



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

August 9, 2015

Docket No. 03001274
EA-15-120

License No. 06-08544-01

James Haynes
Vice President of Operations
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

SUBJECT: DANBURY HOSPITAL, NOTICE OF VIOLATION - INSPECTION REPORT NO.
03001274/2015001

Dear Mr. Haynes:

This letter provides you with the U.S. Nuclear Regulatory Commission's (NRC) enforcement decision for the apparent violations identified during an announced, on-site special inspection conducted on February 3, 2015, at Danbury Hospital (Danbury), Danbury, Connecticut, with continued in-office review through April 17, 2015. The special inspection consisted of a review of the medical event reported to the NRC Operations Center on January 23, 2015 (Event Notification 50756), and of a complete review of the radioactive seed localization (RSL) program. During the inspection, the NRC identified two additional, potential medical events. The in-office review included: (1) an assessment of your 15-day written medical event report; (2) a review of your written procedures in place prior to January 2015; and (3) a review of your proposed corrective and preventive actions as described in your letter dated April 16, 2015. At the conclusion of the in-office review, Ms. Penny Lanzisera, of this office, discussed the results of the inspection with you and several members of your organization during a telephonic final exit meeting on April 17, 2015. The NRC Inspection Report and letter dated May 28, 2015, ML15152A371¹, described two apparent violations.

Based on the information developed during the inspection, the NRC has determined that one violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it were described in detail in the May 28, 2015, letter and in the subject inspection report. The violation involved the failure to develop, implement, and maintain written procedures that provided high confidence that each administration was conducted in accordance with the written directive. Specifically, written directives for RSL implants required seeds to be removed within 5 days of implantation. However, Danbury procedures did not similarly require the scheduling of RSL removal surgeries within that timeframe, as documented in the written directive. As a result, prior to April 17, 2015,

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS

several patients were implanted with a single iodine-125 (I-125) seed for RSL; to be removed within 5 days, but the seeds were ultimately removed much later, contrary to the written directive. In response to exceeding the removal timeframe, Danbury did not conduct dosimetric assessments to assess that the dose delivered was in accordance with the written directive or to determine if the NRC reporting requirements were met.

In our letter dated May 28, 2015, a second apparent violation was described involving the failure to notify the NRC Operations Center of two medical events no later than the next calendar day as required by 10 CFR 35.3045. Specifically, during the special inspection, the NRC inspector reviewed documentation of 76 RSL cases, including the case reported to the NRC on January 23, 2015. Of the 76 cases reviewed, the inspector identified that two patients implanted on November 26 and December 2, 2014, did not return for removal until December 10 and 16, 2014, a period greater than 5 days. Danbury evaluated the doses delivered and concluded that the doses administered exceeded 50 rem to the tissue and therefore, met the requirements in 10 CFR 35.43045. After subsequent reviews of the reporting requirements in 10 CFR 35.3045, it was determined that the two cases identified on February 3, 2015, did not meet the requirements of 10 CFR 35.3045, and therefore, were not medical events. Specifically, for these two cases, the doses did not differ from the prescribed doses or the doses that would have resulted from the prescribed dosages by more than 50 rem to an organ or tissue.

Although the two cases described above did not result in medical events, the NRC concluded that Danbury demonstrated a programmatic weakness in its development and implementation of procedures for administrations requiring a written directive. Specifically, on several occasions prior to April 17, 2015, Danbury exceeded the 5 day removal time frame. Of the cases that exceeded the five day removal timeframe, one was determined to be a medical event, and therefore, the potential existed for other implants to have resulted in medical events. Additionally, the NRC noted that Danbury procedures did not require a dosimetric assessment to be conducted when a removal exceeded the 5 day timeframe, to assess the dose delivered in order to determine if the NRC reporting requirements were met. Therefore, the potential also existed for medical events to not be reported to the NRC, as required.

A programmatic failure to implement written directives or procedures for administrations requiring a written directive is a significant regulatory concern and is normally characterized as a Severity Level (SL) III violation. However, because: (1) RSL is a diagnostic procedure that uses a low level activity of a single I-125 seed to locate suspicious tissue for impending surgical removal; (2) the radiation dose associated with the procedure is localized to a small area surrounding the seed; and (3) the seed is eventually removed along with the tissue that was excised, the NRC concluded that the risks from your use of I-125 for diagnostic studies was minimal. As a result, the NRC has determined that this case is more appropriately categorized this violation at a SL-IV.

The NRC notes that Danbury took corrective actions to address the violation. Specifically, Danbury: (1) revised the written policy for RSL procedures to include detailed instructions and dosimetric assessment for all patients who do not return by the date on the written directive for explant surgery and to report to the NRC, when required; (2) reduced the implant activity to extend the time frame for removal based on a 50 rem limit; (3) retrained the surgeons to notify radiation safety staff when a patient's planned removal surgery is delayed; (4) retrained surgeons' nurse schedulers on: (a) not scheduling implants more than 5 days prior to the removal surgery; (b) ensuring patients requiring medical clearance for removal surgery have the clearance prior to implant; and (c) not scheduling implants for patients awaiting genetic testing

results; and (5) required radiation safety staff to audit all RSL medical procedures and to develop a spreadsheet to flag when a patient has not returned by the specified removal date. The NRC has concluded that information regarding: (1) the reasons for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001274/2015001 and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room and 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, if you choose to provide one, 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).

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>.

J. Haynes

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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.

Sincerely,

/RA/

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

Enclosure:
Notice of Violation

cc w/enclosure: State of Connecticut

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.

Sincerely,

/RA/

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

Enclosure:
 Notice of Violation

cc w/enclosure: State of Connecticut

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NOTICE OF VIOLATION

Danbury Hospital
Danbury, Connecticut

Docket No. 03001274
License No. 06-08544-01
EA-15-120

During an NRC inspection conducted on February 3, 2015, with continued in-office review through April 17, 2015, for which a final exit meeting was conducted on April 17, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b)(2) requires, at a minimum, that the procedures verify that the administration is in accordance with the treatment plan and the written directive.

Contrary to the above, prior to April 17, 2015, Danbury Hospital failed to develop, implement, and maintain written procedures that provided high confidence that each administration was in accordance with the written directive. Specifically, although written directives specified that radioactive seed localization (RSL) implants were to be removed 5 days after implantation, Danbury Hospital procedures did not similarly require the scheduling of RSL removal surgeries within that timeframe. As a result, prior to April 17, 2015, several patients were implanted with a single iodine-125 seed for RSL; to be removed within 5 days, as documented in the written directives. However, contrary to the written directives, the seeds were ultimately removed much later.

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

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001274/2015001 and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation EA-15-120," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Notice of Violation
Danbury Hospital

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

Dated this 9th day of August, 2015