From: Janda, Donna
To: Wen, Carol; Elliott, Robin; Tindle-Engelmann, Elizabeth
Cc: Dam, Hung Q; Anzilotti, Kert
Subject: RE: RE: NRC / Christiana Care Health Services Inspection Report
Date: Monday, October 5, 2020 11:19:09 AM

Licensee Name: Christiana Health Care Services, Inc.
License No.: 07-12153-02
Docket No: 030-01303
Inspection No: 03001303/2020003

Good morning Carol,

This refers to your request for clarification of the facts listed in the inspection report dated September 28, 2020. In an email dated September 30, 2020, you provided the following information regarding the Y-90 Microsphere program and we agree with the clarifications you provided as described below:

- For Theraspheres: Per our IRB, all potential Theraspheres must be seen at the Helen F. Graham Cancer and research Institute's Hepatobiliary Multi-Disciplinary Committee (HFGCC&RI MDC). Here, a team of physicians from surgery, interventional radiology, medical oncology, and nuclear medicine collective decide the patient's management.

- For SIR-spheres: not under the control of the IRB. Mostly all patients are also seen at the HFGCC&RI MDC. However, occasionally medical oncologists send the patients directly to the interventional radiology. When this happens, both interventional radiology and nuclear medicine physicians see the patient together at the interventional radiology clinic.

- The actual microspheres treatment only involves the interventional radiology and nuclear medicine physicians and support staff.

- Radiation oncologists are not involved with microspheres therapies.

- AMP's are not involved with microspheres therapies. The dose and delivery systems are prepared by the nuclear medicine AU's and technologists.

In addition, you expressed concern that the violations of 10 CFR 35.60 and 10 CFR 35.63 that were cited were misleading because they resulted from the failure to train one of the authorized users utilizing the Rubidium generator. NRC Enforcement Guidance Memorandum (EGM) entitled "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," was established for inspectors to exercise discretion for certain violations of NRC regulations if certain criteria are met. One of these criteria is that all authorized users for medical uses under 10 CFR 35.200 who use Rb-82 chloride must complete training specific to the manufacture and model of the generator and infusion cart being used. Because this criterion was not met, the two violations associated with use of the Rb-82 generator, and described in the EGM, were issued.

If you do not agree with the violations as issued, you may contest the violations by following the process noted in the Notice of Violation issued on September 28, 2020.

This email will be placed in the Agencywide Documents Access and Management System as a publicly available document.

Sincerely,

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
U.S. NRC Region I
Work: 610-337-5371
Fax: 610-337-5269
Donna.Janda@nrc.gov

From: Wen, Carol <Xiaoqian.Wen@ChristianaCare.org>
Sent: Thursday, October 1, 2020 1:50 PM
To: Elliott, Robin <Robin.Elliott@nrc.gov>; Tindle-Engelmann, Elizabeth <Elizabeth.Engelmann@nrc.gov>
Cc: Janda, Donna <Donna.Janda@nrc.gov>; Dam, Hung Q <HDam@Christianacare.org>; Anzilotti, Kert <KAnzilotti@Christianacare.org>
Subject: [External_Sender] RE: NRC / Christiana Care Health Services Inspection Report

