INDIANA UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT
FOR UNIVERSITY ACADEMIC AFFAIRS
University Environmental Health and Safety

IUPUI/IUMC Radiation Safety Office

26 October 2020

Materials Licensing Branch
U.S. Nuclear Regulatory Commission – Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Written Report to Follow-up Notification of Reportable Event on 13 October 2020

NRC License No. 13-02752-03
Notification No. 54946

To Whom it May Concern:

This letter is to satisfy the written report requirement of a notification of a medical event, as outlined in 10 CFR 35.3045(a)(1)(i)(A & B). On 13 October 2020, I notified the NRC Operations Center by telephone of a possible reportable event (Notification No. 54946). Details are provided below.

Licensee Name: Indiana University-IUPUI/IU Medical Center Campus (NRC License No. 13-0252-03)

Prescribing Physician: Sabah D. Butty, MD

Description of Event: On 13 October 2020, a 70-year-old male patient was scheduled to receive 46.7 mCi of Y-90 TheraSpheres to the segments 5/8 of the liver, and 56.8 mCi and 28.6 mCi (in two individual dosages) to segments 6/7 of the liver during a standard radioembolization procedure. Initial activities, respectively, assayed at 54.0 mCi at 7:44 am (116% of prescribed); 56.8 mCi at 7:42 am (100% of prescribed); and 28.6 mCi at 7:43 am (100% of prescribed). The intended dose to the liver treatment volume was 120 Gy. Both administrations to segments 6/7 were completed without issue. As the physician attempted to administer the radioactive material to segments 5/8, it was noted that the radiation level in the room was constant at 45 mR/hr at 10 feet and was not dropping. The physician stated that microspheres were visibly clogged in the catheter, and when brought close to this area, the survey meter reached its maximum reading at 110 mR/hr. The physician discontinued the administration.

The radiation safety staff member surveyed the patient both in the interventional suite (with shielding in place) and in the post-operation holding room. Near contact with the patient, the maximum exposure rate was 10 mR hr^{-1} using an energy-compensated GM survey meter (SE International Model Inspector+, S/N 18960). Measurement of the administration set, dose vial, waste materials, etc. showed approximately 46.0% of the activity remaining, indicating an administration of 54.0% (25.2 mCi). A summary of administered activity and used components is provided in Table 1.

Table 1. Summary of administration and components used.

Administration		1	2	3	4
	Date	10/13	10/13	10/13	10/20
	Target Site	Segs. 6&7a	Segs. 6&7b	Segs. 5&8	Segs. 5&8 (#2)
	Prescribed Activity	28.6 mCi	56.8 mCi	46.7 mCi	46.7 mCi
	Admin'd Activity	28.1 mCi	56.4 mCi	25.2 mCi	53.9 mCi
	% Delivered	98.3%	99.3%	54.0%	115.4%
Y-90 Vial	**Lot #**	2099472	2099472	2099469	2099487
	Vial #	99	129	159	89
Admin Kit	**Lot #**	197D	197D	197D	197D
	Exp.	5/7/21	5/7/21	5/7/21	5/7/21
Catheter	**Manufacturer**	Progreat	Progreat	Progreat	Merit
	Ref #	MC*PV2815Y	MC*PV2815Y	MC*PC2015Y	28MC24150SN
	Lot #	200727	200617	200629	H1911990
	Exp.	6/30/2022	5/31/2022	5/31/2022	8/21/2023
	Distal OD	2.8 Fr.	2.8 Fr.	2.0 Fr.	2.4 Fr.
	ID	0.027"	0.027"	0.019"	0.020"

Why the Event Occurred: For administration to segments 5/8, the physician requested a 0.020" ID micro-catheter (2.4 Fr at the distal end), but none were found in inventory, so a different catheter was used (2.0 Fr distal end, 0.019" ID). It is suspected that the smaller catheter created a blockage of microspheres at the entry site or within the catheter itself. The physician indicated before administration that the full dose may not be delivered due to catheter size, but decided to treat the patient in an attempt to deliver the dose. A picture of the catheter is shown in Fig. 1; some yellowing is potentially visible within the line, which may indicate either microspheres "stuck" within the line, or radiation damage to the plastic.

