Beaumont Health System
3601 West Thirteen Mile Road
Royal Oak, Michigan 48073

Notice of Medical Event **November 13, 2014**

Licensee: Beaumont Hospital Royal Oak, 3601 West Thirteen Mile Road, Royal Oak, MI
Date/Time of Discovery: October 30, 2014 at 10:00 a.m.
Referring and Attending Physician: Steven Vartanian, M.D.
Authorized User (AU): Stephen Vartanian, M.D.
NRC License No. 21-01333-01

NRC Operations notified on October 30, 2014 at 5:30 p.m. (Event No. 50584)

A. Description of Event

On October 30, 2014, a patient was prescribed two Y-90 SIR-Sphere treatment doses: one to the anterior and one to the posterior portion of the right lobe of the liver to treat metastatic rectal cancer. This is called the dual dose protocol and is applicable to Y-90 SIR-Sphere by Sirtex. The dose to the anterior portion of the right lobe of the liver was administered in accordance with the written directive. The prescribed dose on the written directive was 0.52 GBq Y-90 SIR-Sphere and 64.1 Gy. The administered dose to the anterior portion of the right lobe of the liver was 0.43 GBq Y-90 SIR-Sphere and an absorbed dose of 53.4 Gy.

The medical event occurred before the anterior right lobe was treated. The patient had a prescribed dose of 0.39 GBq Y-90 SIR-Sphere (64.5 Gy) to the posterior portion of the right lobe. The dose administered was 0.47 GBq Y-90 SIR-Sphere and 77.5 Gy which is 20.8% more than the prescribed dose to the posterior portion of the right lobe. The posterior right lobe of the liver was treated with the dose intended for the anterior right lobe of the liver.

The total dosage to the right lobe of the liver (both posterior and anterior portions) was 0.90 GBq Y-90 SIR-Sphere compared to the planned dose of 0.91 GBq Y-90 SIR-Sphere.

The treatment planning form was prepared in advance of the patient treatment and includes the prescribed activity in GBq Y-90 SIR-Sphere and average dose to the treatment site in Gy. The treatment plan was checked by both a second authorized medical physicist and the authorized user. The quality management form (QM form) was completed by the authorized user as the dosage is drawn by the radiopharmacy and prepared for dispensing. The written directive is part of the QM form and includes (a) radiopharmaceutical, (b) treatment site, (c) prescribed dose to the treatment site in Gy, (d) prescribed Y-90 SIR-Sphere activity in GBq, (e) authorized user signature, date and time.

Two dose labels are also printed out, with one attached to the top of the dose vial shield (i.e., this is the shielded container that houses the vial that contains the Y-90 SIR-Sphere) and one attached to the dose label form. In the presence of the authorized user, radiopharmacy staff and authorized medical physicist, the radiopharmacy staff prepared the first dosage for the posterior right lobe. Because the prescribed dose to the right lobe was 0.39 GBq Y-90 SIR-Sphere, it was difficult to draw up such a small amount of activity. The dose that was drawn was 0.51 GBq Y-90 SIR-Sphere, which was more than the prescribed dose to the posterior right lobe, but very close to the prescribed dosage for the anterior right lobe, which was 0.52 GBq Y-90 SIR-Sphere. After the time out, the decision was made to add a little more activity to this dosage, making it closer to the anterior right lobe dose. On the QM form there is a

section for data entry of the dose calibrator assays that serves as the confirmation of the written directive prior to treatment. This section was crossed off on the QMP form for the posterior right lobe and initialed by the AU. A little more activity was drawn into this first dose and this dose was now within the prescribed dose for the anterior right lobe. The QM form with the initialed cross offs, treatment planning form, and dose label form for the posterior right lobe were set aside. The QM form, treatment planning form, and dose label form for the anterior right lobe were brought to the dose drawing station. The radiopharmacy assigned a green dot to color code the anterior right lobe treatment site. Green dots were applied to all three of these forms. After the dosage was approved by the AU, then the labels were printed. One label was placed on the dose label form and one on the dose vial shield. A green dot was applied to both the dose label form and to the dose vial shield. After the verifications were completed in accordance with our quality management program, the radiopharmacy staff passed the QM form, treatment planning form, dose label form and the labeled dose vial shield to the medical physicist.

