



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

November 22, 2016

Docket No. 03001274

License No. 06-08544-01

Ruth Shanley
Radiation Safety Coordinator
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

SUBJECT: NRC INSPECTION REPORT NO. 03001274/2016001, DANBURY HOSPITAL, DANBURY, CONNECTICUT SITE AND THE DANBURY HOSPITAL MEDICAL ARTS CENTER, DANBURY, CONNECTICUT, AND NOTICE OF VIOLATION

Dear Ms. Shanley:

On October 19-21, Farrah Gaskins of this office conducted a safety inspection at the above address and the Danbury Hospital Medical Arts Center, 111 Osborne Street, Danbury, 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. Additional information provided in the correspondence dated October 26, 2016, sent by Vassiliki Potari-Farina, was also examined as part of the inspection. The findings of the inspection were discussed with you on November 4, 2016.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved: the failure to conduct full calibration in accordance with 10 CFR 35.633. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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 Web site 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 Web site 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 Web site 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).

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 Ms. Gaskins at (610) 337-5143 if you have any questions regarding this matter.

Sincerely,

/RA/

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

Enclosure:
Notice of Violation

cc w/Encl: Vladimir Monastyrenko, Ph.D.,
Radiation Safety Officer
State of Connecticut

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James P. Dwyer, Chief
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Enclosure:
Notice of Violation

cc w/Encl: Vladimir Monastyrenko, Ph.D.,
Radiation Safety Officer
State of Connecticut

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NOTICE OF VIOLATION

Danbury Hospital
Danbury, CT

Docket No. 03001274
License No. 06-08544-01

During an NRC inspection conducted on October 19-21, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Regulations set forth in 10 CFR 35.633(a)(2)(i) requires, in part, that a licensee authorized to use a remote after loader unit for medical use shall perform full calibrations measurements on each unit following the replacement of the source.

10 CFR 35.633(b) require, in part, that full calibration must include determination of length of the source transfer tubes, length of the applicators, and function of the source transfer tubes, applicators, and transfer tube-applicator interface.

Contrary to the above in 2015 and 2016, through October 18, 2016, full calibration did not include determination of the function of source transfer tubes, applicators, and transfer-tube applicators interface. In addition, the licensee only performed the determination of length of source transfer tubes and length of applicators one time in 2015 and not at every source change, the frequency required by 10 CFR 35.633. In addition, the determinations were not being maintained as a record as part of the full calibrations being conducted at source change.

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

Pursuant to the provisions of 10 CFR 2.201, Danbury 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 22nd_ day of November 2016.