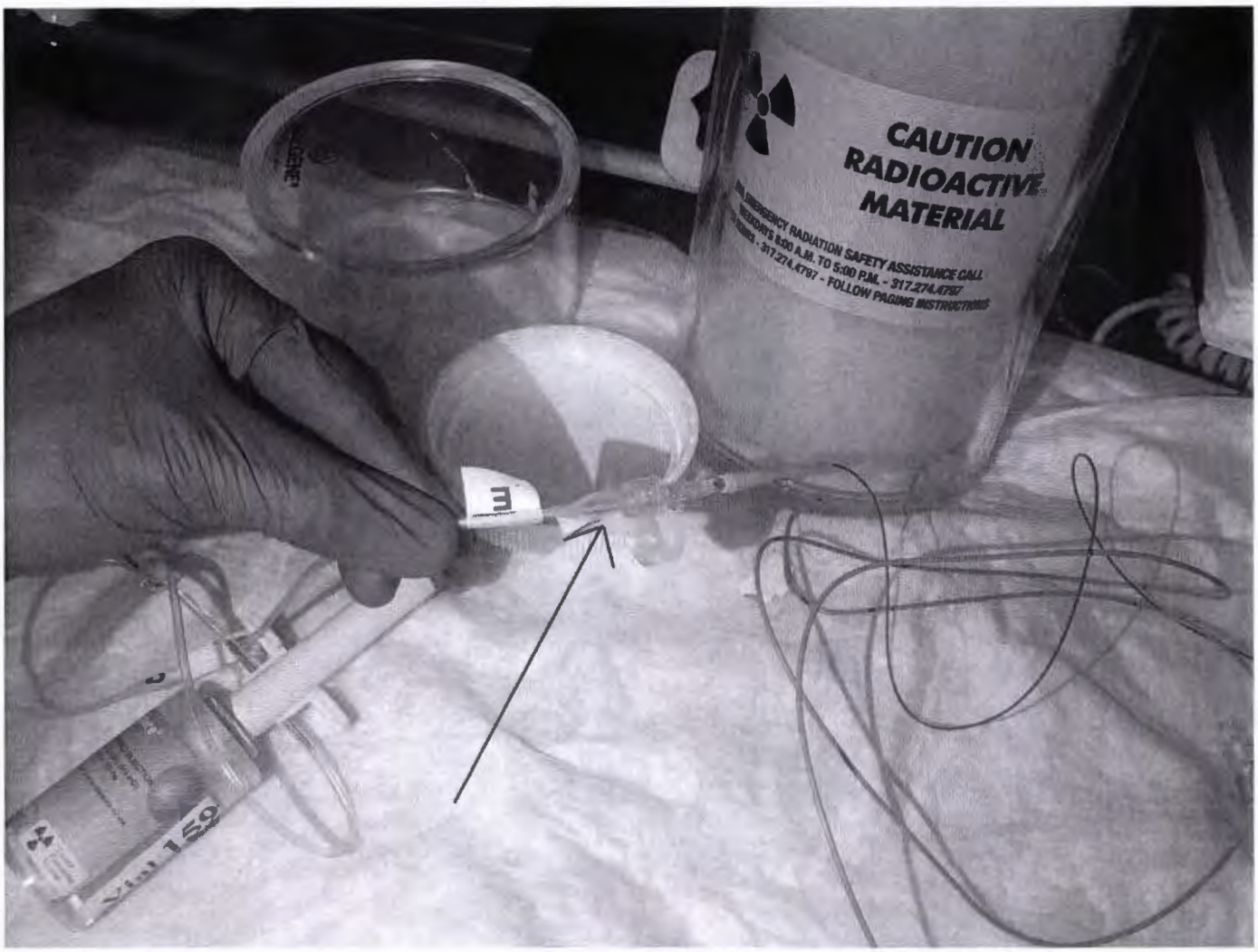

Figure 1. Microcatheter post administration; red arrow indicates location of yellowing and potential blockage.

Effect to Patient Receiving Administration: The patient will have no adverse effects from the approximately 25.7 mCi that he received. The patient returned on 20 October 2020 to receive the intended prescription of 46.7 mCi, which was delivered successfully.

Actions to Prevent Recurrence: It is difficult to provide conclusive actions to prevent recurrence at this time, as the true root cause is not yet known. All components of the administration kit and catheter were retained for analysis. As some of the activity was delivered to the patient, stasis may be partially responsible for the cessation of delivery. The Permit Holder (AU, Director of Interventional Oncology, Chief of Vascular and Interventional Radiology) was informed of the incident on 14 October 2020. The device manufacturer, BTG, has been notified; we will be returning all components (device, dose, microcatheter) to the manufacturer for further analysis with their microscopic equipment. However, this will not occur until approximately the second week of November due the activity present and time required for decay. We intend to develop and implement actions to prevent recurrence based on the future determination of the root cause.

Certification of Notification to Patient: On the day of the procedure, the prescribing physician verbally notified the patient of this event.

Notification of Referring Physician: On the day of the procedure, the prescribing physician notified the referring physician of this event. In addition, an annotated version of this report will be provided to both the administering AU and the referring physician, as required in 10 CFR 35.3045(g).

While the root cause is yet unclear, the radiation safety office intends to work closely with the physician and vendor to investigate this misadministration and to develop and implement corrective actions to prevent future misadministrations due to the same cause. Thankfully, the patient was not adversely affected, and was able to receive and complete treatment at a later date. I trust that the included information will satisfy your request. Additional information may be made available to the commission as it is collected. Should you have any questions, please feel free to contact me.

Sincerely,

Michael Martin, PhD

Digitally signed by Michael Martin, PhD
DN: cn=Michael Martin, PhD, o=IUPUI, IU Health, Eskenazi Health, ou=Radiation Safety Officer, email=mimart@iu.edu, c=US
Date: 2020.10.26 09:44:54 -04'00'

T. Michael Martin, PhD, DABHP
IUPUI/IUMC Director of Health Physics & Radiation Safety Officer
(317) 274-0331
mimart@iu.edu / tmartin24@iuhealth.org

Enclosures:

Written Directive and Administration Documents

1. Successful Treatment of Segments 6&7(a)
2. Successful Treatment of Segments 6&7(b)
3. Reportable Treatment of Segments 5&8
4. Successful Retreatment of Segments 5&8

10 GBq

1. Segments 6&7a

RADIOPHARMACEUTICAL WRITTEN DIRECTIVE: 90-YTTRIUM MICROSPHERES

Patient Name	DOB	Medical Record #	Hospital
[redacted]	[redacted]	[redacted]	Methodist 10/13/2020 GB 0743

PRE-ADMINISTRATION

Liver to be Treated	% Shunting	Device	Prescribed Activity (or Activity at Stasis)
seg 6 and 7 (a)	10	Theraspheres	2.77 GBq = ~~74.8 mCi~~ 28.6 mCi

