Secure Message Center

From: yongli.ning@providence.org
Sent: Thu 6/29/2017 5:14 PM
To: katanic janine <janine.katanic@nrc.gov>
Cc: honeycutt robert <robert.honeycutt@providence.org>; hazelbaker scott <scott.hazelbaker@providence.org>; hernandez pete <pete.hernandez@nrc.gov>; stratman joe <joseph.stratman@providence.org>
Subject: RE: ProvSecure RE: NRC inspection related to reported medical event
Attachments: PAMC Report to NRC for 6-14-2017 TheraSphere event for lung.doc [52 KB]
PAMC TheraSphere Corrective Plan.docx [16 KB]

Dr. Katanic,

Please see the attached for the updated corrective plan and a separate written report for the organ (lung) involved in the 6/14/2017 TheraSphere event following the phone call to NRC Operation Center yesterday (6/28/2017).

Both reports uses the same Event #52807. A hard copy was handed to you today.

Thank you.

Yongli Ning, MS
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
Providence Alaska Medical Center & Providence Imaging Center

From: Ning, Yongli
Sent: Monday, June 26, 2017 11:16 AM
To: 'Katanic, Janine' <Janine.Katanic@nrc.gov>
Cc: Hernandez, Pete <Pete.Hernandez@nrc.gov>; Hazelbaker, Scott <Scott.Hazelbaker@providence.org>; Stratman, Joe <Joseph.Stratman@providence.org>; Honeycutt, Robert <Robert.Honeycutt@providence.org>
Subject: ProvSecure RE: NRC inspection related to reported medical event

Dr. Katanic,

Please see the attached for the written report that is following the telephone report to NRC for a medical event during a TheraSphere treatment happened on 6/14/2017, per Reg 10 CFR 35.3045.

A hard copy will be mailed to you upon request.

Thank you.

Yongli Ning, MS
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
Providence Alaska Medical Center & Providence Imaging Center

From: Katanic, Janine [mailto:Janine.Katanic@nrc.gov]
Sent: Monday, June 19, 2017 11:18 AM
To: Ning, Yongli <Yongli.Ning@providence.org>
Cc: Hernandez, Pete <Pete.Hernandez@nrc.gov>
Subject: NRC inspection related to reported medical event

Yongli:

As discussed, the NRC plans to perform a reactive inspection related to the medical event that you reported to the NRC on June 15, 2017. I will be the lead inspector and Mr. Pete Hernandez, Health Physicist, will also be participating in the inspection. We will be arriving at your facility on Tuesday June 27 and expect that the inspection will take 2 to 3 days. We would like to get started first thing in the morning on June 27, with an entrance meeting involving hospital administration and any other applicable individuals.

I would like to speak with the appropriate individual in your management or hospital administration to discuss logistics and expectations for the inspection. If someone could contact me as soon as possible, that would be appreciated. My office phone number is below.

Thank you.

Dr. Janine F. Katanic, CHP

Senior Health Physicist

US Nuclear Regulatory Commission

Region IV

Division of Nuclear Materials Safety

office: 817-200-1151

email: Janine.Katanic@nrc.gov

PROVIDENCE
Alaska
Medical Center

June 28, 2017

Nuclear Materials Safety Branch B
Region IV
Arlington, TX 76011

Subject: Report to NRC for TheraSphere Medical Event Regarding Lung

Event #: 52807
Report date: 6/15/2017

Licensee: Providence Alaska Medical Center
License number: 50-17838-01, Amendment No. 70

Authorized user: Eric J. Maurer, M.D

This is to follow up the telephone report to NRC for a medical event during TheraSphere treatment that happened at 2:40 PM, 6/14/2017, per Reg 10 CFR 35.3045 (a) (3).

The event indicated a wrong dose delivered to the patient (MRN: [redacted] when the patient was treated with Y90 TheraSphere microspheres.

A series of mistakes contributed to this misadministration. First, the radioactive source was ordered to a calibration date of 6/11/2017 instead of 6/4/2017 as calculated, leading to a much higher activity on 6/14/2017 due to a shorter decaying. Also, the directive sheet was not filled out and reviewed by the Authorized User before treatment. Second, the source was surveyed with dose calibrator but the abnormal results did not rouse attention by comparison to the calculated data. Also the results were not recorded in the directive sheet before treatment. All these caused a much higher dose 540.6 Gy instead of 110 Gy as prescribed, to be delivered to the treatment site: the right lobe of the liver.

The mistake was realized after the procedure was completed and the directive sheet was filled out on the day of treatment. The physician Dr. Maurer was informed of the error. He discussed the unanticipated dose administration and possible complications with the patient. The patient was offered a hospital admission for observation but preferred to go home. The patient will receive early and frequent follow-ups including provider calls and lab checks. All these were recorded in the medical record in Epic.

Nuclear medicine scans were obtained the same day of the treatment and the next day. They showed the expected distribution of the tracer within the right lobe of the liver. The radiation to lung per lung shunting calculation indicates 25.76 Gy for this treatment and 34.49 Gy for cumulative dose, referring the vendor's manual indicating that lung dose should not exceed the limit of 30 Gy per single infusion and 50 Gy cumulatively. The final evaluation for lung with radiation is pending for Authorized User's analysis.

The hospital started UOR (unusual occurrence report) procedure at the same time to work on a root cause analysis process, to review and summarize the event, and to adopt corrective actions to prevent recurrence.

The TheraSphere procedure hence is suspended till further notice following the NRC inspection, scheduled on 6/27/2017.

Yongli Ning, M.S.
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
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3200 Providence Drive
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Appendix for the written report to NRC
With regard to medical event with TheraSphere

Event #: 52807

A Corrective Plan

The current policy and procedure was reviewed. While it was determined that the current procedure is still standing to guarantee the correctness of source order and dose delivery, considering the importance of the step-by-step implementation, the following will be stressed and reiterated in the policy as a part to be added:

1. Before ordering the source, the written directive is to be filled out and signed/dated by the AU in the Pre-Treatment Planning section.

   Specifically, the item "Dose to Target Volume at Treatment, accounting for lung shunt (Gy)" must match the item "Desired Dose to Target Volume (Gy)" within 10%.

2. Before delivering the dose, the written directive is to be filled out and signed by Technologist in the Pre-Treatment Dose Calibrator (DC) Measurement section.

   Specifically, the item "DC Measured Activity, with correction factor (GBq)" must match the item "Nominal Activity in Vial at time of Treatment (GBq)" within 10%.

A method will be developed by using either survey meter or dosimeter to measure the dose rate (mR/h) by the Authorized User to compare with a calculated data to confirm the correct activity to be used before delivering the dose to patient.

All staff, including Authorized Users and technologists will go through a refresher course to strengthen the expertise and proficiency.

For the next five cases, the source ordering procedure will be closely monitored by the medical physicist, the RSO and the order will not be placed without the approval by the medical physicist, the RSO.

The event will be reviewed, discussed and evaluated in the radiation safety committee (RSC) and the results will be reported to the hospital management.

Yongli Ning, M.S.
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
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