SPECTRUM HEALTH

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**Evan J. Boote, Ph.D.**
Director, Physics and Technology

May 10, 2016

Ryan Craffey
Region III
United State Nuclear Regulatory Commission
24453 Warrenville Road, Suite 210
Lisle, IL 60532

Dear Mr. Craffey:

Please find enclosed our report on a medical event that occurred at our facility on April 27, 2016. This report is to fulfil our commitment to 10 CFR 35.3045. This event was reported by phone to Mark Abramovitz (NRC Operations Center) at 16:57 EDT on April 27, 2016. An email was sent to hoo.hoc@nrc.gov following this conversation.

Since you were at our site on Tuesday, May 3 for a reactive inspection and you are familiar with the circumstances, I have sent this report to you. Please let me know if I need to forward this to the attention of a different individual.

A copy of this communication, along with the patient's name and medical record number, have been forwarded to the referring physician.

Sincerely,

Evan J. Boote, Ph.D., RSO
Director, Physics and Technology
Radiology, Spectrum Health

cc: Dr. Brad Betz, Chair, Radiation Safety Committee
Larry Genzink, Director, Radiology Services, Spectrum Health

(i) *Licensee:* Spectrum Health (NRC License #21-00243-06)

(ii) *Prescribing Physician:* Michael Doherty, M.D.

(iii) *Brief Description:* On April 27, 2016 at 14:05 EDT, Yttrium 90 microspheres (Therasphere) were used in a treatment of a patient diagnosed with hepatocellular carcinoma. The patient was previously treated in the medial segment, left hepatic lobe (Segment 4) with 0.82 GBq (Y90 Therasphere) on January 27, 2016. The written directive for this treatment prescribed 3.3 GBq of activity to deliver a 120 Gy dose to segments 5, 6, 7 and 8 (Right lobe). The catheter was placed in the right hepatic artery and the position was confirmed using subtraction angiography. The microspheres were infused without incident. However, when post-infusion bremsstrahlung imaging was performed, it was recognized that the dose had been delivered to segment 4. The patient and family were informed immediately following this recognition. The patient's referring physician was informed the next day (4/28).

(iv) *Why the event occurred:* During the time between catheter placement and attachment of the Therasphere infusion, patient movement and/or breathing shifted the position of the catheter tip sufficiently to cause the improper infusion of microspheres to segment 4. The normal procedure steps would have used fluoroscopic imaging along with a small amount of iodinated contrast agent (immediately prior to connection of the Therasphere treatment device) to verify the catheter position and flow to the correct segment(s) of the liver. In this particular instance, this step was not performed. It is possible that using fluoroscopic imaging might have revealed the change in catheter position and retrograde flow that apparently caused this event.

(v) *The effect, if any, on the individual who received the administration:* The individual experienced symptoms similar to those experienced in the normal course of these therapies (nausea and fatigue); however, no other deleterious effects have been observed. The patient did have residual disease in the segment that received the microspheres and likely would have been re-treated at some point in the future. This segment of the liver will atrophy as a result of the total dose of approximately 500 Gy from the Jan 27 and April 27 infusions. The prognosis for the patient has not changed substantially; the physician anticipates that the patient will return in four to five weeks to have segments 5 through 8 treated. Potentially, the most serious impact on the patient is the delay in treatment as a result. Follow-up with the patient, including a check of liver function tests was to be performed during the week of May 9, 2016. As of the time of this report, the patient has been rescheduled for a treatment of the right lobe (segments 5,6,7,8) on May 31.

(vi) *Actions taken to prevent recurrence:* Spectrum Health uses an in-room checklist (see attached) that is read by an assistant (technologist or nurse) during the procedure. This checklist does stipulate that the position of the catheter must be verified prior to connection to the Therasphere box/vial. As a last-moment check, this checklist has been modified to specify that fluoroscopic imaging along with iodinated

contrast agent is to be used to verify catheter position. (see attached checklist and noted modifications) This checklist was put into practice immediately following the event on April 28, 2016.

(vii) *Certification of notification:* The physician who performed the infusion (Doherty) informed the patient and his family immediately after (approximately 16:30 EST on April 27, 2016) discovering the incorrect segment infusion. The RSO (Evan Boote) was present in Butterworth Hospital Room A325 (Radiology Prep and Recovery) at this time. The following day, April 28, the patient's referring physician was unavailable; Dr. Doherty explained the event to his nurse.