Maximum Dose Acceptable to Sites Outside Primary Treatment Site Due to Shunting	30 Gy

Authorized User Signature	Date Signed
Butty	10/13/2020
Authorized IR Physician Signature	**Date Signed**
Butty	10/13/2020

Manufacturer Lot #	Date of Measurement	Time
2099472 Vial 99	10/13/2020	7:43am

Drawn Dose	Measurement Verified By
28.6 mCi	[signature]

POST-ADMINISTRATION

Waste Activity	Activity Delivered	Radiation Safety Office Designee
0.5 mCi	28.1 mCi	[signature]

Calculated Activity Delivered to Liver	Calculated Activity Outside of Liver Due to Shunting
25.3 mCi	2.8 mCi

AU COMMENTS AND SIGNATURE (UPON STASIS OR EMERGENT PATIENT CONDITION ONLY)

☐ Treatment terminated due to stasis (decreased dose delivered) ☐
Treatment not completed due to emergent patient condition described below

Authorized User Signature Upon Stasis	Date Signed
Choose AU	

^{90}Y TheraSphere Dose Administration Sheet

Patient Initials: [redacted] Patient MRN: [redacted] Date: 10/13/2020

Hospital: ☐ University ☑ Methodist ☐ Eskenazi ☑ Identity of patient confirmed

Prescribed Dose (mCi): 28.6 -20%: 22.9 +20%: 34.3
NOTE: 1 GBq = 27 mCi

Treatment of: ☐ Whole Liver ☐ Right Lobe ☐ Left Lobe ☑ Other: Seg 6 and 7 (a)

I. Therasphere Dose (use setting 443)

Lot #: 2099472 Vial #: 99

Vial Information
Date: 10/04/2020 Time: 12 pm Activity (GBq or mCi): 9.96 GBq

A. Dose measured in dose calibrator : 28.6 mCi at 7:43 am (time)

B. Dose within 20% of Written Directive Dose? ☑ Yes ☐ No
(If "No", refer to IR Physician administering the dose)

II. TheraSphere Measurements

A. Initial Dose Vial Measurement (taken at 3 inches on template)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	Avg. Vial (mR/h)	Time
11.07	11.46	14.31	12.80	12.41	8:03 am

B. OPTIONAL: Decayed Dose Rate & Dose **Tx time:**_____ **Elapsed time (h):**_____

(Initial mR/h)$e^{-(0.693/64h)(t)}$ = _____ mR/h

(Initial mCi)$e^{-(0.693/64h)(t)}$ = _____ mCi

C. Waste Measurements (taken at 3 inches)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	Avg. Waste (mR/h)	Time
0.221	0.257	0.191	0.209	0.220	9:39 am

D. Percent Dose Delivered: 1 - (Avg. Waste Measurement "C"/Avg. Initial Measurement "A") X 100 98.2 %

Dose Administered (based on drawn dose): Drawn Dose X % Dose Delivered 28.1 mCi

Percent of Written Directive: Dose Administered ÷ Prescribed Dose 98.2 %

E. Does dose administered differ from the prescribed dose by more than 20% : ☐ Yes* ☑ No
(If "yes", explain)

Comments:_____

Name/Initials: EC Meter Used: ☑ Inspector #18960 ☐ Inspector #35821 ☐ Inspector #21380 ☐ Other _____

Seq 6/7 (a)

TheraSphere™

Calibration Data Sheet

PRODUCT:	TheraSphere™ Y-90 Glass Microsphere
LOT NUMBER:	2099472
VIAL #:	99
DOSE SIZE:	10.0 GBq
CALIBRATION DATE and TIME:	2020-10-04 @ 12:00 ET
MEASURED TOTAL ACTIVITY*:	9.96 GBq
EXPIRATION DATE:	2020-10-16 @ 23:59 ET

* value at calibration date and time

Please note: When the TheraSphere™ Y-90 Glass Microsphere dose vial is received, the site will confirm it is the correct activity for the patient treatment by measuring in a dose calibrator (activimeter).

Biocompatibles UK Ltd, a BTG International group company
Chapman House
Farnham Business Park
Weydon Lane
Farnham
Surrey GU9 8QL
UK

BTG

TheraSphere Checklist

Patient Initials: [redacted] ***Patient MRN:*** [redacted] ***Date of Treatment:*** 10/13/2020

Treatment of: ☐ ***Whole Liver*** ☐ ***Right Lobe*** ☐ ***Left Lobe*** ☑ ***Other:*** Seg 6 and 7(a)

Microcatheter Brand & Lot/Serial: Progreat, Ref: MC*PV2815Y, Lot: 200727
Exp: 2022/06/30

(OR PLACE STICKER HERE)

TheraSphere Administration Set Lot # 197D ***Expiration Date:*** 2021/05/07

1. ***Items Required for TheraSphere Administration:***

- Patient prescription for TheraSphere (signed Written Directive)
- Geiger-Mueller (GM) contamination meter (by RSO)
- A floor drape applied under the cart in the angiography suite
- A sterile drape placed on the cart

Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***

• Hemostat
• Scissors
• Sterile adhesive strips (i.e., Steri-strip)
• Towels
• Gauze
	• Administration Set (in packaging)
	  ○ **Verify the expiry date**
	• TheraSphere Administration Accessory Kit (acrylic box)
	  ○ Remove the top shield
	  ○ Fully extend the stainless steel arm
	  ○ Install the bag hook
	• Electronic dosimeter (RADOS RAD 60R or equivalent)
	  ○ Turn the dosimeter on and set to mR/h
	  ○ Clip the dosimeter to its bracket on the acrylic box
	• Saline bag (in packaging) or bottle (minimum 100 mL)
	• Alcohol swabs
	• 2L Nalgene waste container with beta shield (brought by RSO)
	• TheraSphere dose vial, in lead pot (brought by RSO)

