Edward B. Silberstein, M.D.

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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

Edward B. Silberstein, M.D.

MEDICAL CONSULTANT REPORT (SHORT FORM)
Official Use Only

Medical Consultant Name: Edward B. Silberstein MD **Report Date:** 8/6/16

Signature: Edward B. Silberstein

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 Insert Technique from Nordion 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 Carroll, Sr. Clinical Risk Mgr, four times (no answer twice)

Description of incident:
89.7 mCi of Y-90 labeled Therasphere, 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 Y-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 2½ months after the misadministration, the tumor in segment 4b is larger. The rise & fall is consistent with pattern of enzyme radionecrosis of the liver also. / E.B. Silberstein

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

Therasphere Order

GBq	mCi	Date	Time	
	0.00	4/24/2016 (Sunday)	12:00	*Special*

Prescribed Activity

GBq	mCi	Scheduled Date	Scheduled Time	Elapsed (hr)
3.32	89.73	4/27/2016 (Wednesday)		60.00

Estimated Dose Fraction to the Lung from MAA Study

Fraction F	Activity GBq	Activity mCi	Mass kg	Dose Gy
5.0%	0.17	4.49	1.0	6.30

Estimated Liver Dose - Left Lobe (4a, 4b) Tumor

Mass kg	Dose Gy
0.361	4.77

	Therapy Date / Liver Region	Gy	Gy	Gy	Cumulative Total Gy
Previous Lung Dose					6.30
Previous Liver Dose					

Measured Actvity from the Dose Calibrator

GBq	mCi	Date	Time	% Difference
	0.00	4/27/2016		-100.0%

GBq	mCi	Date	Time	% Difference
0.00	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.
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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
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