MIDDLESEX
HOSPITAL

ADMINISTRATION

May 17, 2016

Tara Weidner
Health Physicist
Division of Nuclear Material Safety
U.S. NRC Region I
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Re: ***Therasphere Y-90 Policy and Staff Training***

Dear Ms. Weidner:

Enclosed please find a copy of the Therasphere Y-90 policy for Middlesex Hospital.

On May 16, 2016 and May 17, 2016, the Middlesex Hospital Radiation Safety Officer trained the authorized user, the interventional radiology technologists, and the nuclear medicine technologists on Middlesex Hospital Therasphere Y-90 policy. The training included that part of the policy which defined and classified a reportable medical event, the need for immediate notification of the appropriate hospital personnel, reporting to the NRC Operations Center within one calendar day, the requirement for submission of a written report to the NRC Region 1 office within 15 days of the event, and written notification to the referring physician within 15 days.

Please inform Dr. Joan Merton, Middlesex Hospital Radiation Safety Officer, via her e-mail Joan.Merton@midhosp.org or by calling 860-358-6470 if the NRC requires any further information. Thank you for your kind attention to this matter.

Sincerely,

Garrett Havican
Vice President
Strategic Planning /Ambulatory Operations

Enclosure

cjc

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MIDDLESEX HOSPITAL
AND MEDICAL CENTERS
RADIOLOGY DEPARTMENT

TheraSphere Y-90 Policy

Purpose: To establish a policy and procedure for administration of TheraSphere Y-90

Authorized User:

1. Only the authorized user can administer TheraSphere Y-90.
2. The authorized user must be approved by the Nuclear Regulatory Commission (NRC) and be listed on the Middlesex Hospital NRC license No. 06-00649-03 as an authorized user of Yttrium 90 TheraSphere.
3. The authorized user must have met all condition, education, and training prescribed by the NRC and the NRC Micro-sphere Brachytherapy Source and Devices Guide.

Initial Training:

1. The Interventional technologists assembling the Y-90 delivery system(under the supervision of the AU) and the Nuclear Medicine technologists participating in any aspect of the Y-90 procedures must have documented training.
2. The authorized user (AU) must be on the hospital NRC license and must have the required documented training.
3. The Radiation Safety Officer must have documented Nordion/BTG Radiation Safety Training.

Annual Training:

Effective June 1, 2016, all Nuclear Medicine technologist, Interventional Radiology technologists and Authorized Users, who are involved with Y-90 proceedures, must have documented annual training on this policy including reportable medical event requirements. The training is to be provided by the hospital RSO.

Written Directive:
A blank written directive is attached to this Policy as Appendix A
The written directive must include the following:

1. Patient name
2. Treatment date and time
3. Signature of authorized user for TheraSphere Y-90
4. Treatment site
5. Radionuclide including physical form
6. Prescribed dose activity
    a. Prescribed dose must be in units of rads, Grays, mCi, or GBq.
7. Manufacturer
8. Maximum acceptable dose/activity acceptable to sites (eg. lung) outside of the primary treatment site.

Reasons for changes in the written directive, due to emergent patient issues, must be entered on the written directive.

Administration of TheraSphere Y-90:

1. Administration of the TheraSphere Y-90 must be performed according to the written directive
2. If administration is terminated due to a patients condition (eg stasis) :
    a. The total dose/activity reported is the dose/activity delivered at the start of the event (eg stasis).
    b. A record will be prepared within 24 hours and will include the name of the individual making the assessment, date and signature of the Authorized User.

Calculation/Documenting Dose:

1. The Manufacturer's procedure for calculating and documenting dose is to be followed for:
    a. Treatment site
    b. Areas other than the treatment site (eg lung)
    c. Preparing dose for administration
    d. Pre vial dose measurements
    e. Post vial dose measurements

The manufacturer's forms for calculating and documenting dose is attached (see Appendix A and B).