2. Segments 6&7b

RADIOPHARMACEUTICAL WRITTEN DIRECTIVE: 90-YTTRIUM MICROSPHERES

Patient Name	DOB	Medical Record #	Hospital
[redacted]	[redacted]	[redacted]	Methodist

PRE-ADMINISTRATION

Liver to be Treated	% Shunting	Device	Prescribed Activity (or Activity at Stasis)
seg 6 and 7 (b)	10	Theraspheres	2.77 GBq = ~~74.8 mCi~~

Maximum Dose Acceptable to Sites Outside Primary Treatment Site Due to Shunting 30 Gy

Authorized User Signature	Date Signed
Butty	
Authorized IR Physician Signature	**Date Signed**
Butty	

Manufacturer Lot #	Date of Measurement	Time
2099472 Vial 129	10/13/2020	7:42 am

Drawn Dose	Measurement Verified By
56.8 mCi	

POST-ADMINISTRATION

Waste Activity	Activity Delivered	Radiation Safety Office Designee
0.4 mCi	56.4 mCi	

Calculated Activity Delivered to Liver	Calculated Activity Outside of Liver Due to Shunting
50.8 mCi	5.6 mCi

AU COMMENTS AND SIGNATURE (UPON STASIS OR EMERGENT PATIENT CONDITION ONLY)

☐ Treatment terminated due to stasis (decreased dose delivered) ☐

Treatment not completed due to emergent patient condition described below

Authorized User Signature Upon Stasis	Date Signed
Choose AU	

^{90}Y TheraSphere Dose Administration Sheet

Patient Initials: [redacted] Patient MRN: [redacted] Date: 10/13/2020

Hospital: ☐ University ☑ Methodist ☐ Eskenazi ☑ Identity of patient confirmed

Prescribed Dose (mCi): 56.8 -20%: 45.4 +20%: 68.2
NOTE: 1 GBq = 27 mCi

Treatment of: ☐ Whole Liver ☐ Right Lobe ☐ Left Lobe ☑ Other: Seg 6 and 7(b)

I. Therasphere Dose (use setting 443)

Lot #: 2099472 Vial #: 129

Vial Information
Date: 10/04/2020 Time: 12 pm Activity (GBq or mCi): 19.59 GBq

A. Dose measured in dose calibrator : 56.8 mCi at 7:42 am (time)

B. Dose within 20% of Written Directive Dose? ☑ Yes ☐ No
(If "No", refer to IR Physician administering the dose)

II. TheraSphere Measurements

A. Initial Dose Vial Measurement (taken at 3 inches on template)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Vial (mR/h)**	**Time**
23.92	23.53	26.74	27.65	25.46	8:07 am

B. OPTIONAL: Decayed Dose Rate & Dose **Tx time:**_____ **Elapsed time (h):**_____

(Initial mR/h)$e^{-(0.693/64h)(t)}$ = _____ mR/h

(Initial mCi)$e^{-(0.693/64h)(t)}$ = _____ mCi

C. Waste Measurements (taken at 3 inches)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Waste (mR/h)**	**Time**
0.191	0.221	0.209	0.179	0.200	10:00 am

D. Percent Dose Delivered: 1 - (Avg. Waste Measurement "C"/Avg. Initial Measurement "A") X 100 99.2 %

Dose Administered (based on drawn dose): Drawn Dose X % Dose Delivered 56.4 mCi

Percent of Written Directive: Dose Administered ÷ Prescribed Dose 99.2 %

E. Does dose administered differ from the prescribed dose by more than 20% : ☐ Yes* ☑ No
(If "yes", explain)

Comments:_____

Name/Initials: EC Meter Used: ☑ Inspector #18960 ☐ Inspector #35821 ☐ Inspector #21380 ☐ Other _____

TheraSphere Checklist

Patient Initials: [redacted] ***Patient MRN:*** [redacted] ***Date of Treatment:*** 10/13/2020

Treatment of: ☐ ***Whole Liver*** ☐ ***Right Lobe*** ☐ ***Left Lobe*** ☑ ***Other:*** Seg 6 and 7(b)

Microcatheter Brand & Lot/Serial: Progreat, Ref: MC*PV2815Y, Lot: 200617
Exp: 2022/05/31

(OR PLACE STICKER HERE)

TheraSphere Administration Set Lot # 197D ***Expiration Date:*** 2021/05/07

1. ***Items Required for TheraSphere Administration:***

- Patient prescription for TheraSphere (signed Written Directive)
- Geiger-Mueller (GM) contamination meter (by RSO)
- A floor drape applied under the cart in the angiography suite
- A sterile drape placed on the cart

Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***

• Hemostat
• Scissors
• Sterile adhesive strips (i.e., Steri-strip)
• Towels
• Gauze
	• Administration Set (in packaging)
	  ○ **Verify the expiry date**
	• TheraSphere Administration Accessory Kit (acrylic box)
	  ○ Remove the top shield
	  ○ Fully extend the stainless steel arm
	  ○ Install the bag hook
	• Electronic dosimeter (RADOS RAD 60R or equivalent)
	  ○ Turn the dosimeter on and set to mR/h
	  ○ Clip the dosimeter to its bracket on the acrylic box
	• Saline bag (in packaging) or bottle (minimum 100 mL)
	• Alcohol swabs
	• 2L Nalgene waste container with beta shield (brought by RSO)
	• TheraSphere dose vial, in lead pot (brought by RSO)

