Katanic, Janine

From: Ning, Yongli <Yongli.Ning@providence.org>
Sent: Friday, June 30, 2017 5:54 PM
To: Katanic, Janine
Cc: Hernandez, Pete; Honeycutt, Robert; Hazelbaker, Scott; Steeves, Erica; Davis, Melissa A; Baldwin, Betsy; Goss, Ella; Stratman, Joe
Subject: [External_Sender] Final written report to NRC for TheraSphere event of 6/14/2017
Attachments: Final PAMC Report to NRC for 6-14-2017 TheraSphere event.pdf; Final PAMC Report to NRC for 6-14-2017 TheraSphere event for lung.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dr. Katanic,

I am sending you the written reports for the TheraSphere event of 6/14/2017 again. This version, per your instruction, has patient's indicator (MRN) removed, and has "Final" adding to the subject.

Please contact me if you have any question.

Thank you.

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

PROVIDENCE
Alaska
Medical Center

June 30, 2017

Nuclear Materials Safety Branch B
Region IV
Arlington, TX 76011

Subject: **Final Report to NRC for TheraSphere Medical Event**

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.

The event indicated a wrong dose delivered to a patient 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 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
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, AK 99516-6604

Note: Appendix is on the next page

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.

The dose calibrator that is used to measure the activity of the source vial will be re-calibrated with an Y90 source from the vendor.

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.

PROVIDENCE
Alaska
Medical Center

June 30, 2017

Nuclear Materials Safety Branch B
Region IV
Arlington, TX 76011

Subject: **Final 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 a patient 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
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, AK 99516-6604