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

May 28, 2015

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

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

SUBJECT: NRC INSPECTION REPORT NO. 03001274/2015001, DANBURY HOSPITAL, DANBURY, CONNECTICUT

Dear Mr. Haynes:

On February 3, 2015, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of a medical event reported to the NRC on January 23, 2015, and two additional medical events reported on February 3, 2015. Additional information provided in your correspondence dated February 5 and 18, and April 17 and 21, 2015, was also examined as part of the inspection. The findings of the inspection were discussed with your radiation safety staff at the conclusion of the on-site inspection on February 3, 2015, and with you and several members of your organization on April 17, 2015. The enclosed report presents the results of this inspection.

The NRC in-office review continued through April 21, 2015, and 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 described in your letter dated April 16, 2015. Based on the result of this inspection, two apparent violations of NRC requirements were identified.

The apparent violations involved:

1. The failure to develop procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2); and

2. 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(c).

A more detailed description of the apparent violations and the circumstances surrounding the apparent violations may be found in the enclosed inspection report.

Because the NRC has not made a final determination in this matter with respect to the apparent violations, a Notice of Violation for these findings is not being issued at this time. You will be advised by separate correspondence when a final determination has been made.

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 or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

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).

No reply to this letter is required. Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

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

Enclosure:
Inspection Report No. 03001274/2015001

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

Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

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Sincerely,

/RA/

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

Enclosure:
Inspection Report No. 03001274/2015001

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

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001274/2015001
Docket No.	03001274
License No.	06-08544-01
NMED Item No.	150057
Licensee:	Danbury Hospital
Location:	24 Hospital Avenue Danbury, Connecticut 06810
Inspection Dates:	February 3, 2015 April 17, 2015 (telephonic exit)
Date Follow-up Information Received:	February 5 and 18, April 17 and 21, 2015

Inspector: ***/RA/*** _____ ***05/28/15*** _____

Penny Lanzisera, Senior Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/*** _____ ***05/28/15*** _____

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

EXECUTIVE SUMMARY

Danbury Hospital
NRC Inspection Report No. 03001274/2015001

An announced, special inspection was conducted on February 3, 2015, at Danbury Hospital in Danbury, Connecticut to review the circumstances surrounding a medical event reported on January 23, 2015, (NMED Item Number 150057). The medical event was identified by the licensee after performing a dose assessment for a patient delayed from returning to surgery to remove an iodine-125 seed within five days as scheduled. Additional information provided by Danbury Hospital on February 5 and 18, and April 17 and 21, 2015, was also reviewed. The inspection consisted of a review of licensed activities associated with the radioactive seed localization (RSL) program at Danbury Hospital. The last routine inspection of the facility was performed on May 20, 2014, however, the RSL program did not commence until June 18, 2014. Therefore, the inspection reviewed the entire RSL program, and during the course of the review two additional medical events were identified. For both of these cases, the patients also did not return within the five days noted on the written directive. The additional events were reported by the licensee on February 3, 2015. The inspector coordinated with headquarters and determined that a medical consultant was not necessary in these cases because the doses did not significantly exceed the 50 rem reporting limit and the tissue receiving this dose was removed along with the iodine-125 seed during surgery. In-office evaluation of the medical event, the RSL program, and Danbury Hospital's corrective actions continued through April 17, 2015. An exit was conducted with the licensee on April 17, 2015, and the licensee submitted corrective and preventative actions on April 21, 2015.

Based on the results of this inspection, the inspector identified two apparent violations:

- Danbury Hospital did not develop written procedures to provide high confidence that
- each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, on November 26 and December 2, 2014, patients were implanted with a single iodine-125 seed for radioactive seed localization to be explanted within 5 days and the seeds were instead both explanted 14 days later. The licensee's procedure required an evaluation of the dose delivered only if a month had passed and therefore, Danbury Hospital did not determine that the delivered doses differed from the prescribed doses by greater than 20% and had resulted in two medical events.

- Danbury Hospital did not notify the NRC Operations Center of two medical events in accordance with 10 CFR 35.3045(c). Specifically, the licensee identified that two patients implanted on November 26 and December 2, 2014, did not return for source removal until December 10 and 16, 2014, a period greater than 5 days and 20 percent; however, the licensee did not evaluate that the dose administered exceeded 50 rem to the tissue and therefore, did not notify the NRC Operations Center until prompted during an inspection on February 3, 2015.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

An announced, special inspection was conducted on February 3, 2015, at Danbury Hospital in Danbury, Connecticut to review the circumstances surrounding a medical event (NMED Item Number 150057) that was reported to the NRC on January 23, 2015. Additional information provided by Danbury Hospital on February 5 and 18, and April 17 and 21, 2015 was also reviewed. The inspection was performed in accordance with NRC Inspection Procedure 87103 and Management Directive 8.10 and consisted of a review of licensed activities associated with the RSL program, license commitments, and the details of the reported medical event.