Seg 6(7(b)

TheraSphere™

Calibration Data Sheet

PRODUCT:	TheraSphere™ Y-90 Glass Microsphere	
LOT NUMBER:	2099472	
VIAL #:	129	
DOSE SIZE:	20.0 GBq	
CALIBRATION DATE and TIME:	2020-10-04	@ 12:00 ET
MEASURED TOTAL ACTIVITY*:	19.59 GBq	
EXPIRATION DATE:	2020-10-16	@ 23:59 ET

* value at calibration date and time

Please note: When the TheraSphere™ Y-90 Glass Microsphere dose vial is received, the site will confirm it is the correct activity for the patient treatment by measuring in a dose calibrator (activimeter).

Biocompatibles UK Ltd, a BTG International group company
Chapman House
Farnham Business Park
Weydon Lane
Farnham
Surrey GU9 8QL
UK

BTG

1968

3. Segments 5&8 (Failed)

RADIOPHARMACEUTICAL WRITTEN DIRECTIVE: 90-YTTRIUM MICROSPHERES

Patient Name	DOB	Medical Record #	Hospital
[redacted]	[redacted]	[redacted]	Methodist

PRE-ADMINISTRATION

Liver to be Treated	% Shunting	Device	Prescribed Activity (or Activity at Stasis)
seg 5/8	10	Theraspheres	1.73 GBq = 46.7 mCi

Maximum Dose Acceptable to Sites Outside Primary Treatment Site Due to Shunting	30 Gy

Authorized User Signature	Date Signed
Butty	10/13/2020
Authorized IR Physician Signature	**Date Signed**
Butty	10/13/2020

Manufacturer Lot #	Date of Measurement	Time
2099469 Vial 139	10/13/2020	7:44 am

Drawn Dose	Measurement Verified By
54.0 mCi	

POST-ADMINISTRATION

Waste Activity	Activity Delivered	Radiation Safety Office Designee
28.8 mCi	25.2 mCi	

Calculated Activity Delivered to Liver	Calculated Activity Outside of Liver Due to Shunting
22.7 mCi	2.5 mCi

AU COMMENTS AND SIGNATURE (UPON STASIS OR EMERGENT PATIENT CONDITION ONLY)

☐ Treatment terminated due to stasis (decreased dose delivered) ☐

Treatment not completed due to emergent patient condition described below

Authorized User Signature Upon Stasis	Date Signed
Choose AU	

^{90}Y TheraSphere Dose Administration Sheet

Patient Initials: [redacted] Patient MRN: [redacted] Date: 10/13/2020

Hospital: ☐ University ☑ Methodist ☐ Eskenazi ☐ Identity of patient confirmed

Prescribed Dose (mCi): 46.7 -20%: 37.4 +20%: 56.0
NOTE: 1 GBq = 27 mCi

Treatment of: ☐ Whole Liver ☐ Right Lobe ☐ Left Lobe ☑ Other: Seg 5/8

I. Therasphere Dose (use setting 443)

Lot #: 2099469 Vial #: 159

Vial Information
Date: 10/04/2020 Time: 12 pm Activity (GBq or mCi): 18.59 GBq

A. Dose measured in dose calibrator : 54.0 mCi at 7:44 am (time)

B. Dose within 20% of Written Directive Dose? ☑ Yes ☐ No
(If "No", refer to IR Physician administering the dose)

II. TheraSphere Measurements

A. Initial Dose Vial Measurement (taken at 3 inches on template)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Vial (mR/h)**	**Time**
24.00	19.99	23.80	29.05	24.21	8:10 am

B. OPTIONAL: Decayed Dose Rate & Dose **Tx time:**_____ **Elapsed time (h):**_____

(Initial mR/h)$e^{-(0.693/64h)(t)}$ = _____ mR/h

(Initial mCi)$e^{-(0.693/64h)(t)}$ = _____ mCi

C. Waste Measurements (taken at 3 inches)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Waste (mR/h)**	**Time**
9.29	17.23	15.88	9.21	12.9	10:13 am

D. Percent Dose Delivered: 1 - (Avg. Waste Measurement "C"/Avg. Initial Measurement "A") X 100 46.7 %

Dose Administered (based on drawn dose): Drawn Dose X % Dose Delivered 25.2 mCi

Percent of Written Directive: Dose Administered ÷ Prescribed Dose 54.0 %

E. Does dose administered differ from the prescribed dose by more than 20% : ☑ Yes* ☐ No
(If "yes", explain)

Comments:_____

Name/Initials: EC Meter Used: ☑ Inspector #18960 ☐ Inspector #35821 ☐ Inspector #21380 ☐ Other _____

Seq 8/8

TheraSphere™

Calibration Data Sheet

PRODUCT:	TheraSphere™ Y-90 Glass Microsphere	
LOT NUMBER:	2099469	
VIAL #:	159	
DOSE SIZE:	19.0 GBq	
CALIBRATION DATE and TIME:	2020-10-04	@ 12:00 ET
MEASURED TOTAL ACTIVITY*:	18.59 GBq	
EXPIRATION DATE:	2020-10-16	@ 23:59 ET

* value at calibration date and time

Please note: When the TheraSphere™ Y-90 Glass Microsphere dose vial is received, the site will confirm it is the correct activity for the patient treatment by measuring in a dose calibrator (activimeter).

