACHIEVED: May 12, 1989

Sincerely,

Michael L. Gordon

Michael L. Gordon
Executive Director

Dan Ho

Dan Ho
Chief Radiologic Technician

/sls

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

APR 25 1989

Woodlawn Hospital
ATTN: Mr. Michael Gordon
Administrator
1400 East 9th Street
Rochester, IN 46975

License No. 13-20338-01

Gentlemen:

This refers to the routine safety inspection conducted by Mr. W. P. Reichhold of this office on April 13, 1989, of activities authorized by NRC Byproduct Material License No. 13-20338-01, and to the telephone discussion of our inspection results with you on April 17, 1989.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined your actions to correct the apparent violation found during the December 28, 1983, inspection. We have no further questions regarding these matters.

During this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

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

Enclosure: Notice of Violation

cc w/enclosure:
DCD/DCB (RIDS)

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NOTICE OF VIOLATION

Woodlawn Hospital
Rochester, Indiana

Docket No. 030-18270
License No. 13-20338-01

As a result of the inspection conducted on April 13, 1989, and in accordance with 10 CFR Part 2, Appendix C - General Statement of Policy and Procedure for NRC Enforcement Actions (1988), the following violations were identified:

1. License Condition No. 18 states that the license is based on statements and representations contained in certain referenced applications and letters.

   The referenced application dated January 5, 1988, states that doses that differ from the prescribed dose by more than 10 percent will not be used.

   Contrary to the above, doses that differed from the prescribed dose by more than 10 percent were used. For example, on March 8, 9, 29 and April 10, 1989, doses used for bone scans were about 44 percent higher than the prescribed dose.

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

2. 10 CFR 35.59(d) states the activity of wipe test samples shall be expressed in units of microcuries.

   Contrary to the above, the activity of wipe test samples analyzed on February 4, November 18, 1988, and January 24, 1989, were expressed in counts per minute rather than microcuries.

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

3. License Condition No. 18 states that the license is based on statements and representations contained in certain referenced applications and letters.

   The referenced application dated January 5, 1988, states that a cobalt-57 source will be used for checking the accuracy of the dose calibrator.

   Contrary to the above, since the license was issued in March 12, 1988, a cobalt-57 source has not been used for checking the accuracy of the dose calibrator.

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

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4. 10 CFR 35.70(f) states that the instrument used to analyze wipe samples shall be capable of detecting 2,000 disintegrations per minute.

   Contrary to the above, on March 15, 23, 29, 31, and April 6, 1989, wipe samples were analyzed with a G-M meter, an instrument not capable of detecting 2,000 disintegrations per minute.

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

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 actions that have been taken and the results achieved; (2) the corrective actions 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.

APR 25 1989
Dated

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