The inspector also reviewed 76 RSL treatment records for patient treatments that occurred since June 18, 2014, and visited all departments involved in receipt, implant, explant, and pathology to discuss the program and review procedures with staff in each area.

b. Observations and Findings

Danbury Hospital is a medical institution authorized for the possession and use of radionuclides permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and RSL. A cesium-137 sealed source is also authorized for instrument calibration. The licensee added RSL to their license on May 15, 2014, and initiated use on June 18, 2014. Since then, 76 patients have been treated. Initially the implants of the iodine-125 localization seeds were conducted by the Radiation Oncologists until training could be provided to the Radiologists, who now primarily perform the implants. Removal of the iodine-125 seed is performed by the breast surgeon and the tissue containing the seed is then transferred to pathology. Tracking of the seed is maintained throughout the procedure and discussions with all personnel involved in the procedure indicated good understanding of the licensee's procedures. Scheduling of the implant and surgery to remove the seed is done separately. Therefore, some patients were implanted who were not cleared for surgery to have the seed removed.

The inspector reviewed documentation of 76 RSL cases, including the case reported to the NRC on January 23, 2015. Written directives were completed, as required, and included the information described in 10 CFR 35.40 in addition to the scheduled date of surgery to remove the seed as committed to in the licensee's letter dated May 1, 2014. The surgical date was primarily set at five days after the implant and was originally based on implanting a 0.3 millicurie iodine-125 seed. As discussed further in the Medical Event Reporting section, in January 2015, the licensee identified that a patient had not returned from surgery "within a few days" of the scheduled date and, in accordance with commitments made in their letter dated May 1, 2014, reported the event to the NRC. For this RSL procedure, the licensee calculated the dose to tissue and determined that a medical event had occurred. Prior to this event, the licensee had noted that occasionally, a patient did not return by the scheduled surgery date, but had

not previously calculated the dose received by the small volume of tissue implanted. A review of the licensee's procedures in place prior to January 2015, noted that the procedure required an evaluation of the dose delivered only if a month had passed. Specifically, Danbury Hospital's procedure entitled, "Radioactive Seed Handling – For Localization of Breast Mass," indicates that, "if the patient fails to return for explantation, the Breast Surgeon will notify the Authorized User…if a seed is not returned to the Nuclear Medicine within one month of implantation, the Nuclear Medicine technologist will notify the Authorized User and the Radiation Safety Officer who will investigate and perform a dose assessment." No implants exceeded one month, however, as described below, 16 exceeded the five day explant time frame and several exceeded "within a few days of the scheduled date" requiring further evaluation. The licensee discussed this issue further during a meeting conducted on January 29, 2015, with all involved personnel.

During the review of the 76 RSL cases, the inspector noted that in 16 of the RSL cases, the patient did not return for surgery by the scheduled surgery date. Further review noted that the licensee had revised their process to use lower activity seeds (i.e., 0.15 millicuries) instead of the 0.3 millicurie seeds used for originally scheduling the surgery date. Therefore, the inspector noted that only five implants needed further evaluations to assess the dose delivered. The RSO completed the evaluation later that day and determined that two additional cases for implants performed on November 26 and December 2, 2014, warranted reporting to the NRC, with doses of 54 and 57 rads; slightly in excess of the reporting requirement of 50 rem to the tissue. In both cases, the patients were delayed for surgery and Danbury Hospital did not previously make an assessment of the dose delivered to the tissue upon noting the delay.

10 CFR 35.41(a)(2) requires, for any administration requiring a written directive, that the licensee develop, implement, and maintain written procedures to provide high confidence that, in part, each administration is in accordance with the written directive. 10 CFR 35.41(b)(2) requires, at a minimum, that the procedure verify that the administration is in accordance with the treatment plan and the written directive. Danbury Hospital did not develop procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, Danbury Hospital's written procedures for RSL provided for dose assessment at one month, well in excess of the five day explant date documented on the written directive.

Medical Event Reporting

Danbury Hospital reported the initial event on January 23, 2015, following submittal of the dose assessment to the NRC that indicated a dose of 83.6 rads instead of the expected dose of 18.4 rads. In this case, the licensee identified the event after performing a dose assessment for a patient delayed from returning to surgery to remove an iodine-125 seed within five days as scheduled.

As noted above, two additional events for implants performed on November 26 and December 2, 2014, and delayed for surgery warranted reporting to the NRC, with doses of 54 and 57 rads; slightly in excess of the reporting requirement of 50 rem to the tissue.

The medical events were reported on February 3, 2015. The inspector noted that even though the licensee reported the January 23, 2015 event due to a delay in surgery, the licensee did not perform an "extent of condition" analysis and confirm that other administrations where patients were delayed from returning for surgery did not trigger the medical event reporting requirements.

