



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

April 7, 2005

Docket No. 03001244

License No. 06-00819-03

Arthur P. Lemay, R.Ph.
Administrative Director
Yale-New Haven Hospital
20 York Street
New Haven, CT 06504

SUBJECT: INSPECTION 03001244/2005001, YALE-NEW HAVEN HOSPITAL, NEW HAVEN, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Lemay:

On January 25, 2005, Mr. Randolph Ragland of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. On March 14, 2005, an additional safety review was performed by telephone with Mr. Michael Bohan, Radiation Safety Officer (RSO). The inspection was limited to a review of dosimetry, training, and waste processing. The findings of the inspection were discussed with you at the conclusion of our onsite inspection, and our final findings were discussed with Mr. Michael Bohan at the conclusion of our inspection on March 14, 2005.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations and guidance are available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

A. Lemay
Yale-New Haven Hospital

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Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

NRC Web site addresses
NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

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

A. Lemay
Yale-New Haven Hospital

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Distribution:
D. J. Holody, RI

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NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, CT

Docket No. 03001244
License No. 06-00819-03

During an NRC inspection conducted on January 25, 2005, and concluded by telephone on March 14, 2005, one violation of NRC requirements with two examples was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

10 CFR 20.2001 restricts the methods that NRC licensee's can dispose of licensed materials to 1) transfer to an authorized recipient; 2) decay in storage; 3) release in effluents within the limits in 10 CFR 20.1301; and 4) as authorized under 10 CFR 20.2002, 20.2003, 20.2004, or §20.2005.

Contrary to the above, the licensee did not restrict disposal methods pursuant to 10 CFR 20.2001. Specifically,

- A. On February 16, 2004, Yale-New Haven Hospital released a package of medical waste, containing licensed radioactive material (Tc-99m with package dose rate of 5 mrem/h), for disposal by an unauthorized recipient: New York Environmental Services, Autoclave facility, located at 31 Lower River Road, Oneonta, NY.
- B. On February 24, 2005, Yale-New Haven Hospital released a package of general hospital waste, containing licensed radioactive material (Tc-99m with a package dose rate of 0.02 mrem/h), for disposal by an unauthorized recipient: Bridgeport RESCO, located at Howard Avenue, Bridgeport, CT.

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

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington,

Notice of Violation
Yale-New Haven Hospital

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DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at <http://www.nrc.gov/reading-rm.html>. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 7 day of April 2005