



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 26, 2005

Docket No. 03001244
EA No. 05-116

License No. 06-00819-03

I. George Zubal, Ph.D.
Chairman, Radiation Safety Committee
Yale-New Haven Hospital
20 York Street
New Haven, CT 06504

**SUBJECT: RESPONSE TO JULY 12, 2005 REQUEST FOR ENFORCEMENT
DISCRETION FOR THE SECOND EXAMPLE OF THE APRIL 7, 2005 NOTICE
OF VIOLATION ISSUED IN INSPECTION 03001244/2005001, YALE-NEW
HAVEN HOSPITAL**

Dear Dr. Zubal:

Thank you for your July 12, 2005 letter, Reply to Response to Disputed Violation, wherein you described the reason for the disputed violation, your corrective actions taken to prevent future violations of this type, and the date when full compliance was achieved. These actions will be reviewed in a future inspection of licensee programs.

By letter dated April 7, 2005, NRC issued Yale-New Haven Hospital one Notice of Violation (NOV), with two examples, for the failure to dispose of licensed radioactive materials pursuant to 10 CFR 20.2001. By letter dated May 10, 2005, you acknowledged the first example and provided an acceptable response, but you disputed the second example citing that the package dose rate was below your minimum detection capability and within the normal fluctuation of background. In our June 13, 2005 letter, Response to Disputed Violation, we informed you that we reviewed the basis for your denial of the second example of the referenced violation, and we concluded that the waste contained detectable radioactive licensed material, that your program should have detected radioactivity in the waste, and that the violation occurred as stated in the Notice.

In your July 12, 2005 letter, Reply to Response to Disputed Violations, you no longer deny the second example of the violation and you provided your corrective and preventive actions. However, your letter requested that the NRC exercise enforcement discretion and reconsider issuance of the second example of the April 7, 2005 NOV. In support of your request, you asked that the NRC consider the following arguments: 1) that your detection system is designed to monitor large volumes of bulky solid waste and may be less sensitive than a direct survey of a container using a GM meter due to greater distances and shorter survey times, and that increasing the sensitivity of your current system will result in additional retained waste volumes, which may increase the non-radiological risks associated with handling them; 2) that Information Notices 91-03 and 99-33 imply that even with good practices, materials may be released and that this does not necessarily indicate noncompliance with NRC requirements; and 3) that the NRC should consider this situation using a risk-informed basis and that it is

imprudent for the NRC to maintain a regulatory model that appears to expose medical licensees to a subjective “zero tolerance” standard.

The NRC has carefully considered your request for enforcement discretion as stated above. The second example of the NOV issued on April 7, 2005 was classified as SLIV which is the least risk significant categorization of cited violations. Exercising enforcement discretion in this case would be to classify this violation as a non-cited violation (NCV). NCVs may only be assigned to Severity Level IV (SLIV) violations that are non-repetitive, licensee-identified and corrected violations (Section VI.A.8 of the NRC Enforcement Policy). This violation was repetitive (there was another example in the NOV) and it was not licensee-identified. Therefore, the severity level of the violation is as stated in the NOV dated April 7, 2005. The current Enforcement Policy is included on the NRC’s Web site at www.nrc.gov; select **What we Do, Enforcement**, then **Enforcement Policy**.

We have the following comments concerning your arguments for discretion:

1. The NRC did not identify concerns with the detection capabilities of your survey instrumentation, nor did the NRC require that you increase the sensitivity of your waste monitoring detection instruments. Instead, based on direct observations made by our inspector during an on-site inspection on January 25, 2005, and discussions with members of your staff, including your Radiation Safety Officer, we believe the improper disposal was likely due to deficiencies in training, implementation in monitoring procedures, and/or a temporary inoperability of your radiation monitor interlock system.
2. IN 99-33 states that, “...detection of radioactive material in nonradioactive waste streams does not necessarily indicate poor management of radioactive waste or noncompliance with NRC requirements.” However, the IN clearly indicates that this only applies to waste from patients who are not required to be hospitalized for radiological purposes. You did not determine the origin of the waste that was improperly disposed and thus this policy does not apply in this instance.
3. The NRC considers each apparent violation prior to issuance. The severity level of each violation is based on risk. We determined that the second example of the NOV issued on dated April 7, 2005 was of more than minor safety significance and warranted enforcement action. The subject violation was classified as SLIV which is the least risk significant categorization of violations.

I. Zubal
Yale-New Haven Hospital

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No response to this letter is necessary. Your cooperation with us is appreciated.

Sincerely,

Original signed by Francis Costello

George Pangburn, Director
Division of Nuclear Materials Safety

cc:
Michael J. Bohan, Radiation Safety Officer
State of Connecticut

I. Zubal
Yale-New Haven Hospital

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