Leak Test

1. Leak tests are not required for TheraSphere Y-90.

Survey and Wipe Test

1. A Survey and Wipe test, which includes the unique identifierfor the package, is to be performed by the Nuclear Medicine technologist once the package is delivered to the Nuclear Medicine Hot Lab.
2. A Survey and Wipe tests will be performed on all areas/floors shown on the attached Nuclear Medicine Department/Interventional Suite diagram post procedure. (see Appendix C)
3. All values of the of the survey and wipe tests, including background, will be entered into the Nuclear Medicine Information System (NMIS).

Physical Inventory of TheraSphere Y-90

Y-90 waste will be stored within the well in the Save-For-Decay room. A physical quarterly inventory of the Y-90 waste is to be performed by the consultant Nuclear Medicine Physicist in the company of the Nuclear Medicine technologist. The consultant Nuclear Medicine Physicist is to confirm that the actualY-90 waste agrees with the information stored in the NMIS as to the following:

1. Radionuclide = Y-90 TheraSphere
2. Unique identifier in the NMIS matches the unique identifier on the waste container.
3. The amount of Y-90 activity for each container/vial.
4. Location of vials (eg. Save-for-Decay room)

The inventory records must be maintained for 3 years.

Pregnant or Nursing Patients

TheraSphere Y-90 infusion will not be administered to pregnant patients or patients who are nursing.

TheraSphere Y-90 Patient Release

Patients are released with the attached instruction form (See Appendix G) when the administered activity is five (5) GBq or less. In the unusual case when the administered activity is to be greater than five (5) GBq, the AU must consult with the Radiation Safety Officer regarding any additional release instructions or restrictions.

Reportable Medical Events for TheraSphere Y-90

Events should be reported to the NRC per 10 CFR 35.3045.

A reportable event is described as one that includes a dose/activity different from the prescribed dose or prescribed activity on the written directive by:

1. more than 5 rem effective dose equivalent OR
2. 50 rem to an organ or tissue and the total dose activity administered differs from the prescribed dose activity by 20% or more OR
3. That exceeds 5 rem effective dose equivalent or exceeds 50 rems to an organ or tissue from an administration to
    a. a wrong patient OR
    b. by a wrong route OR
    c. by the wrong mode of treatment
4. to an organ or tissue other than the treatment site that exceeds 50 rem to an organ or tissue and by 50 percent of more of the prescribed dose/activity expected to that site from the administration of Y-90.

Per 10 CFR 35.3045 The NRC Operations Center must be notified (301-816-5100) no later than the next calendar day after discovery of the reportable event. A written report must be sentto the NRC Region 1 office within 15 days after discovery of the reportable event. A copy of the annotated report with the patients name and medical record number must be sent to the referring physician within 15 days.

The Post Treament Template and Reportable Medical Events

After the Y-90 proceedure is completed the technologists must take 4 measurements around the waste container. These 4 measurements are entered by the technologist in the Post Treatment Template on the Therashere Y-90 Written Directive Excel Spreadsheet. The spreadsheet then calculates the "% Delivery to the Target Tissue".

If the percent delivery is less than 80% or greater than 120% than the following actions must be performed:

1. The NM technologist must notify the Authorized User, RSO and radiology administration immediately.
2. The Authorized User or RSO will notify the NRC at 301-816-5100 no latter than the next calendar day if a reportable medical event is confirmed.
3. The radiology administrator, RSO or Authorized User will notify senior hospital administration.

Procedural Steps to be Followed for Y-90 TheraSphere treatments:
The following three pages of this policy list the procedures.

A. Preliminary (prior to day of Y-90 treatment) Procedures:

1. Authorized User to complete Written Directive

2. The Nuclear Medicine Technologist will enter the intended procedure date/time on calendars of: Authorized User, Lead IR tech, Lead Nuc Med tech, RSO, and all Nuc Med techs.

3. Radiology Scheduling will schedule the patient into the Radiology Information System (RIS).

4. The Nuclear Medicine Technologist will complete the BTG TheraSphere Order Form and email or Fax the form to BTG by 5 PM Friday for calibration on Sunday. (see Appendix D)

5. The Nuclear Medicine Technologist will alert the storeroom when the dose is expected to be delivered by Fed Ex.

6. The Storeroom will contact Nuclear Medicine when the package(s) arrives.

7. The Nuclear Medicine Technologist will pick up the package from the Storeroom and, after inspecting the package for damage or leaks, deliver it to the Hot Lab.

