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

January 11, 2017

Docket No. 03001303 License No. 07-12153-02

Michael S. Eppehimer, MHSA, FACHE
Senior Vice President, Service Line
Operations
Christiana Care Health Services, Inc.
Management Suite - Room 1270
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: NRC INSPECTION REPORT NO. 03001303/2016002, CHRISTIANA CARE HEALTH SERVICES, INC., NEWARK, DELAWARE SITE

Dear Mr. Eppehimer:

On April 11, 2016, Janice Nguyen 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 Operations Center on April 1, 2016. Additional information provided in your correspondence dated April 14 and June 9, 2016, and during the telephone conversation on December 22, 2016 with you and other members of your staff were also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Within the scope of this inspection, no violations were identified.

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 Janice Nguyen at 610-337-5006 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. 03001303/2016002

cc: Xiaoqian Wen, Radiation Safety Officer
State of Delaware

No reply to this letter is required. Please contact Janice Nguyen at 610-337-5006 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. 03001303/2016002

cc: Xiaoqian Wen, Radiation Safety Officer
State of Delaware

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	JNguyen/jn		JDwyer/jpd					
DATE	01/09/17		01/11/17					

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001303/2016002
Docket No.	03001303
License No.	07-12153-02
Licensee:	Christiana Care Health Services, Inc.
Location:	4755 Ogletown-Stanton Road Newark, Delaware 19718
Inspection Dates:	April 11, 2016 December 22, 2016 (telephonic exit)
Date Followup Information Received:	April 14 and June 9, 2016

Inspector: ***/RA/*** ***01/09/17***

Janice Nguyen, Senior Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/*** ***01/11/17***

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

Enclosure

EXECUTIVE SUMMARY

Christiana Care Health Services, Inc.
NRC Inspection Report No. 03001303/2016002

An announced, special inspection was conducted on April 11, 2016, at Christiana Care Health Services, Inc. (CCHS) in Newark, Delaware, to review the circumstances surrounding a medical event reported on April 1, 2016 (NMED Item Number 160159). The event involved the delivery of yttrium-90 microspheres to a patient on April 1, 2016, where it was determined after the completion of the procedure that only 75.8% of the prescribed dosage was administered. Additional information provided by CCHS on April 14 and June 9, 2016, was also reviewed. The inspection consisted of a review of licensed activities associated with the use of microspheres at CCHS. CCHS requested that BTG, the TheraSphere manufacturer, examine their delivery system for defects. In-office evaluation of the medical event, the microsphere manufacturer's assessment of their respective device, and CCHS's corrective actions continued through December 22, 2016. The microsphere manufacturer determined on May 24, 2016, that the direct cause of the event was an obstruction in the microcatheter. The source of the obstruction could not be determined conclusively, although inspection of the returned post-treatment materials suggested that kinks in the microcatheter could be the cause, and the residual pressure in the tubing was consistent with the observation of continued flow into the pressure relief vial. Contributing factors may also have included a fragment of septum or a bolus of microspheres or a blood clot which may have contributed to flow obstruction. The licensee reviewed this information with the Authorized User and believes that a blood clot was the most likely cause. They have concluded that minimizing the time between the flush of the microcatheter and dose administration would prevent blood clot formation in the microcatheter. The licensee forwarded their final report to the NRC on June 9, 2016.

Based on the results of this inspection, no violations were identified.

REPORT DETAILS

I. Event Description

a. Inspection Scope

An announced, special inspection was conducted on April 11, 2016, at CCHS in Newark, Delaware to review the circumstances surrounding a medical event reported on April 1, 2016 (NMED Item Number 160159). The inspection was conducted in accordance with Inspection Procedure 87103 and Management Directive 8.10. An in-office review to evaluate the event, the microsphere manufacturer's evaluation of their device, and CCHS's corrective actions continued through December 22, 2016. The medical event was identified by CCHS during a routine patient treatment on April 1, 2016. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event. The inspector also reviewed CCHS's procedures related to microsphere use, documentation, and medical event follow up.

b. Observations and Findings

Microsphere Program

License No. 07-12153-02 authorizes CCHS to provide microsphere treatments using the TheraSphere delivery system at its facility in Newark, Delaware. The licensee began its TheraSphere program in July 2013 and currently has three authorized users (AUs) approved for performing these treatments.

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

April 1, 2016 – A patient scheduled to receive 83 millicuries of yttrium-90 TheraSpheres instead received 62.2 millicuries. A written directive was prepared, as required. According to the AU, when he injected the microspheres, there was immediate saline flow into the pressure relief valve despite only limited pressure on the injection syringe, and the dosimeter reading did not decrease as expected. The AU realized there was an issue and stopped injecting. After discussing possibilities including improper assembly of the delivery system, the AU and Interventional Radiology (IR) physician suspected that either the infusion microcatheter was obstructed or the pressure relief valve was malfunctioning. The pinch clamp at the outlet tubing "E" was open and had been massaged to remove any dents so this was not felt to be the cause. Since occlusion of microcatheters is not uncommon, the physicians felt that this was most likely the probable cause. To flush the occlusion, the pinch clamp at outlet tubing "E" was closed and the tubing was disconnected from the microcatheter and a saline syringe was attached to flush the microcatheter. The IR physician felt immediate resistance to injection, but then overcame the resistance with more pressure. The syringe was then removed and outlet tubing "E" was reattached. The pinch clamp was then released and any dents in the tubing were massaged out. The AU began to inject again and immediately saw that the saline was again entering the pressure relief valve. However, the dosimeter reading began to decrease so the AU continued to inject and completed the procedure. Post-procedure survey by the Nuclear Medicine Technologist (NMT) revealed a small amount of microsphere contamination at the procedure site. All contaminated items were placed into waste storage by the NMT. The AU measured the remaining activity in the waste. Final calculations indicated that 75.8% (94.8 Gy) of the