Biocompatibles UK Ltd, a BTG International group company
Chapman House
Farnham Business Park
Weydon Lane
Farnham
Surrey GU9 8QL
UK

BTG

TheraSphere Checklist

Patient Initials: [redacted] ***Patient MRN:*** [redacted] ***Date of Treatment:*** 10/13/2020

Treatment of: ☐ ***Whole Liver*** ☐ ***Right Lobe*** ☐ ***Left Lobe*** ☑ ***Other:*** Seg 5/8

Microcatheter Brand & Lot/Serial: Progreat, Ref: ~~MC*PV2815Y~~ MC*PC2015Y, Lot: ~~200727~~ 200629 Exp: ~~2022/06/30~~ 2022/05/31

(OR PLACE STICKER HERE)

TheraSphere Administration Set Lot # 197D ***Expiration Date:*** 2021/05/07

1. ***Items Required for TheraSphere Administration:***

- Patient prescription for TheraSphere (signed Written Directive)
- Geiger-Mueller (GM) contamination meter (by RSO)
- A floor drape applied under the cart in the angiography suite
- A sterile drape placed on the cart

Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***

• Hemostat
• Scissors
• Sterile adhesive strips (i.e., Steri-strip)
• Towels
• Gauze
	• Administration Set (in packaging)
	  ○ **Verify the expiry date**
	• TheraSphere Administration Accessory Kit (acrylic box)
	  ○ Remove the top shield
	  ○ Fully extend the stainless steel arm
	  ○ Install the bag hook
	• Electronic dosimeter (RADOS RAD 60R or equivalent)
	  ○ Turn the dosimeter on and set to mR/h
	  ○ Clip the dosimeter to its bracket on the acrylic box
	• Saline bag (in packaging) or bottle (minimum 100 mL)
	• Alcohol swabs
	• 2L Nalgene waste container with beta shield (brought by RSO)
	• TheraSphere dose vial, in lead pot (brought by RSO)

4. Segments 5&8 (Succesful)

RADIOPHARMACEUTICAL WRITTEN DIRECTIVE: 90-YTTRIUM MICROSPHERES

Patient Name	DOB	Medical Record #	Hospital
[redacted]	[redacted]	[redacted]	Methodist

PRE-ADMINISTRATION

Liver to be Treated	% Shunting	Device	Prescribed Activity (or Activity at Stasis)
seg 5/8	10	Theraspheres	1.73 GBq = 46.7 mCi

Maximum Dose Acceptable to Sites Outside Primary Treatment Site Due to Shunting	30 Gy

Authorized User Signature	Date Signed
Butty	10/13/2021
Authorized IR Physician Signature	**Date Signed**
Butty	10/13/2021

Manufacturer Lot #	Date of Measurement	Time
2099487/89	10/20/2020	11:45

Drawn Dose	Measurement Verified By
54.1 mCi	

POST-ADMINISTRATION

Waste Activity	Activity Delivered	Radiation Safety Office Designee
0.2 mCi	53.9 mCi	

Calculated Activity Delivered to Liver	Calculated Activity Outside of Liver Due to Shunting
48.51 mCi (103.9 %)	5.39 mCi

AU COMMENTS AND SIGNATURE (UPON STASIS OR EMERGENT PATIENT CONDITION ONLY)

☐ Treatment terminated due to stasis (decreased dose delivered) ☐
Treatment not completed due to emergent patient condition described below

Authorized User Signature Upon Stasis	Date Signed
Choose AU	

^{90}Y TheraSphere Dose Administration Sheet

Patient Initials: [redacted] Patient MRN: [redacted] Date: 10/20/20

Hospital: ☐ University ☑ Methodist ☐ Eskenazi ☐ Identity of patient confirmed

Prescribed Dose (mCi): 46.7 -20%: 37.36 +20%: 56.04
NOTE: 1 GBq = 27 mCi

Treatment of: ☐ Whole Liver ☐ Right Lobe ☐ Left Lobe ☑ Other: Seg. 5+8

I. Therasphere Dose (use setting 443)

Lot #: 2099487 Vial #: 89

Vial Information
Date: 2020-10-11 Time: 12 pm Activity (GBq or mCi): 19.48

A. Dose measured in dose calibrator : 54.1 mCi at 11:45 (time)

B. Dose within 20% of Written Directive Dose? ☑ Yes ☐ No
(If "No", refer to IR Physician administering the dose)

II. TheraSphere Measurements

A. Initial Dose Vial Measurement (taken at 3 inches on template)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Vial (mR/h)**	**Time**
27.09	22.87	18.20	22.65	22.70	11:50

B. OPTIONAL: Decayed Dose Rate & Dose **Tx time:**_____ **Elapsed time (h):**_____

(Initial mR/h)$e^{-(0.693/64h)(t)}$ = _____ mR/h

(Initial mCi)$e^{-(0.693/64h)(t)}$ = _____ mCi

C. Waste Measurements (taken at 3 inches)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Waste (mR/h)**	**Time**
0.077	0.143	0.101	0.047	0.092	14:12

D. Percent Dose Delivered: 1 - (Avg. Waste Measurement "C"/Avg. Initial Measurement "A") X 100 99.59 %

Dose Administered (based on drawn dose): Drawn Dose X % Dose Delivered 53.88 mCi

Percent of Written Directive: Dose Administered ÷ Prescribed Dose 115.37 %

E. Does dose administered differ from the prescribed dose by more than 20% : ☐ Yes* ☑ No
(If "yes", explain)

Comments:_____

Name/Initials: MM Meter Used: ☑ Inspector #18960 ☐ Inspector #35821 ☐ Inspector #21380 ☐ Other _____