The Nuclear Medicine technologist must perform items 8 to 20 below.

8. The Package will be surveyed and wiped and the values will be entered into the NMIS. The Lot Number will also be used as the Case ID number.

9. Tilt the Lead Pig containing the TheraSphere Y-90 vial 90^0 and tap the Lead Pig on a hard surface.

10. Measure the activity of the Y-90 vial in a dose calibrator using the Y-90 button which is set to the calibration factor of 49 X10. Record the activity in mCi and GBq.

11. Compare measured activity to Nordion stated activity. If it disagrees by >3%, contact the RSO and Lead Nuclear Medicine Technologist.

12. Store the TheraSphere Y-90 vial, in a Lead Pig behind the 2nd L block to the left of the well in the safe and decay room (SFD) room. The door to this room must always be locked. Remember to call Security before entering the SFD room so they are aware of why the alarm is activated in Security.

13. Notify the Authorized User, the RSO, Lead IR tech, Lead Nuc Med tech, and all the Nuc Med techs. that the dose is in the SFD room.

14. Place all shipping documents and the Calibration Data Sheet in the Y-90 binder.

B. Procedures for Day of Treatment

15. Check that the survey meter, ionization meter and rados (electronic dosimeter) are operational.

16. Obtain patient pamphlet, Case Worksheet, TheraSphere Checklist and Discharge Instruction form. (see Appendix E, F, G)

17. Tilt the TheraSphere Y-90 vial, in Lead Pig, 90^0 and tap the Lead Pig on a hard surface. Do this three times. Measure the activity of the vial in the Dose Calibrator using the Y-90 button which is set to the calibration of 49 X10. Record the activity in mCi and GBq. Compare measured activity to Nordion/BTG stated activity. If it disagrees by >3%, contact the RSO and Lead Nuclear Medicine Technologist.

18. Use the Survey meter to measure, in mR/hr, the pre-treatment activity, the activity being emitted from the TheraSphere Y-90 vial placed on the Nordion/BTG template. (Measure background before Y-90 is brought into the room.)

19. Place green Herculite on the floor of the Interventional Suite. Place blue chuck pads on the floor inside the suite in front of the door leading to the control booth.

20. Obtain background readings of the Interventional Suite.

21. All personnel entering the treatment room shall wear protective equipment as needed, including scrubs or disposable gown, hair cover, face mask, gloves, shoe covers and during fluoroscopy a lead apron.

22. All personnel in the treatment room shall wear personnel dosimeters.

23. After the patient enters the Interventional Suite, the NM technologist must obtain and document the survey readings at patient surface and at 1 meter using the ionization chamber.

24. Check that Rados is set to mR/hr.

25. The Interventional Radiology technologist is to placea drape on the cart, and place the TheraSphere delivery system components on top of the drape. Follow instructions from the Nordion TheraSphere checklist. (See Appendix F)

26. The Nuclear Medicine technologist is to record the Rados inital and final readings.

27. The Interventional Raiology technologist assemles the deliery system in the IR room per the BTG directionds in Appendix F.

28. The Nuclear Medicine technologist reads the step by step instructions for the IR technologist assembly and for the AU radiologist delivery per Appendix F.

29. The AU radiologist confirms the set-up of the delivery system and prepares the vial and tubing for Y-90 therassphere delivery per BTG instructions (Appendix F).

30. The AU radiologist delivers the aY-90 therasphere dose to the patient.

31. After the waste is removed from the Interventional Suite, the NM technologist is to obtain and document the survey readings at patient surface and at 1 meter using the ionization chamber.