The radiopharmacy staff proceeded to draw and prepare the dosage for the posterior right lobe. In the presence of the authorized user, radiopharmacy staff and authorized medical physicist, the radiopharmacy staff prepared the second dosage for the posterior right lobe. A dose of 0.45 GBq Y-90 SIR-Sphere was drawn and that was within the acceptable range for a prescribed dose to the posterior right lobe of 0.39 GBq Y-90 SIR-Sphere The QM form, treatment planning form, dose label form for the posterior right lobe were present at the dose drawing station. An orange dot was applied to the all three of these forms. After the dosage was approved by the AU, then the labels were printed. One label was placed on the dose label form and one on the dose vial shield. An orange dot was applied to both the dose label form and to the dose vial shield. After the verifications were completed in accordance with our quality management program, the radiopharmacy passed the QM form, treatment planning form, dose label form and the labeled dose vial shield containing the Y-90 SIR-Sphere to the medical physicist.

The medical physicist uses a tool called the Checklist that provides the step by step process for setting up the Y-90 SIR-Sphere cart and delivery device. On this occasion, the medical physicist had the checklists for both the anterior right lobe and the posterior right lobe in his assigned work area in the radiopharmacy. He asked the radiopharmacy for an orange and green dot. He applied the green dot to the checklist he intended to use for posterior right lobe, instead of to the checklist for the anterior right lobe. He applied the orange dot to checklist he intended to use for anterior right lobe, instead of to the checklist for the posterior right lobe. This step was not double checked and there was no process in place that required this. While there was no specific process written, the pharmacy typically has all the available paperwork near the dose drawing station including the checklist, and the radiopharmacy applies the color coded dot to the checklist as well as to the QMP form, treatment plan form and dose label form. In this case, the medical physicist took both checklists away from the dose drawing station to his work station so he could start preparing the dose delivery cart.

The physicist took both Y-90 SIR-Sphere dose vial shields, delivery boxes, paperwork, and cart up to the interventional radiology lab. The delivery box was assembled step by step in accordance with the checklist. It was difficult to see and use the label on the dose vial shield to verify the proper dose prior to treatment because of (1) dim lighting in the interventional radiology suite, (2) the size of the font on the label was too small to easily read, and (3) the dosage was in units of Curie, and did not include the dosage in Bq. Before putting on his sterile gown and gloves, the medical physicist looked at the checklists. The colored dots were only on the first page of each checklist, so he wrote green, larger and

posterior on the 2nd page of the checklist that was marked with the green dot since the shielded dose with the green dot was the larger dose labeled in units of Ci rather than Bq; and he wrote orange, smaller and anterior on the 2nd page of the checklist that was marked with an orange dot since the shielded dose with the orange dot was the smaller dose labeled in Ci. He used the color coded checklist instead of the QM form to select which Y-90 SIR-Sphere dose vial would be placed inside the delivery device. The medical physicist prepared himself to enter the sterile field, prepared the delivery device, and waited until the authorized user (AU) identified which treatment site in the right lobe would be treated first. The AU accessed the posterior portion of the right lobe first and requested the dosage for that treatment site. Since the medical physicist was on the second page of the checklist, he referred to his note that said, "green, larger, posterior" and passed the dose labeled with the green dot to the AU. The dose labeled with the green dot was prescribed for the anterior right lobe instead of the posterior right lobe of the liver. Upon completion of the dose administration, the medical physicist put the waste vial in the shield, moved the used delivery box to the cart, and began to assemble the next dose. While placing the new paperwork for the next treatment on the clipboard, the medical physicist noticed the discrepancy. The QMP form, treatment planning form, and dose label form for the posterior lobe were all labeled orange; only the checklist had a green dot.

Once the medical physicist identified the error, he reported it to the authorized user and RSO. A time out was called and the decision was made to prepare a new Y-90 SIR-Sphere dosage for the anterior portion of the right lobe in accordance with the written directive. The Y-90 SIR-Sphere dose was then administered to the anterior portion of the right lobe of the liver in accordance with the written directive.

B. Why the Event Occurred

The radiopharmacy staff and authorized user correctly labeled the QMP, treatment planning and dose label forms with the correct colored dots. The physicist applied the wrong colored dot (i.e., green) to the checklist for the posterior instead of anterior right lobe (i.e., orange). The physicist then used the checklist instead of the written directive on the QMP form to verify the dose with the authorized user prior to placing it into the delivery device. Contributing factors include: (1) the physicist thought that the larger dose was planned for the posterior rather than the anterior right lobe of the liver, (2) there was not a process in place to double check the color coded dot added to the checklist by the medical physicist, and (3) at the time the AU requested the posterior right lobe dose, the physicist was in the sterile field without ready access to the written directive on the QM form, the treatment planning form and the dose label form that would enable him to use these to verify the dose, rather than using the checklist.