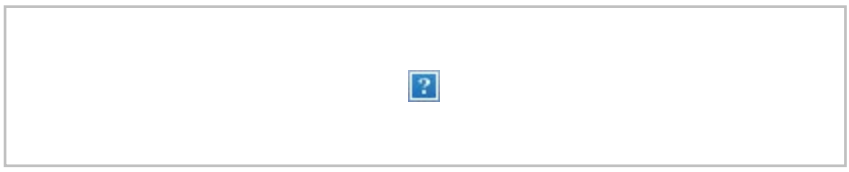
Hi Robin and Elizabeth,

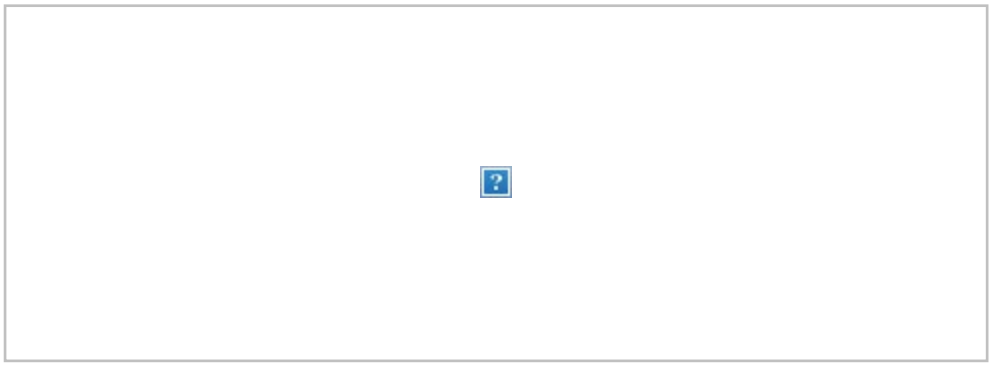
After internal discussions, we would like to request the management of NRC consider and authorize a revision to the current inspection report to:

- clarify the justifications of the two violations involving Rb-82 generator listed in the Notice of Violation (page 4/15 and 5/15) and Report Details (13/15 and 14/15), and
- revise the description of the microsphere program (page 11/15) to accurately reflect our true practice.

Specifically, below is a suggested revision for your consideration.

Current Wording	Proposed Wording
On Page 4/15 and Page 13/15, 14/15	Contrary to the criteria listed in the NRC Enforcement Guidance Memorandum (EGM) 13-003 dated April 18, 2013 with the subject "*Enforcement Guidance Memorandum (EGM) – Interim Guidance For*

	Dispositioning Violations Involving 10 CFR 35.60 And 10 CFR 35.63 For The Calibration Of Instrumentation To Measure The Activity of Rubidium-82 And The Determination Of Rubidum-82 Patient Dosages" the licensee did not meet the AU training criteria required for the enforcement discretion. Specifically, the AU who joined ChristianaCare in 2020 did not complete training specific to the manufacturer and model of generator and infusion cart being used prior to using Rb-82 chloride.
Page 5/15 and Page 14/15 	Contrary to the criteria listed in the NRC EGM the licensee did not meet the AU training criteria required for the enforcement discretion.

	Specifically, the AU who joined ChristianaCare in 2020 did not complete training specific to the manufacturer and model of generator and infusion cart being used prior to using Rb-82 chloride.
Page 11/15 	The licensee used both SIR-Spheres and TheraSpheres as part of their Y-90 microsphere program. TheraSphere therapies were conducted per IRB protocol and managed by the Helen F. Graham Cancer and Research Institute's Hepatobiliary Multi-Disciplinary Committee (HFGCC&RI MDC). The microspheres were received by the NM department. Prior to treatment, a Tc-99m MAA mapping study was performed to map out the

	arteries and determine the lung shunt fraction. The NM department prepared the delivery system and guided by a step-by-step procedure document. A survey of the materials following the procedure was performed and used to calculate the administered dose. Post therapy imaging was performed by NM prior to patient discharge. The final dose was recorded on the written directive and used to evaluate whether the administration followed the prescription or whether a medical event occurred. Waste materials were stored for decay prior to disposal.

We really appreciate your thorough review of our program! NRC inspections always provide valuable insights and opportunities to further tighten up and improve our Radiation Safety Program. We believe the NRC inspection report should provide an accurate description of the issues identified and program

reviewed.

