



**YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE**

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Inspection No.: 2005-001

License No.: 06-00819-03

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

Subject: Reply to Notice of Violation, Dated April 7, 2005.

Gentlemen & Women of the NRC:

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 April 7, 2005. The hospital's response to each item is enclosed as Appendix A.

As a point of information, which bears upon this matter, we would like to give the NRC some background regarding this issue. Yale-New Haven Hospital is a large academic medical research institution. In fiscal year 2003, YNHH conducted 17,157 nuclear medicine studies, which provided significant health benefits to our patients. The hospital processed 2,822 tons of municipal waste and 24 tons of medical waste during fiscal year 2004. We hope the NRC will consider these facts when evaluating the attached response.

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

Sincerely,

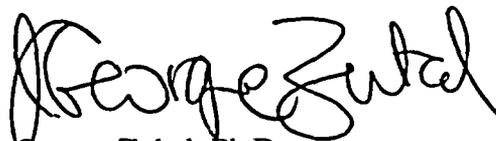
Michael J. Bohan
Radiation Safety Officer/Health Physicist

Raminder Nath
for Arthur Lemay

Arthur P. Lemay, M.S., R.Ph.
Exec. Director, Oncology Services

20 York Street
New Haven, CT 06504

IE07



I. George Zubal, Ph.D.
Chairman, Radiation Safety Committee

Enclosure: Appendix A - Reply to Notice of Violation

cc: USNRC, Region I, Regional Administrator
Director, Office of Enforcement, USNRC, Washington, DC
State of Connecticut - Dept. of Environmental Protection, Rad. Control Unit
Marna P. Borgström, Exec. Vice President, Chief Operating Officer
Ravinder Nath, Ph.D., Director, Radiological Physics

Appendix A

Reply to a Notice of Violation

Violation A

Restatement of the Apparent Violation

On February 16, 2004, Yale-New Haven Hospital (YNHH) released a package of medical waste, containing licensed radioactive material (Tc-99m with package dose rate of 5 mrem/hr), for disposal by an unauthorized recipient: New York Environmental Services, Autoclave facility, located at 31 Lower River Road, Oneonta, NY.

YNHH does not contest this violation and presents the reasons for the violation and corrective steps already taken below.

(1) Reason for the Violation

It appears that medical waste, contaminated with patient excreta from a diagnostic nuclear medicine procedure, was released without being properly surveyed. This occurred because the medical waste processing area had recently been relocated to a new area, and the alarming rate meter used for survey purposes, no longer provided an adequate survey, based on the relative locations of the medical waste and the detector. This occurred when the Hospital changed processing vendors whose packaging requirements, necessitated changes to the Hospital's processes. This included the relocation of the waste weight station, based on a different container requirement. Unfortunately, the Radiation Safety Officer (RSO) was not given adequate prior notification about the change in the processing method and location, in order to evaluate prospectively the impact of the changes on the survey system performance characteristics.

(2) Corrective Steps Taken and Results Achieved

- a. The RSO determined that the original alarming survey meter did not have the required sensitivity necessary to adequately survey the medical waste stream due to the increased distances and processing changes. On February 20, 2004, the RSO ordered a new medical waste monitoring system with a higher sensitivity.
- b. As an interim measure, in February 2004, the RSO provided a hand held survey meter with a scintillation probe to the medical waste supervisory staff. He trained and instructed them to perform a hand survey of each medical waste package, immediately prior to their release to the processing vendor.
- c. The management of the medical waste program was instructed to inform the RSO, in advance, about any significant changes in the program that might compromise the effectiveness of the medical waste, radiation survey system.
- d. The new higher sensitivity, medical waste alarming survey system, was received, installed and calibrated by the RSO upon receipt. It is operationally checked by radiation safety personnel on a weekly basis.

(3) Corrective Steps Taken to Avoid Further Violations

- a. The medical waste processing area is inspected by radiation safety personnel on a weekly basis and the alarm system is operationally tested at that time.
- b. The RSO has notified the supervisory personnel of the Environmental Services Department to provide adequate prior notice before making any future changes that might compromise the medical waste radiation survey program.
- c. The Vice Presidents in charge of Environmental Services and Facilities Management will be informed to consult with the RSO prior to any renovations involving monitored waste streams.

(4) Date when Full Compliance Will Be Achieved

Full compliance was achieved in February 2004, with the implementation of an interim hand survey program until a new radiation alarm system was obtained and installed.

Violation B

Restatement of the Apparent Violation

On February 24, 2005, Yale-New Haven Hospital released a package of general hospital waste, containing licensed radioactive material (Tc-99m with package dose rate of 0.02 mrem/hr), for disposal by an unauthorized recipient: Bridgeport RESCO, located at Howard Avenue, Bridgeport, CT.

YNHH respectfully contests this as a violation, since the reported dose rate value is within normal fluctuations of the ambient background levels in CT.

(1) Reason for the Apparent Violation

It is believed that this incident occurred due to the marginal level of radioactivity found upon survey. The level of radioactivity in the normal waste shipment was so low that it could have easily been below the minimum detection capacity of the radiation alarm system. The Connecticut State DEP inspector, who performed the initial hand survey on the waste container, reported a maximum measured dose rate of only 0.04 mrem/hr. It is not uncommon to observe levels twice above background (which is what this reading represents) during normal daily fluctuations. The normal ambient background radiation levels, on the Connecticut shoreline, are approximately 0.02 mrem/hr, and can vary as high as two to four times background.

(2) Corrective Steps Taken and Results Achieved

- a. The waste shipment was returned to YNHH, on the afternoon it was reported and surveyed by RSO personnel. A survey, performed with a pancake GM type survey meter could not detect any radiation levels that were distinguishable from normal background levels (0.02 mrem/hr). A second survey, using a hand held, low energy scintillation detector (normal background: 300 - 400 cpm), held at contact with numerous individual trash bags removed from the container, was performed with a negative result.

(3) Corrective Steps Taken to Avoid Further Violations

- a. The normal hospital waste radiation monitoring systems are inspected by RSO personnel on a weekly basis and each alarm, detection and interlock system is operationally tested at that time. This quality assurance has been active since the radiation alarm systems have been activated and identified the operational problems before the NRC inspection. As set forth in the response to Violation A above, all of the process changes should ensure no future violations.

(4) Date when Full Compliance Will Be Achieved

We believe that this system has been in compliance and that this specific incident was due to an inherent minimum detection limit (i.e. represent dose rate levels within normal daily variations), rather than due to non-compliance with NRC regulations. Nonetheless, all of the steps taken as described in response to Violation A above have caused us to be in full compliance.