



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

July 2, 2012

Docket No. 03001244

License No. 06-00819-03

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

SUBJECT: NRC INSPECTION REPORT NO. 03001244/2012001, YALE-NEW HAVEN
HOSPITAL, NEW HAVEN, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Lemay:

On April 30 through May 4, 2012, Tara Weidner of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in the telephone conversation on June 1, 2012, between Michael Bohan of your organization and Tara Weidner of this office, were also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your organization during the telephonic exit meeting on June 14, 2012.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation involved the failure to provide information pertaining to the licensee's inventory of radium-226, by August 31, 2011, as required by License Condition 13. Specifically, you were required to provide either a decommissioning funding plan with associated financial assurance for the radium-226, in accordance with 10 CFR 30.35; or all available information identified in 10 CFR 32.210(c) concerning the radium-226 sources that are not registered with the Commission, and, if applicable, the device, in accordance with 10 CFR 30.32(g)(3).

The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your

response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please note that the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

USNRC – Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Please contact Tara Weidner at 610-337-5272 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

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

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Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

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

Distribution:
D. J. Holody, RI

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SUNSI Review Complete: TWeidner

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OFFICE	DNMS/RI	N	DNMS/RI				
NAME	TWeidner/jpd f/		JDwyer/jpd				
DATE	07/02/12		07/02/12				

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, CT

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

During an NRC inspection conducted on April 30 through May 4, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 13 of License No. 06-00819-03 requires, in part, that Yale-New Haven Hospital provide by August 31, 2011, either: (i) a decommissioning funding plan with associated financial assurance for their radium-226, in accordance with 10 CFR 30.35; or (ii) all available information identified in 10 CFR 32.210(c) concerning the radium-226 sources not registered with the Commission, and, if applicable, the device, in accordance with 10 CFR 30.32(g)(3).

Contrary to the above, as of June 14, 2012, Yale-New Haven Hospital has not provided either a decommissioning funding plan with associated financial assurance for their radium-226, in accordance with 10 CFR 30.35; or all available information identified in 10 CFR 32.210(c) concerning the radium-226 sources in accordance with 10 CFR 30.32(g)(3). Specifically, Yale-New Haven Hospital has not provided the information pertaining to the radium-226 sources (i.e. description of the source or device, including design, manufacture, prototype testing, quality control program, and labeling; description of the radiation safety features; and results of recent leak tests of the sources directly, especially of the suspected leaking source) or a decommissioning funding plan, with associated financial assurance, for the unsealed radium-226.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

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, 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. 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 of receipt.

Dated This 2 day of July 2012