

## Edward B. Silberstein, M.D.

TELEPHONE: (513) 584-9032  
FAX: (513) 584-7690  
E-MAIL: edward.silberstein@uchealth.com

15 August 2016

From: Edward B. Silberstein, M.D.

To: Ryan Craffey, Fax 630-515-1259

Attached is the report/analysis on the misadministration at Spectrum Health Hospitals April 27, 2016.

Sincerely/



Edward B. Silberstein, M.D.

**MEDICAL CONSULTANT REPORT (SHORT FORM)**  
Official Use Only

Medical Consultant Name: Edward B. Silbert, M.D. Report Date: 8/6/16

Signature: Edward B. Silbert

Licensee Name: Spectrum Health Hospitals

License No.: 21-00243-06 Docket No.: 030-01989

Facility Name: Spectrum Health Hospitals Incident Date: 4/27/16

\* Estimated Dose to Individual or Target Organ: 400 Gy to liver segments 4a, 4b  
(437 Gy by our calculation - see attached)

Probable Error Associated with Estimation: \_\_\_\_\_

Prescribed Dose: 120 Gy

Method used to calculate dose:

\* by AU.  
we calculated dose using Therasphere Package Insect Technique from Neutron Corp. assuming 5% lung shunting, and found 437.5 Gy to segments 4a & 4b.

General description of records reviewed:

Incident report to Region III office.

Individuals contacted (name and title):

Ms. Lesley Caroll, Sr. Clinical Risk Mgr.,  
four times (no answer twice)

Description of incident:

89.7 mCi of T-90 labeled Theraspheres, prescribed to palliate hepatocellular carcinoma, were accidentally injected into segments 4a & 4b instead of segments 5-8 of the patient.

Why a site visit is not required:

Records of accident very clear and cause obvious, as the AU failed to verify position of microcatheter tip just before injection of T-90.

Assessment of probable deterministic effects of the radiation exposure on the individual:

Hepatic and tumor necrosis are anticipated while increasing retraction and volume loss have been documented in segment 4 on a CT scan done 2 1/2 months after the misadministration. The tumor in segment 4b is larger. The pattern of enzyme rise & fall is consistent with radiation necrosis of the liver also a / E. B. Silbert

Enclosure 7

## Y-90 TheraSphere Dose Calculations

Patient:	Craffey, Ryan	Date:	08/08/16
MRN:		DOB:	
Patient Height (ft):		Total Liver Volume (cc):	1290.000
Patient Weight (lbs):		Left Lobe (4a, 4b) Lobe Volume (cc):	350.000
% Lung Shunting:	5.0%	Tumor Volume (cc):	
Medical Physicist: Morton/Ristagno			

GBq	mCi	Therasphere Order Date	Time	Special
	0.00	4/24/2016 (Sunday)	12:00	
		Prescribed Activity		
		Scheduled Date	Scheduled Time	Elapsed (hr)
	89.73	4/27/2016 (Wednesday)		60:00
Estimated Dose Fraction to the Lung from MAA Study				
Fraction	Activity	Mass	Dose	
F	GBq	kg	Gy	
5.0%		1.0	8.30	
Estimated Liver Dose - Left Lobe (4a, 4b) Tumor				
Mass	Dose			
kg	Gy			
0.361				

Therapy Date	Liver Region	Gy	Gy	Cumulative Total
Previous Lung Dose:				
Previous Liver Dose:				

GBq	mCi	Date	Time	% Difference
	0.00	4/27/2016		-100.0%
		Date	Time	% Difference
	0.00	4/27/2016		-100.0%
Dose Administered to Patient				
	Liver (Gy)			Lung (Gy)
	0.00			0.00

## Craffey, Ryan

---

**From:** Silberstein, Edward (silbereb) <silbereb@ucmail.uc.edu>  
**Sent:** Thursday, August 25, 2016 10:12 PM  
**To:** Craffey, Ryan  
**Subject:** [External\_Sender] RE: Spectrum Health Medical Event Follow-up

I do not expect any significant consequences for the patient because of the destruction of segments 4a and 4b. These are small and were shrinking 2-3 months post y-90. The problem for the patient was that the tumor there was enlarging. *Cirrhosis and cancer will determine his life span, not a small amount of hepatic radionecrosis.*

Sincerely,

Edward B. Silberstein, M.A., M.D.  
Eugene L. and Sue R. Saenger Professor  
of Radiological Health and Medicine, Emeritus  
G026 Mont Reid Pavilion  
University of Cincinnati Medical Center  
234 Goodman St.  
Cincinnati, OH 45219  
[Edward.silberstein@ucmail.uc.edu](mailto:Edward.silberstein@ucmail.uc.edu)  
(o) 513-584-9024 (fx) 513-584-7690  
(c) 513-532-7367

---

**From:** Craffey, Ryan [Ryan.Craffey@nrc.gov]  
**Sent:** Thursday, August 25, 2016 6:14 PM  
**To:** UCH-Silberstein, Edward (Edward.Silberstein)  
**Subject:** Spectrum Health Medical Event Follow-up

Good evening Dr. Silberstein,

Thank you again for following up with us on the Spectrum Health medical event.

Could you please confirm whether you expect any consequences for the patient which are directly attributable to the radionecrosis caused by the medical event? For example, loss of liver function, the need for additional treatment, etc.

If you do expect any consequences, can you describe the significance of them relative to the effects of other pre-existing conditions which the patient is already experiencing?

**Ryan Craffey**  
Health Physicist  
US Nuclear Regulatory Commission  
Materials Inspection Branch, Region III  
(630) 829-9655

## **RIIIDNMS\_ADMIN Resource**

---

**From:** Craffey, Ryan  
**Sent:** Thursday, September 01, 2016 12:16 PM  
**To:** RIIIDNMS\_ADMIN Resource  
**Subject:** Submit Doc to ADAMS  
**Attachments:** 665S - Spectrum Medical Consultant Report.pdf; Spectrum Medical Consultant Report.pdf

Good afternoon,

Since I'm on telework, would it be possible to have the attached document submitted to ADAMS via email? The 665 is also attached.

Thanks!

**Ryan Craffey**

Health Physicist  
US Nuclear Regulatory Commission  
Materials Inspection Branch, Region III  
(630) 829-9655