Katanic, Janine

From: Schippers, Dale <dschippers@Queens.Org>
Sent: Tuesday, May 21, 2019 8:34 PM
To: Katanic, Janine; MSHD Resource
Cc: Goerner, Frank
Subject: [External_Sender] RE: NRC reported medical event
Attachments: Y-90 Medical Event, May8, 2019 NRC Report.pdf

Please find attached our report for the medical event that occurred on May 8, 2019.

Report of Medical Event

Date of this report: May 21, 2019

Date of the event: May 8, 2019 1:17 PM

Ordering Physician: Ryan Matsuo, MD;

Medical Oncologist for the patient: J. Acoba, MD

Licensee's name: The Queen's Medical Center (license 53-16533-02)

Brief Description:

The radioactivity of the Y-90 vial was assayed in our dose calibrator and the activity was confirmed by a second individual to agree with the prescribed dose on the patient's Written Directive.

The administration set was primed by Darren Tasaka, RT (R).

The patient was prepared for the Therasphere administration in the Interventional Radiology (IR) room. The catheter was positioned into the right hepatic artery for a treatment to the right lobe. The IR physician, Jean Colon-Pons, MD, verified the catheter position, performed the time out and started the infusion at 1:17 PM (HST). Shay Lee, MD, as the Authorized User, was present and supervising the dose administration. Shortly after the initiation of source delivery the Interventional Radiologist experienced high resistance to flow and most of the saline was released into the vented vial (and not into the patient via the delivery system/catheter). The cause of the obstruction is still under investigation but Dr. Colon-Pons noticed several small air bubbles in the delivery line. Our hypothesis, at this point, is that the micro catheter was obstructed either by a small air pocket or a kink.

Due to the difficulty experience in delivering the dose, Jhun Fronda (physics tech) called Dr. Frank Goerner (medical physicist) to assist. Dr. Goerner joined the team in the IR room and reviewed the situation with Dr. Colon-Pons, Dr. Lee and the IR staff. Dr. Goerner determined, from ion chamber measurements, that a large portion of the dose was still in the delivery system. Together the team decided that nothing more could be done to inject all of the Y-90 dose.

Dr. Colon-Pons removed the micro catheter from the patient and the catheter and administration set were placed into the Nalgene bottle.

The staff present in the room were surveyed upon exit. The room was surveyed for radioactive contamination and none was found. The residual activity in the Nalgene bottle was measured using an ionization survey meter and determined to be 40% of the total dose (total dose=3 GBq).

At approximately 4:00 PM, the patient and the administration/catheter set were imaged using our PET scanner to better evaluate the delivered activity to the patient and the residual activity in the dose delivery system. It was confirmed that 491 MBq (13.2 mCi) was delivered to the patient

and the residual activity was 737 MBq (19.9 mCi). So 40% of the dose was delivered to the patient with 449 MBq (38.5%) to the right lobe of the liver and approximately 42 MBq to the lungs. The lung activity was per our plan as stated on the Written Directive (8.5% lung shunt).

Why the event occurred:

Shortly after the initiation of source delivery the Interventional Radiologist experienced high resistance to flow and most of the saline was released into the vented vial (and not into the patient via the delivery system/catheter). The cause of the obstruction is still under investigation but Dr. Colon-Pons noticed several small air bubbles in the delivery line. Our hypothesis, at this point, is that the micro catheter was obstructed either by a small air pocket or a kink.

The effect on the patient:

No harm was done to the patient since the activity was delivered to the target organ and the dose did not exceed the prescribed dose. The patient may be asked to return for retreatment depending upon tumor response.

Actions taken or planned to prevent recurrence:

1. Re-training of physicians and staff on proper Y-90 administration system setup was done with the vendor on May 15 and 16, 2019.
2. The checklist for the procedure was changed to instruct both the IR technologist and the IR radiologist to check for air bubbles prior to piercing the dose vial.
3. The checklist for the procedure also now requires that the IR radiologist perform a wet connection when connecting the catheter to the administration set. This helps to eliminate air bubbles at the connection point.
4. The administration set and catheter will be sent to the manufacturer (BTG) for their analysis as to the cause of the obstruction.

Notifications to Affected Individuals and NRC

Notifications: Call in time of 1808 EDT to NRC Operations Center. Event number: 54057

The patient's [redacted] was notified of the event by telephone on May 9, 2019 at 11:30 AM.

The ordering physician, and the patient's medical oncologist, were notified on May 9.

This report, with the patient's name and medical record number, was provided to the ordering physician, and the patient's medical oncologist on May 21, 2019.

Report prepared by:

Dale Schippers, RSO, DABR