**Interventional Radiology**

# TheraSphere Checklist

**Patient Name:** _____ **MRN:** _____ **DATE:**_____

1. ***Materials Required for TheraSphere Administration:***
   ***(whs=warehouse stock item)***

- ❑ NM - Signed Written Directive Form (patient prescription for TheraSphere)
- ❑ NM- Remove the lead pot lid and place it upside down on a non-sterile surface.
- ❑ NM- Ionization Survey Meter
- ❑ NM- GM Contamination Meter
- ❑ NM- Spill Kit
- ❑ **IR- RN to check patient identification and pregnancy section**
- ❑ Drape for floor – apply under cart in angiography suite
  - Kimberly-Clark #89131 (steril XL drape, 76x100);special order box of 20
- ❑ Place a sterile table cover on the cart.
  - Table Cover #651225 whs
- ❑ Place the following items on the draped cart:

| *Sterile side of cart:* | *Non-sterile side of cart:* |
|---|---|
| ❑ Hemostat<br>▪ WHS #651821<br>❑ Scissors<br>▪ WHS #650283<br>❑ Steri-strips<br>▪ WHS # 650857 (½ x 4" )<br>❑ Towels<br>▪ WHS #651877 (4 pack)<br>❑ Gauze<br>▪ WHS #650089 (2x2)<br>❑ Administration Set → open and remove from the sterile blister pack. (includes 20 mL syringe, 20 mL vial)<br>▪ Provided by theraspheres | ❑ TheraSphere Acrylic Box → remove top shield and fully extend stainless steel arm.<br>❑ Bag hook → install on acrylic box.<br>❑ 250 ml bag Saline (0.9% NaCl) → obtain from pyxis and hang on hook.<br>❑ Electronic dosimeter (RADOS RAD 60Ror equivalent) → turn on, set to **mR/h**, clip to bracket on acrylic box.<br>❑ 2L Nalgene waste container with Beta Shield → remove lids. (provided by NM- lawson express order #71744)<br>❑ TheraSphere Dose Vial (in lead pot)<br>→ Gently rock the lead pot back and forth to wet any microspheres on the vial septum. Place lead pot inside acrylic box holder.<br>❑ Alcohol Swabs |

2. ***Procedure time outs***
   - ❑ ***Patient verification (IR physician and NM WD)***
   - ❑ ***Type of procedure (Theraspheres or Sirspheres)***
   - ❑ ***Location of treatment (Which liver lobes)***
   - ❑ ***Dose to be used (GBq) – prescribed/and or measured***
   - ❑ ***All staff and room properly prepared***

3. ***Administration Set Priming***
   - ❑ Insert the non-vented white piercing spike (CLEAR CAP) into the saline bag.
   - ❑ Insert the white vented spike (BLUE CAP) into the empty 20mL vial and place the empty 20 mL vial in holder on the acrylic box and push the relief valve tube into gripper clip 'A'.
   - ❑ Remove the (RED RUBBER) shield cap from the Needle Injector Assembly and place the Needle Injector Assembly on a sterile towel.
   - ❑ Turn syringe plunger fully clockwise to ensure it is unlocked.
   - ❑ Slowly fill and discharge the syringe to remove air from the Administration Set tubing and syringe. Continue priming until there are no bubbles in the lines and there are continuous streams of saline flowing out of both needle holes in the Needle Injector Assembly. Fill the syringe when priming is complete.

4. ***Dose Vial Preparation-Interventional Radiologist***
   - ❑ Use a hemostat to remove the purple seal from the top of the dose vial acrylic shield. Discard the seal in the Nalgene waste container.
   - ❑ Use a Steri-strip to remove the acrylic shield plug. Discard the plug and Steri- strip in the Nalgene waste container.
   - ❑ Use an alcohol swab and a hemostat to disinfect the dose vial septum. Discard the swab in the Nalgene waste container.

5. ***Final Assembly***
   - ❑ Close the pinch clamp on outlet tubing near label 'E'.
   - ❑ Hold the Needle Injector Assembly and place inlet line through slot 'B' in the acrylic box, and outlet line through slot 'D'.
   - ❑ Insert the Needle Injector Assembly into the acrylic dose vial shield. Press on the GREEN cap to lock in place. **You will hear or feel a click or snap.**
   - ❑ Loop tubing around the side and slide connection firmly into slot 'C'.
   - ❑ Push the YELLOW tabs all the way down, locking the needles into the dose vial. **You will hear or feel a click or snap at the bottom of travel.**
   - ❑ Place the top shield on the acrylic box with the sloped shield towards the catheter. Ensure tubing is not pinched or kinked._____
   - ❑ Have NM technologist Measure and record the initial radiation field for the patient, using an ionization survey meter.
   - ❑ Move the cart close to patient. Lower the bed to lowest position.
   - ❑ Place a sterile towel under the extension arm holder 'E'.
   - ❑ Place a sterile towel across the gap between the acrylic box and the patient.