Nuclear Medicine

Individual Preparing Dose: Michael / Riann Hall

☐ No contamination found in area, or (describe below):

☐ No contamination found on individual, or (describe below):

☑ Unit Dose – survey not required

Individuals in IR Suite

Physician: Butty

Resident/Fellow:

Resident/Fellow:

Rad Tech: Diana Pate

Rad Tech: Rachel Johnson

Nurse: Peggy

Other:

Box Set-up:

Patient Measurements

Final Patient Survey (near contact): 7.8 mR/h @ 1 M: 0.55 mR/h

☑ Integrated exposure at 1m from patient will not exceed 100 mrem (<1.08 mR/hr @ 1 M)

Comments:

IR/POCU Surveys

☑ Survey of individuals/rooms were background or

☐ Items removed from room as described below:

IR Room #: 1

Comments:

POCU Room #: 6

Comments:

POCU Surveyor Name/Initials: MM

POCU Meter: ☑ Inspector #18960 ☐ Inspector #35821 ☐ Inspector #21380

TheraSphere Checklist

Patient Initials: [redacted] ***Patient MRN:*** [redacted] ***Date of Treatment:*** 10/20/20

Treatment of: ☐ ***Whole Liver*** ☐ ***Right Lobe*** ☐ ***Left Lobe*** ☑ ***Other:*** Seg. 5+8

Microcatheter Brand & Lot/Serial: _____

TheraSphere Administration Set Lot # 197D ***Expiration Date:*** 5/7/2021

1. ***Items Required for TheraSphere Administration:***

- Patient prescription for TheraSphere (signed Written Directive)
- Geiger-Mueller (GM) contamination meter (by RSO)
- A floor drape applied under the cart in the angiography suite
- A sterile drape placed on the cart

Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***

• Hemostat
• Scissors
• Sterile adhesive strips (i.e., Steri-strip)
• Towels
• Gauze
	• Administration Set (in packaging)
	  ○ **Verify the expiry date**
	• TheraSphere Administration Accessory Kit (acrylic box)
	  ○ Remove the top shield
	  ○ Fully extend the stainless steel arm
	  ○ Install the bag hook
	• Electronic dosimeter (RADOS RAD 60R or equivalent)
	  ○ Turn the dosimeter on and set to mR/h
	  ○ Clip the dosimeter to its bracket on the acrylic box
	• Saline bag (in packaging) or bottle (minimum 100 mL)
	• Alcohol swabs
	• 2L Nalgene waste container with beta shield (brought by RSO)
	• TheraSphere dose vial, in lead pot (brought by RSO)

TheraSphere Checklist

2. ***Dosage Assay (at Nuclear Medicine):***
   - Obtain completed written directive
   - Check in TheraSphere package according to standard protocol.
   - Shake the lead pot to agitate the dose vial within. Gently tap the lead pot on a hard surface to dislodge any microspheres that may have adhered to the septum during shipment.
   - Remove dose vial from lead pot and place in dose calibrator.
   - Using the dose calibrator setting designated for TheraSphere doses (current setting 443), record the measured activity.

   ☑ ***DOSAGE ASSAY COMPLETED***

3. ***Pre-Procedure Dose Vial Measurements (at Nuc Med by RSO staff) – see RSO worksheet***

4. ***Administration Set Priming (in IR Suite)***
   - Open the Administration Set packaging and remove the Administration Set and 20 mL empty vial.
   - Insert the white NON-VENTED spike into the saline bag. Hang the saline bag on the hook.
   - Insert the white VENTED spike into the empty 20 mL 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 surface (e.g., sterile towel).
   - Turn syringe plunger fully clockwise to ensure it is unlocked (for 20 mL syringe is marked 'VakLok' supplied in kit).
   - Slowly fill and discharge the syringe to remove air from the Administration Set tubing and syringe. Continue priming vigorously with full pressure 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.

   ☑ ***PRIMING COMPLETED***

5. ***Dose Vial Preparation (in IR Suite)***
   - RSO staff will lift the TheraSphere dose vial in its lead pot and tilt and shake the lead pot back and forth to 90 degrees to wet any microspheres on the vial septum and tap the bottom of the lead pot firmly on a hard surface. The RSO staff will then place the lead pot into the pot holder in the acrylic box base.
   - RSO staff will remove the lead pot lid and place it upside down on a non-sterile surface. The lid will be checked for contamination and taken by the RSO staff for disposal.
   - 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 sterile adhesive strip (i.e., Steri-strip) to remove the dose vial acrylic shield plug. Discard the plug and sterile adhesive 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.

   ☑ ***DOSE VIAL PREPARATION COMPLETED***

TheraSphere Checklist

6. ***Final Assembly (in IR Suite)***
   - Close the pinch clamp on outlet tubing near label 'E' **(within an inch of 'E')**. Visually assure that clamp is fully engaged around tubing.
   - 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'. OPTIONAL: Clamp the priming line at label 'C' with a hemostat (or equivalent).
   - Push the YELLOW tabs on the Needle Injector Assembly all the way down, locking the needles into the dose vial. **You will hear or feel a click or snap.**
   - Ensure that the side shield is installed on the acrylic box. Place the top shield on the acrylic box with the sloped shield towards slot 'D.' Ensure that the tubing is not pinched or kinked.
   - Record the dosimeter initial reading:

