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

July 26, 2016

Docket No. 03001242 License No. 06-00649-03

Garrett Havican
Vice President, Strategic Planning/
Ambulatory Operations
Middlesex Hospital
28 Crescent Street
Middletown, CT 06457

SUBJECT: NRC INSPECTION REPORT NO. 03001242/2015002, MIDDLESEX HOSPITAL, MIDDLETOWN, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Havican:

On August 26, 2015, Tara Weidner of this office conducted a safety inspection at the above address of activities authorized by your NRC license. The inspection was limited to a review of a medical event that was reported to the NRC Operations Center on August 13, 2015 (Event Notification (EN) 51317). An in-office review continued through July 13, 2016, and included: (1) an assessment of your 15-day written medical event report; (2) a review of the medical device manufacturer's investigation results; (3) a review of your revised Therasphere administration policy; and (4) a review of your proposed corrective and preventative actions. The findings of the inspection were discussed with Joan Merton, Ph.D., of your organization at the conclusion of the inspection. The enclosed report presents the results of this inspection.

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 notify the NRC Operations Center within one calendar day following the discovery of a medical event as required by 10 CFR 35.3045(c). The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

During the inspection exit meeting on July 13, 2016, Dr. Merton indicated that all staff involved in the Therasphere program received training on the revised Therasphere administration policy. She stated that you have taken corrective and preventative actions to address the violation and that Middlesex Hospital is committed to radiation safety and to compliance with NRC regulations and licensed conditions. In addition, Dr. Merton stated that administration of yttrium-90 Therasphere has been suspended until additional training is received from the Therasphere manufacturer. This training is currently scheduled to occur in September 2016. Also, she stated verbally and you documented in your May 17, 2016, correspondence, that the Therasphere Administration policy was revised and all authorized users, interventional radiology technologists, and nuclear medicine technologists were trained on the revised policy.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated May 17, 2016. Therefore, you are

not required to respond to this letter unless the description of your corrective actions in this letter and your May 17, 2016, correspondence 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, its enclosures, 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 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 contact Tara L. Weidner at 610-337-5272 if you have any questions regarding this matter.

Sincerely,

/RA/

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

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03001242/2015002

cc w/Enclosures:
Joan Merton, Ph.D., Radiation Safety Officer
State of Connecticut

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James P. Dwyer, Chief
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cc w/Enclosures:
Joan Merton, Ph.D., Radiation Safety Officer
State of Connecticut

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NAME	TWeidner/jpd for		JDwyer/jpd					
DATE	7/26/16		7/26/16					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Middlesex Hospital
Middletown, CT

Docket No. 03001242
License No. 06-00649-03

During an NRC inspection conducted on August 26, 2015, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.3045(a)(1) requires, in part, that a licensee report any event, except for an event that results from patient intervention, in which the administration of byproduct material results in a dose that differs from the prescribed dosage by more than 0.5 Sv (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) states that, the licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.
>
> Contrary to the above, on August 12, 2015, the licensee did not notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. Specifically, on August 11, 2015, Middlesex Hospital determined that a medical event had occurred; however, Middlesex Hospital did not notify the NRC Operations Center until August 13, 2015, two calendar days after discovery of the medical event.
>
> This is a Severity Level IV violation (NRC Enforcement Policy, Example 6.9.d.7.).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," and send it 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).

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 _26_ day of _July_ 2016

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001242/2015002
Docket No.	03001242
License No.	06-00649-03
NMED Item No.	150471
Licensee:	Middlesex Hospital
Location:	28 Crescent Street, Middletown, Connecticut
Inspection Dates:	August 26, 2015 July 13, 2016 (telephonic exit)
Date Follow-up Information Received:	February 8, 2016 and May 17, 2016

Inspector: ***/RA/jpd for***
_____ ____7/26/16_____
Tara L. Weidner date
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/jpd***
_____ _____7/26/16_____
James P. Dwyer, Chief date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Middlesex Hospital
NRC Inspection Report No. 03001242/2015002

An announced, special inspection was conducted on August 26, 2015, at Middlesex Hospital in Middletown, Connecticut, to review the circumstances surrounding a medical event that occurred on August 11, 2015. The event involved the failure to administer the entire prescribed dosage of yttrium-90 microspheres to the patient's liver (left lobe), which was not due to stasis. The medical event was reported on August 13, 2015, (EN 51317), two calendar days after the event. Additional information provided by Middlesex Hospital on February 8, 2016 and May 17, 2016, was also reviewed. Middlesex Hospital requested that BTG, the TheraSphere manufacturer, examine their delivery system for defects. BTG stated in their investigation results that the cause of the high residual activity remaining in the catheter could not be conclusively identified. However, BTG suggested that a possible cause may be related to insufficient flow rate during the flushing of the catheter which ultimately resulted in the microspheres falling out of suspension in the tubing and microcatheter. In-office evaluation of the medical event, the microsphere manufacturers' assessment of their device, and the licensee's corrective actions continued through July 13, 2016.

Based on the results of this inspection, the inspector identified one apparent violation.

10 CFR 35.3045(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after the discovery of the medical event. On August 11, 2015, Middlesex Hospital identified that a medical event occurred; however, they did not notify the NRC Operations Center of the medical event until August 13, 2015, two calendar days following the identification of the medical event.