The root cause was that the medical physicist used the checklist to verify the written directive in the interventional radiology lab instead of the written directive on the QMP form. Instead of verifying the Y-90 SIR-Sphere dose by referring to the written directive on the QMP form, the physicist referred to the color coded dot on the checklist. The process used by the AU to verify the dose prior to connecting the dose delivery device to the patient was inadequate and failed to identify the error prior to administration of the treatment dose. Contributing factors are as follows. (1) Color coding was ineffective at preventing this medical event (2) Adding the colored dot to the physicist's checklist was a contributing factor to this medical event, since there was no double check in place to prevent the physicist from applying the wrong colored dot to their checklist. Because there were two different prescribed doses of Y-90 Sir-Sphere in the interventional lab area at the same time, this increased the

risk for human error. The label applied to the dose vial shield was not robust enough to allow it to be used for final verification in the interventional radiology lab prior to loading the Y-90 SIR-Sphere dose into the delivery device.

C. The Effect on the Patient

No adverse effects on the patient are expected from this medical event. Overall the dose to the posterior portion of the right lobe of the liver was slightly more than 20% of the originally prescribed dose. The physician, who is the patient's attending and referring physician, told the patient to expect no clinical consequence as a result, and perhaps a benefit.

D. What Improvements are Needed to Prevent Recurrence

The investigation is ongoing and includes a review of our (1) standard operating procedures for Y-90 treatment planning; microsphere dose preparation, labeling, and dispensing; medical physicists tools (such as the checklist), initial verification process, device delivery set up and final verification in the interventional radiology lab; and process by which the AU verifies the dose prior to connecting the dose delivery device to the patient; (2) training, qualifications and approvals of the authorized users and medical physicists; and (3) a compliance audit of all Y-90 SIR-Sphere dose administrations since May 2011.

The entire process for Y-90 SIR-Sphere dual dose administration is under internal review. This includes: (1) treatment planning; (2) microsphere dose preparation, labeling, and dispensing; (3) medical physicists tools (such as the checklist), initial verification process, device delivery set up and final verification in the interventional radiology lab; and (4) process by which the AU verifies the dose prior to connecting the dose delivery device to the patient. The authorized users, radiopharmacy, medical physicists, nurses and administration have held several meetings since the event occurred.

The Radiation Safety Committee held an emergency meeting on November 12, 2014 and reviewed this notice of medical event for accuracy and effectiveness in preventing recurrence. They also reviewed and approved the following corrective actions related to the dual dose administration: (1) No more than one dosage of Y-90 microsphere is allowed to be present in the interventional radiology lab area at any one time. Since this action has potential medical complications associated with it, the RSC may reconsider this corrective action in the future. Several hard stops are currently under review. Before this restriction is lifted, the RSC requires a risk assessment; submission of a written proposal that includes alternate hard stops and the step by step process; training and skills validation of all authorized team members; and a presentation of the results of a dry run using the revised protocol. (2) Color coding will not be used for Y-90 SIR-Sphere, (3) The Y-90 microspheres checklist will not be used by the medical physicist to verify the dose, GBq or treatment site. (4) A larger label with the dose in both Bq and Ci units will be placed on the dose vial shield. (5) A hard stop was put into place that requires the AU to respond to the following questions posed by the medical physicist and/or qualified nurse prior to connecting the patient to the delivery device and administering the dose:
What is the radiopharmaceutical?
What is the prescribed dosage in GBq?
What is the treatment site?
What is the prescribed absorbed dose to that treatment site?

This will be documented by both the medical physicist or qualified nurse and the AU prior to the dose administration.
(6) All the authorized users, medical physicists, qualified nurses, and radiopharmacy staff will be retrained in these corrective actions and have their skills validated prior to the next Y-90 SIR-Sphere treatment. This training will be documented.
(7) Any changes to the Y-90 microspheres procedure, treatment planning process, device assembly or emergency procedures must be pre-approved by the Radiation Safety Committee.

The training, qualifications and approvals of the authorized users and medical physicists were reviewed by the Corporate Radiation Safety Officer and found to be in conformance with the NRC Licensing Guidance for Y-90 Microsphere Therapy (dated August 2012). The Radiation Safety Committee also reviewed the training, qualifications and approvals of the authorized users and medical physicists and verified that the training and experience of the authorized personnel meets NRC regulations. The Corporate RSO presented the results of the compliance audit. Since May, 2011, 23 of a total of 147 Y-90 SIR-Sphere therapies have been treated with the dual dose protocol and all received the Y-90 SIR-Sphere dosage in accordance with the written directive.

