PDR

YALE-NEW HAVEN HOSPITAL

Michael J. Bohan, Radiation Safety Officer
Radiological Physics - WWW 204
(203) 688-2950

October 13, 1998

Docket No.: 030-01244 Inspection No.: 98-001 License No.: 06-00819-03

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Reply to Notice of Violation, Dated September 11, 1998.

Dear Mr. Shanbaky:

Yale-New Haven Hospital (YNHH) has reviewed each of the apparent items of non-compliance identified in the Notice of Violation attached to your letter dated September 11, 1998. The hospital's response to each item is enclosed as Appendix A.

If you have any further questions, please feel free to contact the Radiation Safety Officer at the address or phone number above.

Sincerely,

Michael J. Bohan
Radiation Safety Officer/Health Physicist

Norman G. Roth
Vice President, Administration

Robert C. Lange, Ph.D.
Chairman, Radiation Safety Committee

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Enclosure: Appendix A - Reply to Notice of Violation

cc: USNRC Public Document Room
State of Connecticut - Dept. of Environmental Protection, Rad. Control Unit
Marna P. Borgstrom, Exec. Vice President, Chief Operating Officer
Ravinder Nath, Ph.D., Director, Radiological Physics

20 York Street
New Haven, CT 06504

Appendix A

Reply to A Notice Of Violation

Violation A

Restatement of the Violation

Quarterly linearity tests on the dose calibrators were not performed during the fourth quarter of 1997 at the Main Nuclear Medicine Hot Lab, and in the Temple Street facility.

(1) Reason for the Violation

The Nuclear Medicine program was in the process of moving most of it's imaging room locations to new, interim quarters. They attempted to perform the tests but apparently lost the testing data during the moving process and failed to repeat the test in accordance with regulatory requirements.

(2) Corrective Steps Taken and Results Achieved

a. The violations were identified by the Radiation Safety Office during a routine monthly audit of the Nuclear Medicine Department. The Assistant Radiation Safety Officer notified the Chief Nuclear Medicine Technologist and the Radiation Safety Officer met with the Manager of Nuclear Medicine.

b. The Manager of the Main and Temple Street Nuclear Medicine section was informed about the missing linearity tests and the required testing frequency.

c. The Technologist Staff were informed about the missing linearity tests during a staff meeting and were retrained in the dose calibration Q.A. requirements by the RSO.

d. The missing linearity tests were examined as part of the responsible Technologist's annual performance review. The Technologist was demoted and a new section Chief Technologist was appointed.

e. The Manager of Nuclear Medicine and the new Chief Technologist have developed an internal audit program to identify program deficiencies and ensure regulatory compliance.

(3) Corrective Steps Taken to Avoid Further Violations

a. A standard testing schedule has been established and implemented.

b. The RSO has published a standard dose schedule to ensure calibrator linearity testing is performed properly and completed on time.

c. Documentation of all required tests will be reviewed by the Radiation Safety program during monthly audits of the Nuclear Medicine programs.

(4) Date when Full Compliance Will Be Achieved

The actions mentioned above have already been implemented.

Violation B

Restatement of the Violation

The license did not survey with a radiation survey instrument at the end of each day of use all areas where radiopharmaceuticals were routinely prepared for use or administered. Specifically, on February 27, 1998 the licensee failed to survey a waste trash barrel before putting it out in the corridor. The barrel was emptied by maintenance personnel and disposed as regular trash without a survey to assure no byproduct material was released.

(1) Reason for the Violation

The hot lab Technologist arranged for Hospital Housekeeping personnel to clean the floor of the hot lab. The Technologist moved the waste barrel into the corridor to facilitate the floor cleaning process and allowed the Housekeeping staff to clean the hot lab without supervision. When the Housekeeping staff finished cleaning the room, they assumed that they should also remove the trash. The trash bag was removed and replaced with a clean bag by Housekeeping before returning the barrel to the hot lab.

(2) Corrective Steps Taken and Results Achieved

a. The responsible technologist was reminded that radioactive materials must be kept secure at all times and should not be allowed to stand in the hallway unsecured without his direct supervision.

b. The hot lab must be completely surveyed and contaminated wastes properly stowed in the decay area before Housekeeping is allowed to enter and clean the hot lab floor.

c. The waste event and inadequate survey were examined as part of the responsible Technologists' annual performance review.

d. This information was reviewed with the entire staff during a Technologist meeting.

(3) Corrective Steps Taken to Avoid Further Violations

a. The Hospital has installed a radiation alarm as a secondary control measure in the hallway leading to the loading dock and the normal trash disposal containers. In this case, a Environmental Services staff member apparently ignored the alarm and proceeded to improperly dispose the contaminated waste. As a result of this incident and other factors, this individual is no longer employed by the Hospital. The Environmental Services staff was reminded of the need to properly segregate contaminated wastes from the normal waste flow.

(4) Date when Full Compliance Will Be Achieved

The actions mentioned above have already been implemented.