REPORT DETAILS

I. Event Description

a. Inspection Scope

An announced, special inspection was conducted on August 26, 2015, at Middlesex Hospital in Middletown, Connecticut, to review the circumstances surrounding a medical event that occurred on August 11, 2015, and was reported on August 13, 2015, (EN 51317). The inspection was conducted in accordance with Inspection Procedure 87103 and Management Directive 8.10. An in-office review continued through July 13, 2016, to evaluate the microsphere manufacturer's assessment of the Therasphere delivery system's performance and Middlesex Hospital's corrective actions. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event. The inspector also reviewed Middlesex Hospital's procedures related to microsphere use, documentation, and medical event follow up.

b. Observations and Findings

Microsphere Program

License No. 06-00649-03 authorizes Middlesex Hospital to provide microsphere treatments using the TheraSphere delivery system at its facility in Middletown, Connecticut. The licensee began its microsphere program in June 2014 and currently has one authorized user (AU) approved for performing these treatments.

Event Chronology, Reporting, On-Site Inspection, and Corrective/Preventative Actions

August 11, 2015 – A patient was scheduled for their fourth and final yttrium-90 TheraSphere treatment. The prescribed activity was 18 millicuries of yttrium-90 TheraSphere. A written directive was prepared, as required. According to the AU, when he injected the microspheres he did not notice any appreciable resistance; however, he did notice that the reading on the radiation monitor did not drop as expected. After three flushes of the catheter, the AU requested that the Therasphere manufacturer, BTG Interventional Medicine (BTG), be contacted for assistance. The BTG representative advised the AU to massage the catheter tubing to remove any potential kinks and flush the catheter two additional times. After following BTG's recommendation, the radiation monitor reading failed to drop to normal levels and the procedure was terminated. Post-administration measurements of the delivery system were performed by the Chief Nuclear Medicine Technologist. The measurements indicated that 60% of the prescribed dose was delivered to the left lobe of the liver and 40% of the prescribed dose remained in the delivery system. The Radiation Safety Officer (RSO) was not present at the administration and was notified four hours after the treatment was terminated that 60% of the dose was delivered to the liver.

August 12, 2015 – The RSO measured the radiation exposure levels from the delivery system while the delivery system was stored in the waste jar. Based on her measurements, the highest readings were from the vial and plunger. The RSO

contacted BTG to discuss her findings. BTG advised the RSO to hold the delivery system for decay, then return the system to BTG for further analysis.

August 12, 2016 – The AU reviewed the final calculations and documented on the written directive that the patient received 10.9 millicuries of yttrium-90 Therasphere, 40% less than intended.

August 13, 2015 – The RSO contacted a Region I inspector and was advised to contact the NRC Operations Center to report the medical event. Middlesex Hospital reported the medical event to the NRC Operations Center.

August 26, 2015 – NRC Region I conducted an on-site inspection to review the circumstances surrounding the reported medical event. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event. The inspector also reviewed Middlesex Hospital's procedures related to microsphere use. Middlesex Hospital submitted its 15-day report in accordance with 10 CFR 35.3045. In the report, Middlesex Hospital described the event, the suspected cause of the event, the patient notification of the event, and planned future actions. The inspector held a preliminary exit meeting with the licensee's management and staff.

January 18, 2016 – BTG examined the TheraSphere delivery system and determined: (1) that residual microspheres remained in the outlet tubing, the tubing that connects the dose vial to the patient's catheter; (2) that the components were successfully flushed, with expected flow rates; (3) the catheter used, Boston Scientific Model Renegade Hi-Flo, met the specifications described in the TheraSphere package insert; and (4) the root cause of the high residual activity could not be conclusively identified. BTG suggested that the possible cause was insufficient flow rate during flushing that resulted in the microspheres falling out of suspension.

May 17, 2016 – Middlesex Hospital confirmed that the authorized users, interventional radiology technologists, and the nuclear medicine technologists were trained in the revised Therasphere Y-90 policy. Specifically, the revised policy included medical event reporting, the need to immediately notify designated licensee personnel when the administration does not proceed as expected, the need to report medical events to the NRC Operations Center within one calendar day of identification, the need to submit a written report to the NRC Region I office within 15 days of the event, and the need to notify the referring physician of the medical event in writing within 15 days.

July 13, 2016 – A final exit meeting was conducted via telephone with the licensee's RSO. During the exit, the inspector summarized the event, the event reporting, the manufacturers' review, and Middlesex Hospital's corrective and preventative actions.

c. Conclusions

Middlesex Hospital did not report the medical event in the timeframe required by 10 CFR 35.3045(c). 10 CFR 35.3045(c) states that, "The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after the discovery of the medical event." Middlesex Hospital had the information available to determine that a medical event occurred on August 11, 2015, but, failed to notify the NRC Operations

Center until August 13, 2015, two calendar days after the medical event. Based on the inspector's findings, one violation of NRC requirements was identified.

II. Exit Meeting

A preliminary exit meeting was conducted on August 26, 2015, to discuss the scope of the inspection and the inspector's initial observations. On July 13, 2016, a final exit meeting was held by telephone with the RSO to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Garrett Havican, Vice President, Operations
*Sandra Phillips, Director of Radiology
*+Joan Merton, Ph.D., Radiation Safety Officer
Jeffrey Takahashi, M.D., Authorized User
*Karen Caturano, Chief Nuclear Medicine Technologist

* Present at preliminary exit meeting on February 3, 2015
+ Participated in telephonic exit meeting conducted on July 13, 2016