32. The NM technologist and/or physicist, using the Nordion Template, is to obtain and record the post-treatment readings, in mR/hr, from the Nalgene waste container placed inside the plastic holder. The Nalgene container contains all contaminated waste and the Y-90 vial still attached to the plunger, tubing, and catheter. The waste container is labeled with the unique identifier number obtained from the NMIS and placed in the save-for-decay (SFD) room for 10 half-lives.

33. The NM technologist, AU and/or physicist is to enter on the Nordion (BTG) TheraSphere Y-90 Glass Microspheres Written Directive form the Pre-Treatment Template Measurement, the Treatment/Administration information, and the Post-Treatment Template Measurements (see Appendix A). If the total calculated activity differs from the prescribed activity (GBq/mCi) by more than 10%, contact the RSO and Lead Nuclear medicine technologist as soon as possible. If the calculated activity differs from the perscribed activity ny more than 20% notify the RSO and AU immediately and follow the steps in the *The Post Treament Template and Reportable Medical Events* section of this policy.

34. The Authorized User and the NM technologist or RSO are to review, sign and date the completed TheraSphere Y-90 Glass Microspheres Written Directive (Appendix A).

35. Patient release should follow the Therasphere Y-90 patient release section of the Therasphere Y-90 policy. The radiation safety information form must be filled out by the NM technologist, signed by the patient and given to the patient. (see Appendix G) The "Therasphere A Patients Guide, Important Information for People with Liver Cancer" booklet is to be given to the patient.

36. Waste is released from the SFD room at background and placed in a Large Sharp's container. The NMIS system is to be updated with the waste disposal information. A printed record is kept in the Y-90 book.

Revised: 8/26/15 (SP, JM, KC), 4/18/16 (JM), 5/17/16 (JM, KC)

APPENDIX A

Appendix A

TheraSphere® Y-90 Glass Microsphere Written Directive

Patient Name		Patient ID / MRN	

Pre-Treatment Planning

This section must be approved by the Authorized User.

Target Tissue (Treatment site)		Lung Shunt Fraction (%LSF)	
Target Volume (cc)		Cumulative Previous Dose to the Lungs (Gy)	
Mass (kg)		Manufacturer: Nordion	Device: Y-90 TheraSphere
Desired Dose to Target Volume (Gy)			
Treatment date and time		Required Total Activity at time of Treatment (GBq)	
Time zone of Hospital		Number of vials to be administered to Target Tissue	

	Dose Vial A		
Ordered/Received Dose Size (GBq)			
Calibration Date			
Hours from Calibration to Treatment (hrs)			
Nominal Activity in Vial at time of Treatment (GBq)			
Sum of Nominal Activity in Vial(s) at time of Treatment (GBq)			
Calculated dose to lungs at Treatment time, assuming 1kg lungs (Gy)			
Cumulative dose to lungs (Gy)		Authorized User signature & date	
Dose to Target Volume at Treatment, accounting for lung shunt (Gy)			

Pre-treatment Dose Calibrator (DC) Measurement

Measure the received dose vial(s) in a dose calibrator using TheraSphere setting and correction factor

	Dose Vial A		
Nominal Dose Size (GBq)			
Manufacture's Lot Number and Vial Number			
Date and Time of DC measurement			
DC Measured Activity, with correction factor (GBq)			
Hours from Calibration to DC Measurement (hrs)			
DC Measured Activity referenced to Calibration time (GBq)			
OPTIONAL: Manufacturer's Activity at Calibration (GBq)			
Value to be used in Delivery calculations below:	Dose Calibrator Measurement	Measured by (initials):	

Pre-treatment Template Measurement

Measure the dose vial (no lead pot) @ 30 cm with ion chamber meter on Template

	Dose Vial A		
Date and Time of Template measurement			
Measurement of Dose vial on Template (mR/h)			
Background Measurement (mR/h)			
Net dose rate of Dose vial on Template (mR/h)			
		Measured by (initials):	

Treatment / Administration

Methods used to confirm Patient Identity (select two)			
	Dose Vial A		
Confirm Lot number and Vial number (on label) matches Line 23 above	☐ Check if Lot # & Vial # match	☐ Check if Lot # & Vial # match	☐ Check if Lot # & Vial # match
Administration Start Date & Time			
Patient dose rate, maximum on contact (mR/h)		Measured by (initials):	
Patient dose rate, maximum at 1 meter (mR/h)			

