



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

July 29, 2014

Docket No. 03001244  
EA-14-130

License No. 06-00819-03

Arthur P. Lemay, R.Ph.  
Executive Director, Smilow Cancer  
Hospital Network  
Yale-New Haven Hospital  
Radiological Physics  
20 York Street - WWW 204  
New Haven, CT 06504

**SUBJECT: NRC INSPECTION REPORT NO. 03001244/2014001, YALE-NEW HAVEN HOSPITAL, NEW HAVEN, CONNECTICUT SITE AND THE ST. RAPHAEL'S CAMPUS, NEW HAVEN, CONNECTICUT; NOTICE OF VIOLATION AND EXERCISE OF ENFORCEMENT DISCRETION**

Dear Mr. Lemay:

On June 23-27, 2014, Janice Nguyen of this office conducted a safety inspection at the above address and the St. Raphael's Campus, 1450 Chapel Street, New Haven, Connecticut, 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. The findings of the inspection were discussed with you and other members of your organization at the conclusion of the inspection on June 27, 2014. Additional discussion related to the inspection occurred during a telephone conversation with your Radiation Safety Officer, Michael Bohan, on July 22, 2014.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to periodically (at least annually) review the radiation protection program content and implementation as required by 10 CFR 20.1101(c); 2) the failure to include a representative of the nursing service on the Radiation Safety Committee as required by 10 CFR 35.24(f); and, 3) the failure to determine length of the source transfer tubes and applicators during full calibration measurements on the remote afterloader unit at St. Raphael's Campus in accordance with 10 CFR 35.633(b). The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

In addition, within the scope of this inspection, violations of 10 CFR 35.60 and 35.63 were identified. 10 CFR 35.60 requires calibration of instruments used to measure patient dosages and 10 CFR 35.63 requires measurement of patient dosages prior to administration. Your use of a Bracco CardioGen-82 generator to prepare and administer patient dosages does not allow for a calibration of the instrument used to measure patient dosages nor does it allow for measurement of patient dosages prior to administration; however, the inspector determined that you have a program in place for safely utilizing the CardioGen-82 generator that includes written procedures for periodic testing of the infusion pump flow rate and the radiation detector, requires specific manufacturer's training of the RSO and Authorized Users of the CardioGen-82 generator, and requires the recording of the activity of each patient dosage administered. These two violations would normally be categorized at Severity Level IV; however, in accordance with "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," Enforcement Guidance Memorandum 13-003, dated April 18, 2013, NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

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](http://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](http://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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please contact Janice Nguyen at (610) 337-5006 if you have any questions regarding this matter.

A. Lemay

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Thank you for your cooperation.

Sincerely,

*/RA/*

James W. Clifford, Director  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

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

A. Lemay

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Thank you for your cooperation.

Sincerely,

**/RA/**

James W. Clifford, Director  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

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

Distribution w/enclosure:

OEMail  
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**SUNSI Review Complete: JNguyen**

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OFFICE	DNMS/RI	N	DNMS/RI	N	ORA/RI		DNMS/RI	
NAME	JNguyen/jpd f/		JPDwyer/jpd		BBickett/cjc f/		JWClifford/jwc	
DATE	07/25/14		07/25/14		07/28/14		07/29/14	

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## NOTICE OF VIOLATION

Yale-New Haven Hospital  
New Haven, CT

Docket No. 03001244  
License No. 06-00819-03  
EA-14-130

During an NRC inspection conducted on June 23-27, 2014, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1101(c) requires that each licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of June 23, 2014, the licensee did not periodically (at least annually) review the radiation protection content and implementation. Specifically, annual reviews (audits) of the licensee's radiation safety program were not conducted in 2012 and 2013. The licensee had committed to performing annual audits of the radiation safety program that reviewed all aspects of the radiation safety program, in a letter dated March 3, 2006, referenced in License Condition 24 of the YNHH license.

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

- B. 10 CFR 35.24(f) requires, in part, that the Radiation Safety Committee include a representative of the nursing service.

Contrary to the above, as of June 23, 2014, the Radiation Safety Committee did not include a representative of the nursing service. Specifically, a nursing representative did not attend Radiation Safety Committee meetings from May 4, 2012 to June 23, 2014.

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

- C. 10 CFR 35.633(b) requires, in part, that full calibration measurements on remote afterloader units include the determination of the length of the source transfer tubes and the length of the applicators.

Contrary to the above, as of June 23, 2014, full calibration measurements on the remote afterloader unit at St. Raphael's Campus did not include the determination of the length of the source transfer tubes and the length of the applicators. Specifically, the length of the source transfer tubes and applicators was not measured during full calibration of the remote afterloader unit at St. Raphael's campus.

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 29th day of July 2014