10 CFR 35.3045(a) requires, in part, a licensee shall report any event in which the administration of radiation from byproduct material results in a dose that differs from the prescribed dose by more than 5 rem effective dose equivalent or 50 rem to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more. 10 CFR 35.3045(c) requires the licensee to notify, by telephone, the NRC Operations Center no later than the next calendar day after the discovery of the medical event. The inspector concluded that the initial event was reported in a timely fashion. However, the two additional events were not initially reported when they occurred. A review of the patient's records indicated that the information previously on file provided the licensee with the information needed to determine that a medical event occurred during the two prior implants; however, the licensee did not make the required notification to the NRC Operations Center until prompted by the NRC on February 3, 2015. This is an apparent violation of 10 CFR 35.3045(c).

A 15-day report was received by NRC on February 5, 2015. Danbury Hospital concluded in the 15-day report that the cause of the medical events were delays in surgical removals.

The events were reviewed with NRC Headquarters and because the doses did not significantly exceed the 50 rem reporting limit and the tissue receiving this dose was removed along with the iodine-125 seed during surgery; it was determined that a medical consultant was not necessary to review these cases.

Corrective and Preventative Actions

As a result of the inspection, Danbury Hospital implemented the following corrective and preventative actions as documented in their letter dated April 16, 2015:

1. Revised the written policy for RSL procedures to include detailed instructions when the patient does not return by the date on the written directive for explant surgery.
2. Reduced the implant activity to extend the time frame for explant based on a 50 rem medical event reporting limit.
3. Retrained the surgeons to notify radiation safety staff if the patient's planned explant surgery is delayed.
4. Retrained the surgeons' nurse schedulers that: (a) implants were not to be scheduled more than 5 days prior to explant surgery; (b) patients requiring medical clearance for explant surgery must have the clearance prior to implant; and (c) patients awaiting genetic testing results will not have implants performed.
5. Radiation safety staff began auditing all RSL medical procedures and developed a spreadsheet to flag when a patient has not returned to have the source removed by the specified date.

c. Conclusions

The licensee documents the scheduled surgery date on their written directive in accordance with their license commitments, which ensures that 50 rem to tissue medical event reporting criteria is not exceeded. However, the licensee's internal procedure for evaluating medical events in place in December 2014 stated that the licensee would "investigate and perform a dose assessment" if "a seed is not returned to Nuclear Medicine within one month." Therefore, prior to December 2014, even though the licensee had the data necessary to evaluate whether the implant was in accordance with the written directive, the inadequate procedures prompted the licensee to only perform this assessment only after a month delay instead of after "a few days" delay. In addition, Danbury Hospital did not evaluate the "extent of condition" after reporting the medical event on January 23, 2015, and therefore, did not recognize that the RSL procedures performed in 2014 on November 26 (with explant December 10) and December 2 (with explant December 16), met the reporting requirement in 10 CFR 35.3045(c) until prompted to perform a dosimetric evaluation by the inspector during the February 3, 2015 inspection.

Based on the inspector's observations, two apparent violations of NRC requirements were identified. Specifically:

1. Danbury Hospital did not develop written procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, on November 26 and December 2, 2014, patients were implanted with a single iodine-125 seed for radioactive seed localization to be explanted within 5 days and the seeds were instead both explanted 14 days later. The licensee's procedure required an evaluation of the dose delivered only if a month had passed and therefore, Danbury Hospital did not determine that the delivered doses differed from the prescribed doses by greater than 20% and had resulted in two medical events.

2. Danbury Hospital did not notify the NRC Operations Center of two medical events in accordance with 10 CFR 35.3045(c). Specifically, the licensee identified that two patients implanted on November 26 and December 2, 2014, did not return for source removal until December 10 and 16, 2014, a period greater than 5 days and 20 percent; however, the licensee did not evaluate that the dose administered exceeded 50 rem to the tissue and therefore, did not notify the NRC Operations Center until prompted during an inspection on February 3, 2015.

II. Exit Meeting

A preliminary exit meeting was conducted on February 3, 2015, with radiation safety staff to discuss the scope of the inspection and the inspector's initial observations. On April 17, 2015, an exit meeting was held by telephone with Mr. James Haynes and other members of Danbury Hospital's staff, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+James Haynes, Vice President of Operations
*+ToniAnn Marchione, Admin. Director for Radiology, Pathology and Laboratory Medicine
*+Vladimir Monastyrenko, Radiation Safety Officer
*+Ruth Shanley, Radiation Safety Coordinator
+Joleene Dennison, Radiology Manager
+Mary Kincart, Quality Department
Various additional staff including staff in Nuclear Medicine and Pathology

* Present at preliminary exit meeting on February 3, 2015
+ Participated in telephonic exit meeting conducted on April 17, 2015