AU / ADMINISTERING PHYSICIAN comments (sign & date): ☐ None

Post-treatment Template measurements

Measure the waste jar in beta shield @ 30 cm with ion chamber meter on Template

		Waste Jar - Vial A		
Date and Time of Template measurement				
Waste Container Measurement in Beta shield (mR/h), 4 Cylinder Orientations on Template	Background Measurement (mR/h)			
	0°			
	90°			
	180°			
	270°			
Average of 4 Orientations minus Background (mR/h)				
Hours between Pre- and Post- Treatment Measures (hrs)				
Pre-Treatment Net Rate decayed to Post- Treat time (mR/h)				
Hours between Calibration and Treatment (hrs)				
Activity Administered per Vial at time of Treatment (GBq)				
Overall Percent delivery to Target Tissue		Measured by (initials):		

Final Calculations

Calculated values below use formulas from the TheraSphere package insert. The AU must confirm accuracy.

Total Activity Delivered to Patient at time of Treatment (GBq)		Lung shunt fraction (%)	
(mCi)		Activity to Lungs (GBq)	
Activity Delivered to Perfused Liver Tissue (GBq)		(mCi)	
(mCi)		Radiation to Lungs (Gy)	
Radiation dose to Perfused Liver Tissue (Gy)		Cumulative radiation to Lungs (Gy)	

Physicist/RSO/CNMT signature & date	Authorized User signature & date

APPENDIX B

Appendix B

Patient Name: Patient ID Target Tissue:

Target Volume (cc): 120 Please enter the target volume (cc) Target Liver Mas 0.000

Desired Dose (Gy): Please enter the desired dose (Gy)

Time Zone Variance (h): 0 (see Time Zones tab for details) Places in this Time Zone: Ottawa Ontario, New York NY

ing Shunt Fraction (% LSF):

Anticipated Residual Waste (%): If no number entered, value is a

Previous Dose to the Lungs (Gy): If no number entered, value is assumed to be zero.

Required Activity at Administration (GBq): This value is corrected for LSF and Residual Waste if values are entered above

Calculated Dose to Lungs (Gy):		Dose Limit to the Lungs per treatment (Gy):	30
Cumulative Dose to Lungs (Gy):	0.00	Cumulative Dose Limit to the Lungs (Gy):	50

See Package Insert or Instructions for Use

Lung Dose within recommended cumulative limit for treatment

Use the following tables to select a dose size where the Desired Dose (above) is at a suitable treatment time.

Dose Size Selected (GBq): Optional field for Medical Professional to document treatment dose selected

Date & Time for Administration: Optional field for Medical Professional to document treatment window selected

Tables below show the dose to perfused target tissue, accounting for target mass, time zone variance, lung shunt fraction and residual waste.

Dose Delivered (Gy) for: 3 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for: 5 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for: 7 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for: 10 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for: 15 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for: 20 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Dose Delivered (Gy) for a Custom Dose size: 7 GBq dose size

Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week 2 treatment Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
8:00 AM	Calibration Day @ 12:00 Eastern Time	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
12:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
4:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
8:00 PM		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

All dose vials will have Sunday calibration at 12:00 Eastern Time.

Standard dose vial sizes (3, 5, 7, 10, 15, 20 GBq) are available from inventory for next-day shipping. Order as required.