Actions Taken to Prevent Recurrence

Effective immediately:

(1) No more than one dosage of Y-90 SIR-Sphere is allowed to be present in the interventional radiology lab area at any one time.

(2) Color coding will not be used for Y-90 SIR-Sphere dosages,

(3) The Y-90 microspheres checklist will not be used by the medical physicist to verify the dose, GBq or treatment site.

(4) A larger label with the dose in both Bq and Ci units will be placed on the dose vial shield.

(5) A hard stop was put into place that requires the AU to respond to the following questions posed by the medical physicist and/or qualified nurse prior to connecting the patient to the delivery device and administering the dose:
What is the radiopharmaceutical?
What is the prescribed dosage in GBq?
What is the treatment site?
What is the prescribed absorbed dose to that treatment site?
This will be documented by both the medical physicist or qualified nurse and the AU immediately prior to the dose administration.

(6) To reduce complexity of the paperwork, we eliminated the separate dose label form. The written directive and the treatment planning form provide the necessary safeguards.

(7) All the authorized users, medical physicists, qualified nurses, and radiopharmacy staff will be retrained in these corrective actions and have their skills validated prior to the next Y-90 SIR-Sphere treatment. This training will be documented.

(8) Any changes to the Y-90 microspheres procedure, treatment planning process, device assembly or emergency procedures must be pre-approved by the Radiation Safety Committee.

E. Notification of the Patient and Referring Physician

The referring physician, who is also the authorized user, was notified at 10:00 a.m. on October 30, 2014. The referring physician verbally notified the patient on October 30, 2014 at 11:45 a.m. The patient will receive written notification within 15 days of the event's occurrence.

F. Conclusion

1. A medical event occurred on October 30, 2014 at 10:00 a.m. in which the Y-90 SIR-Sphere dose delivered to the patient's posterior portion of the right lobe of the liver was more than the prescribed dose by 20 percent (10 CFR 35.3045). The patient was prescribed a dose of 0.39 GBq Y-90 SIR-Sphere (64.5 Gy) to the posterior portion of the right lobe of the liver, but administered a dose that was 20.8% more than the prescribed dose. The posterior portion of the right lobe of the liver was administered 0.47 GBq Y-90 SIR-Sphere (77.5 Gy), which was the intended dose for the anterior portion of the right lobe of the liver. After this treatment, the second dose present in the interventional radiology lab was not used. The AU and medical physicist returned to the radiopharmacy. The radiopharmacy drew up a new dose for the treatment of the anterior portion of the right lobe, and this was verified in accordance with our quality management program. The dose administered to the anterior portion of the right lobe of the liver was in accordance with the written directive.
2. No adverse effects on the patient are expected from this medical event. Overall the dose to the posterior portion of the right lobe of the liver was slightly more than 20% of the originally prescribed dose. Dr. Vartanian, who is both the authorized user and the referring physician, told the patient to expect no clinical consequence as a result and perhaps a benefit.
3. The root cause was that the medical physicist used the checklist to verify the written directive in the interventional radiology lab instead of the written directive on the QMP form. Instead of verifying the Y-90 SIR-Sphere dose by referring to the written directive on the QMP form, the physicist referred to the color coded dot on the checklist. The process used by the AU to verify the dose prior to connecting the dose delivery device to the patient was inadequate and failed to identify the error prior to administration of the treatment dose.
4. Prompt corrective actions were initiated and included:
   (1)No more than one dosage of Y-90 SIR-Sphere is allowed to be present in the interventional radiology lab area at any one time.
   (2) Color coding will not be used for Y-90 SIR-Sphere dosages,
   (3) The Y-90 microspheres checklist will not be used by the medical physicist to verify the dose, GBq or treatment site.
   (4) A hard stop was put into place that requires the AU to respond to the specific questions posed by the medical physicist and/or qualified nurse prior to connecting the patient to the delivery device and administering the dose.
   (5) All the authorized users, medical physicists, qualified nurses, and radiopharmacy staff will be retrained in these corrective actions and have their skills validated prior to the next Y-90 SIR-Sphere treatment. This training will be documented.

5. This event was reported to U.S. NRC Operations Center at 5:30 p.m. EST on October 30, 2014 (Event No. 50584). The written report will be submitted to NRC within 15 days of discovery of this event as required.
6. This event was promptly reported to the authorized user and referring physician within 24 hours of discovery. The patient was notified by the authorized user (who is also the referring physician) on October 30, 2014 prior to release from the hospital. The patient will receive a written report within 15 days of discovery of this medical event as required.

Report Prepared By:

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