YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

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

Subject: Reply to Response to Disputed Notice of Violation, Dated June 13, 2005.

Gentlemen & Women of the NRC:

Yale-New Haven Hospital (YNHH) has received and reviewed the Commission's response to the disputed violation in our letter dated May 10, 2005. Although we agree to correction of this violation in the attached letter, we wish to emphasize that the radioactivity in the waste shipment was near background and even with all systems fully operational such waste could in the future pass through our detection system, or those of other similarly situated licensees, without being detected as different from background.

YNHH believes that this incident occurred due to the marginal level of radioactivity found upon survey. The NRC asserts in its letter to YNHH, dated June 13, 2005, that our monitoring system (sodium iodide [NaI] based) is generally more sensitive than the Geiger-Mueller (GM) detector used by the Connecticut Department of Environmental Protection (CDEP) physicist. However, this ignores the fact that a survey with a GM detector at contact with a waste container by a professional physicist can easily exceed the detection capability of a NaI based system designed to monitor large volumes of bulky solid wastes, contaminated with patient excreta from patients who meet the NRC's 10 CFR 35.75 release criteria. This is due to the greater distances and shorter survey time factors involved. In addition, in an alarming system, the operator must establish an alarm threshold at some level over background to avoid too many false positives. The YNHH systems are set to alarm with a threshold of 3 times the nominal background level. In contrast, a hand-held GM survey threshold can be as little as 1.5 - 2 times background. YNHH believes that 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.

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While it is possible that the Hospital could modify its existing system, as we have numerous times over the past 15 years, as alarm thresholds at the waste processing plant have changed, this would add considerable cost and non-radiological consequences.

The NRC has issued two Information Notices (IN) Nos. 91-03 and 99-33 that address the issue of patient excreta contaminated wastes. In IN No. 91-03 the NRC states *"If a licensee detects radioactivity in its waste, or if an operator of a landfill or medical waste incinerator returns to a licensee a waste shipment containing detectable levels of byproduct, source or special nuclear material, absent an exemption, the licensee must manage the waste as licensed material."* It further states, *"Medical use licensees should be aware that radioactive materials may enter their waste-handling process through mechanisms largely beyond their control. Diagnostic and therapy patients who are not required to be hospitalized may discard contaminated items with low, but detectable, levels of radioactivity into waste containers. Therefore, detection of radioactive material in non-radioactive waste streams does not necessarily indicate poor management of radioactive waste or noncompliance with NRC requirements. (Emphasis added). However, licensees may find it prudent to establish a system to monitor all outgoing shipments of the waste for any detectable radioactivity, both to ensure compliance with NRC requirements and to reduce the costs and risks associated with returned shipments.* Information Notice No. 99-33 contains essentially the same guidance.

The Hospital has established such a system to monitor all outgoing waste shipments. In fact, the Hospital currently has five separate systems that monitor the waste flows from the institution. Most wastes are surveyed by at least two of the five systems before they are released. Although the NRC, in both notices, reserves the right to consider enforcement actions, **it exposes licensees to a subjective and inconsistent standard of what constitutes an adequate survey of these wastes that will avoid enforcement actions. The notices imply that even with good practices, materials may be released.** They advise the licensee to manage the wastes as licensed material only after they have been identified by survey either onsite or upon return from an off-site operator. The Hospital believes that it is in compliance with the NRC's guidance. We believe, in this particular case, the NRC should use its enforcement discretion to consider the technical difficulties medical licensees are confronted with in setting up such a system to survey these waste streams. YNHH processes nearly 3,000 tons of municipal wastes and 30 tons of medical wastes on an annual basis while providing nuclear medical services to over 17,000 patients. The Hospital submits that a singular incident, near background, on an annual basis should not be subject to enforcement action. Increasing the sensitivity of our current system will result in additional retained waste volumes, which may increase the non-radiological risks associated with handling them.

Finally, we respectfully request that the NRC consider this situation using a risk-informed basis. The NRC has exempted patient excreta released to the sanitary sewerage system, recognizing the benefit to human health and welfare and absence of significant public risk from such practices. We do not propose that solid wastes, contaminated with patient excreta from diagnostic uses of radiopharmaceuticals be entirely exempted, but on

a risk-informed basis, the NRC should exercise its discretion when incidents, such as this, near the threshold of background occur. We believe that it is imprudent for the NRC to maintain a regulatory model that appears to expose medical licensees to a subjective "zero tolerance" standard.

However, in order to close this issue, the Hospital's response to apparent violation B 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. Boban
Radiation Safety Officer/Health Physicist

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

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. Borgstrom, Exec. Vice President, Chief Operating Officer
Ravinder Nath, Ph.D., Director, Radiological Physics

Appendix A

Reply to a Notice of Violation

Violation B (2nd Response)

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.

(1) Reason for the Apparent Violation

The Hospital believes that the shipment was so close to background levels that the waste did not exceed the alarm thresholds of the multiple monitoring systems used to survey the waste stream.

However, in order to close this issue the hospital has taken the following steps to improve our system.

(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.

b. In the days immediately prior to the date of the NRC's inspection on January 25, 2005, two of the four radiation alarm systems, dedicated to monitoring the normal hospital waste stream, were identified by RSO personnel as having a reduced performance. This was due to some renovation work needed in preparation for a new building project, planned at the hospital, in the near future. These two specific systems are normally interlocked with the two waste receptor systems to prevent the compaction of any waste, if the alarms are activated. The waste compactors were temporarily moved slightly from their original positions. This increased the distance from the detectors to the waste containers and reduced their minimum detection capability, but they were still operational. In addition, the interlock system was found by RSO personnel to be disabled because of the move. However, at least one other system, under which all waste must pass was fully operational during this period and did not identify this waste shipment,

c. The RSO notified the management of the normal hospital waste system that these two specific radiation detection systems needed to be relocated immediately to restore their full sensitivity and the interlock systems needed to be promptly reactivated.

d. As an interim step, normal waste processing personnel were retrained to pause below the radiation detector systems and observe the alarm status before proceeding to the dump point. In addition, they were informed that the interlock system was no longer activated. This alternative survey procedure was operational at the time of the incident in question.

e. Hospital engineering personnel constructed a new mounting point to relocate the detection systems and restored the interlocks. This was delayed for a few weeks, due to the need to order custom length signal cables, necessary to connect the alarms to the newly relocated detectors.

f. The management of the normal hospital waste program was instructed to inform the RSO, in advance, about any significant changes in the program that might compromise the effectiveness of the waste survey system.

(3) Corrective Steps Taken to Avoid Further Violations

a. The RSO has instructed the waste management administrators not to modify the waste management systems without giving the RSO adequate prior notice, in order that he may evaluate the effects on the waste monitoring program. Waste management personnel now have a deeper understanding of the potential consequences of such actions and understand that the RSO must be included in any plans to modify these areas, which may impact the medical and normal hospital waste radiation detection systems.

b. 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.

(4) Date when Full Compliance Will Be Achieved

Full compliance has been achieved as of March 4, 2005.