Sincerely,

Carol

From: Wen, Carol
Sent: Wednesday, September 30, 2020 11:02 AM
To: Tindle-Engelmann, Elizabeth <Elizabeth.Engelmann@nrc.gov>
Cc: Elliott, Robin <Robin.Elliott@nrc.gov>
Subject: RE: NRC / Christiana Care Health Services Inspection Report

Hi Elizabeth,

Dr. Dam pointed out a couple of issues in section 1B, paragraph at top of pdf page 11/15 (or page 6/10 of the document)

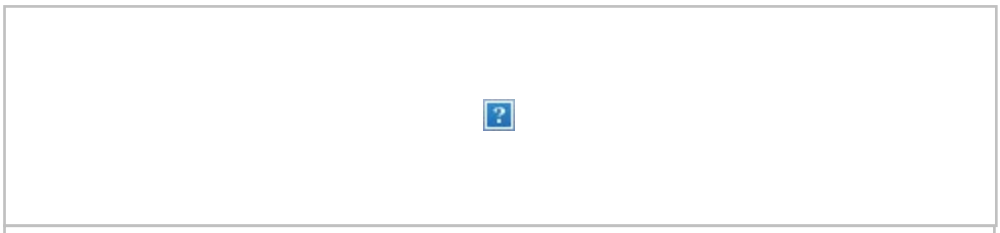
"The NM AU consulted with the **Radiation Oncologist** and the surgeon to evaluate each patient prior to treatment by performing a Tc-99m MAA mapping study to determine the lung shunt fraction. Each treatment involved the participation of NM, Interventional Radiology, **Surgery, Oncology**, and other support staff. The **AMPs** prepared the delivery system using a step-by-step procedure developed by the manufacturer."

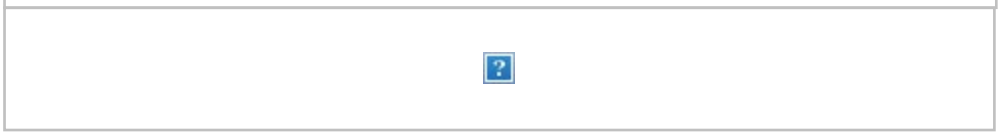
-For Theraspheres: Per our IRB, all potential Theraspheres must be seen at the Helen F. Graham Cancer and research Institute's Hepatobiliary Multi-Disciplinary Committee (HFGCC&RI MDC). Here, a team of physicians from surgery, interventional radiology, medical oncology, and nuclear medicine collective decide the patient's management.

-For SIR-spheres: not under the control of the IRB. Mostly all patients are also seen at the HFGCC&RI MDC. However, occasionally medical oncologists send the patients directly to the interventional radiology. When this happens, both interventional radiology and nuclear medicine physicians see the patient together at the interventional radiology clinic.

-The actual microspheres treatment only involves the interventional radiology and nuclear medicine physicians and support staff.
-Radiation oncologists are not involved with microspheres therapies.
-AMP's are not involved with microspheres therapies. The dose and delivery systems are prepared by the nuclear medicine AU's and technologists.

Also the description of the two violations (page 4/15) regarding Rb-82 generator seems misleading. I understood that we would be cited for violating 10 CFR 35.60(a)(b) and 10 CFR 35.63, however the reason of the violation was due to not meeting one of the criteria listed in the Enforcement Guidance Memorandum and not the reasons described below. We did calibrate the generator based on the instructions provided by the manufacturer and determine and record the activity of each dosage of Rb-82 before medical use.





I don't mean to be nitpicking here, but the report will be available on NRC's website and for the general public's review, so thought it's important to have the wording accurately reflecting the issues identified.

Best,

Carol

From: Tindle-Engelmann, Elizabeth <Elizabeth.Engelmann@nrc.gov>
Sent: Monday, September 28, 2020 2:47 PM
To: Anzilotti, Kert <KAnzilotti@Christianacare.org>
Cc: Robert.Brinsfield@delaware.gov; Elliott, Robin <Robin.Elliott@nrc.gov>; Wen, Carol <Xiaoqian.Wen@ChristianaCare.org>
Subject: [EXTERNAL] NRC / Christiana Care Health Services Inspection Report

Dr. Anzilotti,

This email has a PDF attached. The PDF contains the inspection report and cover letter from the recent inspection. Please contact me or Robin Elliott if you have questions or concerns.

You will not be receiving a paper copy of these documents in the mail. You should save copies of these documents for your records.

Best regards,

Elizabeth Tindle-Engelmann
Health Physicist, Medical and Licensing Assistance Branch
U.S. Nuclear Regulatory Commission
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406
(610) 337-5115 office