- ☐ Interventional Radiologist (IR) flushes catheter to ensure flow. Inspect the visible portion of the catheter for kinks or damage. Replace the catheter if it is damaged or does not have satisfactory flow.
- ☐ Radiologist will confirm proper catheter position with 2 – 3 mls of contrast and perform fluoroscopy to confirm catheter position and flow to the intended treatment site.
- ☐ Disconnect the outlet line labeled 'E' from the priming line at holder 'C'. Firmly connect the outlet line 'E' to the catheter.

**ATTENTION: DO NOT USE A CATHETER EXTENSION OR EXTRA FITTINGS. REPLACE A CATHETER WHICH IS TOO SHORT.**

- ☐ Place the catheter connection into the slotted holder 'E' at end of extended arm. Outlet line 'E' will be above the holder, and the catheter hanging vertically below.
- ☐ IR to verify catheter position.
- ☐ **Release the pinch clamp from the outlet line.**
- ☐ Massage tubing to remove any kinks.

### 6. *TheraSphere Administration*

**ATTENTION: BETA RADIATION FIELDS CAN BE VERY HIGH DURING MICROSPHERE TRANSFER. STAND BEHIND BETA SHIELDING OR MAINTAIN DISTANCE.**

- ☐ Infuse TheraSphere Y-90 glass microspheres using steady pressure on the syringe plunger. Infuse continuously until syringe is empty (20 mL).

  **NOTE**: If the pressure applied to the syringe is over 30 psi, excess fluid will drip into the vented empty vial. If this occurs, reduce the pressure being applied on syringe until no flow is seen going into the vented vial.

- ☐ Observe the outlet line and catheter for proper operation. If a problem is observed, inform team and take corrective action.
- ☐ Re-fill syringe for subsequent flushes by pulling back the syringe plunger.
- ☐ Minimum 3 flushes are recommended. Continue flushes until desired dosimeter reading is achieved.

### 7. *Disassembly*

- ☐ Cut the inlet line at indicated position.
- ☐ Remove the acrylic box top shield and side shield.
- ☐ Lift the catheter connection out of the extended holder 'E'. **Do not disconnect** the catheter from the outlet line.
- ☐ IR to pull the catheter tip inside the guide catheter, then remove both together from the patient. Use gauze or a small towel to handle the catheters and control the tip.
- ☐ Place contaminated waste into the Nalgene waste container (in its beta shield):
  1. catheters and attached tubing and towels/gauze
  - dose vial with attached Needle Injector Assembly (lift lead pot and dump out dose vial)
  - contaminated items - gauze, towels and IR's outer gloves.
- ☐ NM Technologist to survey all staff before they leave the room and document.
- ☐ IR staff to sign worksheet for documentation as they leave.

❑ NM Technologist Measure and record the final radiation field for the patient using an ionization survey meter.

8. ***Cleanup and Waste Disposal (NMT-RSO or designated staff member)***

❑ Use a GM contamination meter to check for contamination on the cart, lead pot, equipment, and the areas under the catheter connection and cart.

**NOTE**: Radiation from fluoroscopy, the patient, and the waste container will affect the ability to detect and measure contamination.

❑ Decontaminate or dispose of items (tubing, lead pot, etc.) as appropriate.
❑ Seal the cap of the Nalgene waste container and place the lid on the beta shield.

9. ***Cleanup and Waste Disposal (IR STAFF))***

❑ (As required) Clean the TheraSphere acrylic box with mild soap, water and a clean soft cloth. In case of blood contamination, alcohol wipes may be used minimally (alcohol may degrade the acrylic adhesive after extended time). Do not use cleaner wipes, ammonia (do not use Windex) or abrasives to clean the acrylic parts of the Accessory Kit.
❑ Place top and side shields back on acrylic box. Retract the extension arm and remove the bag hook. Turn off the dosimeter. Store the kit.

**Notes and Comments:**