UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

February 17, 2021

Timothy Bowers, MS, CIC, FAPIC, CPHQ
Vice President Clinical Effectiveness
Christiana Care Health Services, Inc.
Christiana Care Health System
4000 Nexus Drive
Wilmington, DE 19803

SUBJECT: CHRISTIANA CARE HEALTH SERVICES, INC., CHRISTIANA CARE HEALTH SYSTEM, NRC INSPECTION NO. 03001303/2020002

Dear Mr. Bowers:

This letter refers to the virtual inspection conducted on April 17, 2020, of your Newark, Delaware facility. The inspection was limited to a review of a medical event reported to the NRC Operations Center on April 17, 2020. Additional information provided in your correspondence dated April 30, August 14, and October 22, 2020, was also examined as part of the inspection. A telephonic exit meeting was held on January 19, 2021, with select members of your staff. The enclosed report presents the results of this inspection.

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

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response 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.

No reply to this letter is required. If you have any questions regarding this matter, please contact Janice Nguyen of my staff at 610-337-5006 or via electronic mail at janice.nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

Donna M. Janda

Digitally signed by Donna M. Janda
Date: 2021.02.17 16:37:19 -05'00'

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

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

Enclosure:
Inspection Report No. 03001303/2020002

cc: Xiaoqian (Carol) Wen, Radiation Safety Officer
State of Delaware

CHRISTIANA CARE HEALTH SERVICES, INC., CHRISTIANA CARE HEALTH SYSTEM, NRC INSPECTION NO. 03001303/2020002 DATED FEBRUARY 17, 2021

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U.S. NUCLEAR REGULATORY COMMISSION

REGION I

INSPECTION REPORT

Inspection No.	03001303/2020002
Docket No.	03001303
License No.	07-12153-02
Licensee:	Christiana Care Health Services, Inc. Christiana Care Health System 4000 Nexus Drive Wilmington, DE 19803
Location(s):	Christiana Hospital 4755 Ogletown-Stanton Road Newark, DE 19718
Virtual Inspection Dates:	April 17, 2020, additional information dated April 30, August 14, and October 22, 2020, in office review concluding January 18, 2021, telephonic exit meeting on January 19, 2021

Inspector: Janice E. Nguyen Digitally signed by Janice E. Nguyen Date: 2021.02.17 16:33:05 -05'00'

Janice Nguyen — date
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By: Donna M. Janda Digitally signed by Donna M. Janda Date: 2021.02.17 16:37:54 -05'00'

Donna M. Janda, Chief — date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Christiana Care Health Services, Inc., Christiana Care Health System
NRC Inspection Report No. 03001303/2020002

A virtual inspection was conducted on April 17, 2020, of Christiana Care Health Services, Inc. (CCHS) in Newark, Delaware, to review the circumstances surrounding a medical event reported on April 17, 2020 (NMED Item Number 200193). The event involved the delivery of a split dose of yttrium-90 TheraSpheres to a patient on April 16, 2020, where it was determined after the completion of the first procedure that only 11.5% of the prescribed dosage was administered. Additional information provided by CCHS on April 30, August 14, and October 22, 2020, 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 January 18, 2021. The microsphere manufacturer determined that the direct cause of the event was an obstruction or blockage in the microcatheter. The source of the obstruction could not be determined conclusively, although typical causes would be catheter defect, blood clot, kinks, or some combination. The inspection of the returned post-treatment materials suggested that kinks in the microcatheter would be the most likely root cause for this kind of low delivery event. The manufacturer representative also emphasized that if contrast solution is used to verify the cathether flow, then the catheter must be flushed with saline before administering the dose. Although kinks weren't observed on the outside of the cathether during the procedure, the manufacturer indicated that if there were small or undetectable catheter kinks, it would be very difficult to feel any resistance during the verification of the flow, since saline will pass through catheters with multiple kinks and/or damage. For preventative actions, the licensee confirmed that only saline will be used for the microcatheter flush immediately before connecting the microcatheter to the TheraSpheres outlet tubing, and revised their TheraSpheres checklist to reflect this change. In addition, if a Radiology resident or Interventional Radiology (IR) fellow is performing the microcatheter saline flush, that individual will inform the IR physician if any resistance is felt during the saline flush. The licensee forwarded their final report to the NRC on August 14, 2020, and the manufacturer's report on October 22, 2020.

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

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

Because of the Covid-19 public health emergency (PHE), the inspection was conducted virtually on April 17, 2020, via telephone to review the circumstances surrounding a medical event reported to the NRC Operations Center on April 17, 2020 (NMED Item Number 200193). 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 January 18, 2021. The medical event was identified by CCHS during a routine patient treatment on April 16, 2020. The inspector conducted interviews with licensee personnel 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 four authorized users (AUs) approved for performing these treatments.