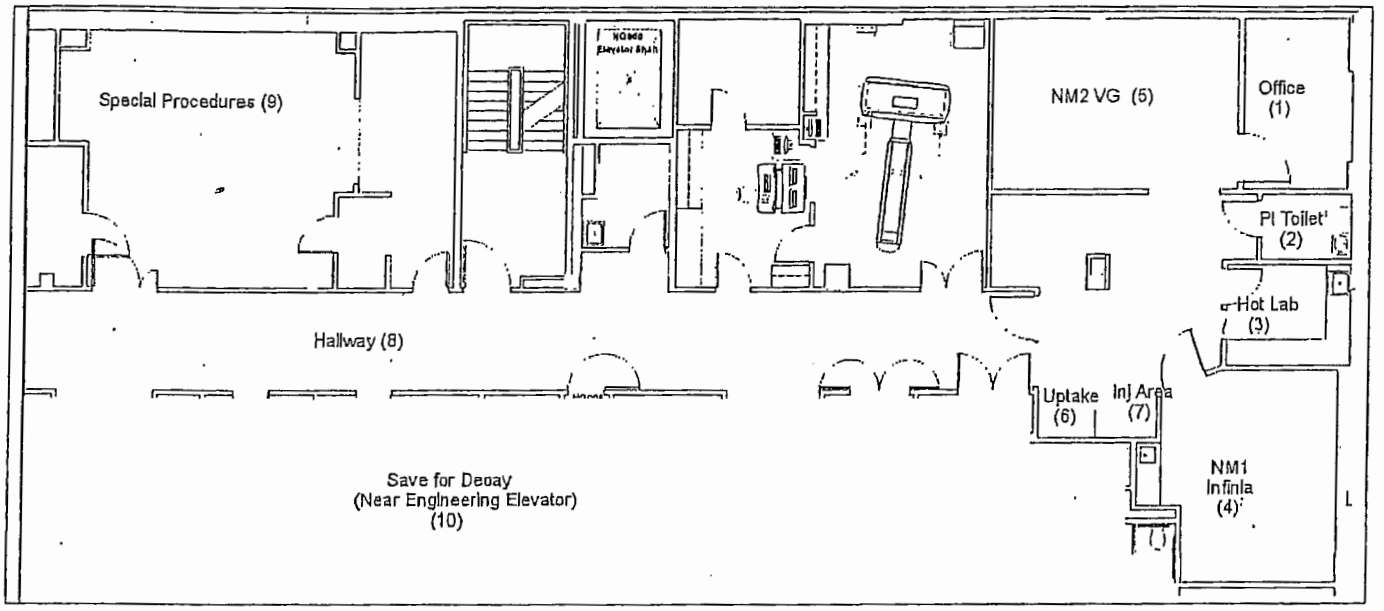
Custom dose vial sizes should be ordered by end of business Tuesday prior to Sunday calibration to ensure availability.

APPENDIX C

Appendix C

MIDDLESEX HOSPITAL

NUCLEAR MEDICINE DEPARTMENT/ INTERVENTIONAL SUITE



Location ID	Description of Survey and Wipe Areas
1.	Lead NM Technologist Office
2.	Nuclear Medicine Patient Toilet and Sink
3.	**Nuclear Medicine Hot Lab (location where Nordion Y-90 microspheres will be prepared)**
4.	NM GE Infinia SPECT Imaging Room 1
5.	NM GE VG SPECT Imaging Room 2
6.	NM Thyroid Uptake Probe
7.	NM Patient Injection Area
8.	Hallway from Nuclear Medicine Department to Special Procedures/Interventional Radiology Room
9.	**Interventional Radiology Suite (location where the Nordion Y-90 microspheres will be injected)**
10.	Save for Decay Room (located near the engineering elevator)

APPENDIX D

BTG

TheraSphere®

APR 14

Appendix D

TheraSphere® Order Form

Customer Service Telephone: 1-866-363-3330

Please complete this form and email to theraspherecustomersupport@btgplc.com or fax to **1-800-268-5299** (North America) or **1-613-482-4843**. All fields are mandatory.

SITE NAME:

LOCATION IDENTIFIER:

CONTACT NAME:

CITY:

TELEPHONE NUMBER:

EMAIL ADDRESS:

FAX NUMBER:

PATIENT REFERENCE:

PURCHASE ORDER NUMBER:

PLANNED TREATMENT DATE: / / /

PLANNED TREATMENT TIME:

Standard Dose Required:

Standard Dose #1 (GBq) 0 Quantity: 0 Calibration Date*: / / /

Standard Dose #2 (GBq) 0 Quantity: 0 Calibration Date*: / / /

Custom Dose Size Required:**

Custom Dose #1 (GBq) 0 Quantity: 0 Calibration Date*: / / /

Custom Dose #2 (GBq) 0 Quantity: 0 Calibration Date*: / / /

* Patient treatment can be planned for 12 days following Calibration Date.