Dose Vial (mR/h)
6.5

☑ ***FINAL ASSEMBLY COMPLETED***

7. ***Patient Connection (in IR Suite by IR)***
   - Move the cart close to the patient. Lower the bed to lowest position.
   - Place a sterile towel under the extension arm holder 'E,' and under holder 'C.'
   - Place a sterile towel across the gap between the acrylic box and the patient.
   - The Interventional Radiologist (IR) will flush the infusion catheter to ensure flow. Inspect the visible portion of the catheter for kinks or damage. Replace the infusion catheter if it is damaged or does not have satisfactory flow. Do not use a catheter extension or extra fittings. Replace the catheter if it is too short.
   - Disconnect the outlet tubing labeled 'E' from the priming tubing at holder 'C.' Firmly connect the outlet tubing 'E' to the catheter.
   - Place the catheter connection into the slotted holder 'E' at the end of the extended arm. Outlet tubing 'E' must be above the holder, with the infusion catheter hanging vertically below.
   - IR to verify catheter position.
   - Release the pinch clamp from the outlet tubing. Dents in the tubing may be reduced by rolling outlet tubing with fingers (e.g., massage).

☑ ***PATIENT CONNECTION COMPLETED***

TheraSphere Checklist

8. ***TheraSphere Administration (in IR Suite)***

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

- Record the starting time of the administration: 14:02
- Infuse TheraSphere Y-90 glass microspheres using steady pressure on the syringe plunger. Appropriate pressure may initially be determined by pushing syringe with just enough force to see saline entering the vented empty vial. At this point, the pressure should be backed off slightly until no flow into the empty vial is seen. Infuse continuously until syringe is empty (≥ 20 cc per minute).

  NOTE: If the infusion pressure is over 30 psi, excess fluid will drip into the vented 20 mL vial. If this occurs, reduce the pressure being applied on syringe until no flow is seen going into the vented vial. If the syringe flow is <20 cc per minute (i.e. appropriate to the flow of the native vessel), this may decrease the delivery efficiency of the administration system and result in higher residual waste.

- Observe the outlet line and catheter for proper operation. If a problem is observed, inform the team and take corrective action.
- Re-fill syringe for subsequent flushes by pulling back the syringe plunger. A minimum of 3 flushes (60 cc total) are recommended. Continue flushes until desired dosimeter reading is achieved. If the dosimeter reads above zero ("0") after the first or second flush, remove the delivery box lid and gently rock the shielded dose vial to facilitate the resuspension of microspheres. If desired reading is not achieved, notify radiation safety staff.
- Record the number of flushes completed: 3
- Record the time that administration was completed: 14:07
- Record the dosimeter final reading:

Dose Vial (mR/h)
0.0

☑ ***ADMINISTRATION COMPLETED***

TheraSphere Checklist

9. ***Disassembly (in IR Suite)***
   - Cut the inlet line at indicated position.
   - Remove the acrylic box top shield and side shield.
   - Do not disconnect the catheter from the outlet tubing. The IR will lift the catheter connection out of the extended holder 'E.'
   - Pull microcatheter into guiding catheter.
   - Use care to control the tip of the infusion catheter and guide catheter as these may be contaminated with microspheres. Use gauze, a small towel, or hemostat to handle the catheters for radiation protection. Any item that has come in contact with microspheres is considered contaminated.
   - Place all contaminated waste into the Nalgene waste container (in its beta shield), including the following:
     - Infusion and guide catheters with <u>attached</u> tubing and towels/gauze
     - Dose vial with <u>attached</u> Needle Injector Assembly (lift the lead pot and dump out the dose vial)
     - IR's outer gloves
     - Other significantly contaminated items
   - Cap the Nalgene waste container and place the acrylic lid on the beta shield. Remove for measurements to determine percent delivery and for disposal (by RSO or Designee).
   - Use a survey meter to check IR's hands for contamination (by RSO or Designee).
   - Survey all staff leaving the room with the survey meter (by RSO or Designee).

   ☑ ***DISASSEMBLY COMPLETED***

10. ***Post Procedure Checklist – see RSO worksheet (in IR Suite by RSO or Designee)***

11. ***Complete Post Calculations – see RSO worksheet (in IR Suite by RSO or Designee)***

12. ***Cleanup and Waste Disposal (in IR Suite by RSO or Designee)***
    - Use 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 and/or dispose of items as appropriate.
    - As required, clean the TheraSphere acrylic box with water, mild soap and a clean soft cloth. Alcohol wipes may be used (minimize alcohol contact with glued joints – alchohol degrades the glue over an extended time). Chlorine (bleach) disinfectants are also acceptable. Always use a clean soft cloth. <u>Do not use</u> industrial cleaner wipes, ammonia or abrasives to clean the acrylic parts of the acrylic box (by IR staff).
    - Replace the top and side shields on the acrylic box. Retract the extension arm and remove the bag hook. Turn off the dosimeter. Store the kit (by IR staff).

TheraSphere™

Calibration Data Sheet

PRODUCT:	TheraSphere™ Y-90 Glass Microsphere	
LOT NUMBER:	2099487	
VIAL #:	89	55.2 @
DOSE SIZE:	20.0 GBq	9:38
CALIBRATION DATE and TIME:	2020-10-11	@ 12:00 ET
MEASURED TOTAL ACTIVITY*:	19.48 GBq	
EXPIRATION DATE:	2020-10-23	@ 23:59 ET

* value at calibration date and time

Please note: When the TheraSphere™ Y-90 Glass Microsphere dose vial is received, the site will confirm it is the correct activity for the patient treatment by measuring in a dose calibrator (activimeter).

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