prescribed activity of 125 Gy was delivered to the right lobe of the liver. The BTG Interventional Medicine (the TheraSphere manufacturer) Sales Representative was on-site for the latter part of the procedure. She recommended that CCHS contact the BTG Sales Director for further evaluation of the cause. It was ultimately determined that the delivery system would be held for decay and then sent back to BTG for the manufacturer's analysis. CCHS reported the medical event to the NRC Operations Center and to Region I.

April 11, 2016 – 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 CCHS's procedures and documentation related to microsphere use.

April 14, 2016 – CCHS submitted its 15-day report in accordance with 10 CFR 35.3045. In the report, CCHS described the event, the suspected cause of the event, the patient notification of the event, and planned future actions.

May 24, 2016 – BTG examined the TheraSphere delivery system and ruled out the possibility of the malfunction of the administration set. BTG determined that the direct cause of the event was an obstruction in the microcatheter. The source of the obstruction could not be determined conclusively, although inspection of the returned post-treatment materials suggested that two kinks in the microcatheter could be the cause, and the residual pressure in the tubing was consistent with the observation of continued flow into the pressure relief valve. It could not be determined if the kinks existed at the time of the patient treatment, or were incurred during the waste handling. Contributing factors may have included an observed fragment of septum, a bolus of microspheres, or a blood clot which may have contributed to the flow obstruction. CCHS reviewed this information with all individuals who participated in the TheraSphere therapy, and believe that the kinks were caused after case completion because the microcatheter flushed very easily initially before the dose administration. It is believed that the first kink was caused by the intentional clamping of the microcatheter at the end of the procedure to prevent any residual radiopharmaceutical from spilling out the catheter during its withdrawal from the patient, and the second kink was caused when the administration set and its attachments were forcefully jammed into the waste jar. Therefore, the kinks on the microcatheter were likely caused by the intentional clamping of the microcatheter and how the waste was handled after the dose administration. CCHS concluded that the source of the original obstruction was likely a blood clot formed inside the microcatheter. The continued pressure built up after the microcatheter was detached and flushed was likely caused by a bolus of microspheres formed in the tubing because of the low flow rate during the first attempt of the dosage administration, which was caused by the blood clot. Their corrective and preventative action is to minimize the time between the flush of the microcatheter and dose administration to prevent blood clot formation in the microcatheter. The BTG sales representative also recommended aborting the procedure should a similar situation happen again.

June 9, 2016 - CCHS provided a copy of their report to the NRC, which included documentation and pictures of the BTG analysis, and CCHS's conclusion and preventative actions.

December 22, 2016 – A final exit meeting was conducted via telephone with CCHS's Senior Vice President of Service Line Operations, Radiation Safety Officer, and AU.

During the exit, the inspector summarized the event, the event reporting, the manufacturer's review, and CCHS's corrective and preventative actions.

c. Conclusions

CCHS reported the medical event as required by 10 CFR 35.3045 and took appropriate corrective and preventative actions. CCHS also notified the involved patient of the event. The AU decided to not give the patient any more treatment, because the delivered dose was close to the prescribed dose (almost 80%), and the follow-up appointment showed that the patient was doing fine. The AU indicated that they will keep monitoring the patient and the results of the treatment. Based on the inspector's observations, no violations of NRC requirements were identified.

I. Exit Meeting

A preliminary exit meeting was conducted on April 11, 2016, to discuss the scope of the inspection and the inspector's initial observations. On December 22, 2016, an exit meeting was held by telephone with Michael S. Eppehimer, MHSA, FACHE, Senior Vice President of Service Line Operations, and other members of CCHS's staff, to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+ Michael S. Eppehimer, MHSA, FACHE, Senior Vice President of Service Line Operations
* Billie Speakman - Vice President, Center for Heart & Vascular Health
* Kirk Garratt – Associate Director, Center for Heart & Vascular Health
*+ Xiaoqian (Carol) Wen, Radiation Safety Officer
*+ Hung Dam, M.D. – Authorized User
* Timothy Manzone, M.D., J.D. – Authorized User, Section Chief of Nuclear Medicine, Chair of Radiation Safety Committee
* Anthony Gialloreto – Director, Non-Invasive
* Cindy Knotts – Manager, Nuclear Medicine and PET
* Dominique Fleming, CNMT, RT(CT) – Nuclear Medicine Technologist

* Present at preliminary exit meeting on April 11, 2016
+ Participated in telephonic exit meeting conducted on December 22, 2016