** Custom Dose Size orders should be received by close of business on the Tuesday before Sunday calibration date. A confirmation will be sent for standard and custom dose size orders within 24 hours of order receipt.

Administration Sets – Please send: 0

For BTG Use Only

Config: Ship Date: S.O. Number:

Allocated: Confirmed: Booked by:

APPENDIX E

APPENDIX E

THERASPHERE CASE WORKSHEET

Center: _____ Date:

Target Tissue: _____

Ordered Dose Size: _____ Calibration Date:

Lot #:_ Vial #:_ Calibrated Activity:

Treatment Date/Time:

Hour/Fraction Remaining Factor:

Projected Activity at time of treatment:

PRE-TREATMENT DOSE CALIBRATOR MEASUREMENTS

Date and Time of DC Measurement: _____

DC Measured Activity (GBq) (X 27 for mCi):_____ Calibration Factor:_____

Date/Time of 2nd DC Measurement:_____ Activity:_____

PRE-TREATMENT TEMPLATE MEASUREMENTS

Date and Time of Template Measurement: _____

Measurement of Dose Vial on Template (mR/h):_____ Background (mR/h): _____

Date/Time of 2nd Template:_____ Vial:_____ Background:_____

TREATMENT/ADMINISTRATION

Pre-Tx Patient Dose/Rate (max on contact) mR/h: _____ (max at 1 meter): _____

Initial Rados Measurement:_____

Infusion Start Time:_____

Rados to 0.0 time:_____

Number of Flushes:_____

End Time:_____

POST-TREATMENT WASTE TEMPLATE MEASUREMENTS

Post - Tx Patient Dose/Rate (max on contact) mR/h:_____ (max at 1 meter): _____

Date and Time of Template Measurement: _____

Background (mR/h):

Waste: 0: 90: 180: 270: Total Ave:

Percent Delivery: Target Tissue Percent:

APPENDIX F

Appendix F

TheraSphere® Checklist

Patient Name _____ ***Number*** _____

Date of Treatment _____

TheraSphere® Lot Number _____ ***Labeled Quantity (GBq)*** _____

Catheter Information:
(Place catheter sticker in the space provided below)

Measure and record the initial radiation field for the patient, using an ionization survey meter.

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

- ☐ Patient prescription for TheraSphere® (signed Written Directive)
- ☐ Ionization survey meter
- ☐ Geiger-Mueller (GM) contamination meter
- ☐ Spill kit
- ☐ 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 ☐ Towels ☐ Gauze	☐ Administration Set (in packaging) Lot #_____ o Verify the expiry date ☐ TheraSphere® Administration Accessory Kit (acrylic box) o Remove the top shield o Fully extend the stainless steel arm o Install the bag hook ☐ Electronic dosimeter (RADOS RAD 60R or equivalent) o Turn the dosimeter on and set to mR/h o 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 ☐ TheraSphere® dose vial, in lead pot

TheraSphere® Checklist

2. *Administration Set Priming*

- ☐ Open the Administration Set packaging and remove the Administration Set and 20 mL empty vial.
- ☐ Insert the white non-vented spike (CLEAR CAP) into the saline bag. Hang the saline bag on the hook.
- ✳ ☐ Insert the white vented spike (BLUE CAP) into the empty 20 mL vial.
- ☐ Remove the (RED RUBBER) shield cap from the needle injector assembly. Place the needle injector assembly on a sterile surface.
- ☐ 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.
- ☐ ——— (recap (red cover) if needed)

3. *Dose Vial Preparation*

- ☐ Lift the TheraSphere® dose vial in its lead pot and tilt the lead pot back and forth to 90 degrees to wet any microspheres on the vial septum. Tap the bottom of the lead pot firmly on a hard surface. Place the lead pot into the pot holder in the acrylic box base.
- ☐ Remove the lead pot lid and place it upside down on a non-sterile surface.
- ☐ 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 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 swab the dose vial septum. Discard the swab in the Nalgene waste container.
- ☐ Record the dosimeter initial reading from the dose vial (mR/h).