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

April 16, 2020 – A patient with hepatocellular carcinoma was being treated to the right liver lobe with Theraspheres as a split dose. During the administration of the first dose to the right lobe supplied by the anterior right hepatic artery, the AU noticed increase pressure in the syringe. As the AU pushed the syringe further, more than expected saline flow entered the pressure relief vial. The AU performed 3 flushes, but the dosimeter actually rose from a baseline of 11.7 mR/hr to up to 13.8 mR/hr rather than decreasing. The dosimeter was moved to the metal extension arm holding the microcatheter and read 0.7 mR/hr indicating that microspheres were present in the microcatheter. Therefore, due to the possibility of microsphere contamination, the AU decided not to disconnect the microcatheter from the outlet tubing "E" from the TheraSpheres delivery device in attempt to flush any obstruction in the microcatheter.

To attempt to overcome and bypass the high pressure due to a possible malfunction in the pressure relief valve, the AU cut the proximal tubing from the dose vial at the indicated cut line and inserted an adapter into the tubing. A 3 mL syringe was then attached to the adapter. Flushes were attempted but were unsuccessful. A 1 mL syringe was then attached to the adapter. Flushes were attempted but were also unsuccessful. At this point, the AU decided to abort the therapy. The final reading on the dosimeter was 12.5 mR/hr. The microcatheter was pulled into the base catheter to avoid contamination from the tip of the microcatheter during removal and both catheters were removed.

A new base catheter and microcatheter were used for the second dose to the right lobe supplied by the posterior right hepatic artery. The dose was given successfully without any complications. No staff or room contamination was detected after the procedure. The patient, family, and attending oncologist were notified.

The AU measured the remaining activity in the waste. The final calculations are as follows:

Right liver supplied by the *anterior* right hepatic artery:
Prescribed dose: 97.3 mCi (140 Gy).
Dose given: 11.0 mCi (16.1 Gy, 11.5% of the prescribed dose)

Right liver supplied by the *posterior* right hepatic artery:
Prescribed dose: 30 mCi (130 Gy).
Dose given: 27.5 mCi (121.5 Gy, 93.2% of the prescribed dose)

April 17, 2020 – CCHS reported the event to the NRC Operations Center. NRC Region I conducted telephone and email interviews to review the circumstances surrounding the reported medical event.

April 24, 2020 – CCHS emailed the inspector records applicable to the event, which included the written directive, TheraSpheres checklist, etc. The inspector reviewed the records, in addition to CCHS's procedures and documentation related to microsphere use. No issues were identified. The patient had repeat therapy to the right liver supplied by the anterior right hepatic artery without issue.

April 30, 2020 – CCHS submitted its 15-day report in accordance with 10 CFR 35.3045. In the report, CCHS described the event, the possible causes of the event, the patient notification of the event, and confirmed that planned future actions would be solidified once the root cause was established by the manufacturer.

June 29, 2020 – Boston Scientific (BS), which owns BTG, requested that the administration set be shipped to them before the residual activity decayed to background level since they would need the activity in the tubing to help map the microspheres in their investigation. CCHS shipped the TheraSphere administration set to BS to determine the root cause of the medical event.

July 31, 2020 – Because of the PHE, BTG/BS had travel restrictions in place with their manufacturing facility, and the investigation was delayed. BTG examined the TheraSphere delivery system by visual inspection, radiation measurement, digitial microscopy and pressure/flow testing. BTG determined that the direct cause of the event was an obstruction or blockage in the microcatheter. The source of the obstruction could not be determined conclusively, although typical causes would be catheter defect, blood clot, kinks, or some combination. The inspection of the returned post-treatment materials suggested that kinks in the microcatheter would be the most likely root cause for this kind of low delivery event. Although kinks weren't observed on the outside of the cathether during the procedure, the manufacturer indicated that if there was a small or undetectable catheter kink, it would be very difficult to feel any resistance during the verification of the flow, since saline will pass through catheters will multiple kinks and/or damage. Although minor kinks are not enough to occlude saline flow, TheraSpheres are physically solid and will not pass minor kinks easily

relative to liquids. The manufacturer emphasized that if the catheter is flushed with contrast solution, the most important thing is to flush again with saline before the administration. The reason is the contrast solution has high viscosity and will cause high backpressure that hinders the flow of solid microspheres.

For preventative actions, the licensee confirmed that only saline will be used for the microcatheter flush immediately before connecting the microcatheter to the TheraSpheres outlet tubing, and revised their TheraSpheres checklist to reflect this change. In addition, if a Radiology resident or Interventional Radiology (IR) fellow is performing the microcatheter saline flush, that individual will inform the IR physician if any resistance is felt during the saline flush.

August 14, 2020 - CCHS provided an addendum to the previously submitted written report to the NRC, which summarized the BTG analysis, and CCHS's conclusion and preventative actions.

October 22, 2020 – CCHS provided the email chain from BTG/BS which details the investigation.

January 19, 2021 – A final exit meeting was conducted via telephone. During the exit, the inspector summarized the event, the event reporting, the manufacturer's review, and CCHS's conclusion 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 successfully retreated the area on April 24, 2020, without issue. Based on the inspector's observations, no violations of NRC requirements were identified.

I. Exit Meeting

On January 19, 2021, an exit meeting was held by telephone to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
+Individual(s) present for telephonic exit meeting

Kert F. Anzilotti, M.D., MBA, FACR, Chief Medical Officer
Hung Dam, M.D., Chief of Nuclear Medicine, RSC Chair
#+ Xiaoqian (Carol) Wen, RSO