Dose Vial (mR/h)

4. *Final Assembly*

- ☐ Close the pinch clamp on the outlet tubing near label 'E.'
- ✳ ☐ Place the empty 20 mL vial in the holder on the acrylic box and push the relief valve tube into gripper clip 'A.'

Do this under #2

- ☐ Insert the needle injector assembly into the acrylic dose vial shield. Press on the GREEN cap to lock it in place. You will hear or feel a click or snap.
- ☐ Place the inlet tubing through slot 'B' in the acrylic box. Place the outlet tubing through slot 'D' in the acrylic box. Loop the tubing around the side and place the fitting into the holder at 'C.'
- ☐ 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 at the bottom of travel.
- ☐ 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.
- ☐ 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. 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.
- ☐ The IR will verify the infusion catheter position. Release the pinch clamp from the outlet tubing. Dents in the tubing may be reduced by rolling outlet tubing with fingers.

5. *TheraSphere® Administration*

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: _____
- ☐ Infuse TheraSphere® Y-90 glass microspheres using steady pressure on the syringe plunger. 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 the desired dosimeter reading is achieved.
- ☐ Record the number of flushes completed: _____
- ☐ Record the time that administration was completed: _____
- ☐ Record the dosimeter final reading:

Dose Vial (mR/h)

6. *Disassembly*

- ☐ Cut the inlet line at indicated position.
- ☐ Remove the acrylic box top shield and side shield.
- ☐ The IR will remove the infusion catheter from the patient and lift the catheter connection out of the extended holder 'E.' Do not disconnect the catheter from the outlet tubing. 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 attached tubing and towels/gauze
  - Dose vial with attached Needle Injector Assembly
    - Lift the lead pot and dump out the dose vial
  - Contaminated items such as gauze, towels, and gloves
- ☐ Cap the Nalgene waste container and place the acrylic lid on the beta shield. Remove for measurements to determine percent delivery and for disposal.
- ☐ Use a GM contamination meter to check IR's hands for contamination.
- ☐ Survey all staff leaving the room with the GM contamination meter.

7. *Cleanup and Waste Disposal*

- ☐ 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 – alcohol degrades the glue over an extended time). Chlorine (bleach) disinfectants are also acceptable. Always use a clean soft cloth. Do not use industrial cleaner wipes, ammonia or abrasives to clean the acrylic parts of the acrylic box.
- ☐ 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.

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

APPENDIX G

Appendix G

PATIENT LABEL:

DEPARTMENT OF RADIOLOGY
28 CRESCENT STREET
MIDDLETOWN, CT 06457
860-358-6293

RADIATION SAFETY INFORMATION FORM

PATIENT's NAME: _____

PROCEDURE: Yittrium-90 (Y-90) Radioembolization

DATE of PROCEDURE: _____

The external radiation to other individuals is very low and highly unlikely to cause any harm. In the interest of further minimizing these low radiation exposures please follow the instructions below.

PLEASE FOLLOW THE INSTRUCTION 1 and 2 BELOW UNTIL: _____(3 days)

1. Minimize prolonged contact (within 3 feet) with children.
2. Minimize prolonged contact (within 3 feet) with pregnant women.

PLEASE FOLLOW THE INSTRUCTIONS 3 to 5 BELOW UNTIL _____(30 days)

3. Please carry this form with you for international travel.
4. Notify Middlesex Hospital's Radiation Safety Officer (860-358-6293) before surgery is performed.
5. Cremation is not allowed within the 30 days post treatment.

I have received a copy of the pamphlet: "TheraSphere, A Patient's Guide, Important Information for People with Liver Cancer"

_____ _____

Patient Signature upon receipt Date/Time