Ocean Medical Center
MEMBER OF THE MERIDIAN HEALTH FAMILY

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12: 32

December 21, 2005

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

Subject: Reply to a Notice of Violation

Ocean Medical Center
Brick, NJ

Docket No. 03020725 /200500
License No. 29-20690-01

During an NRC inspection conducted on November 8 and 9, 2005, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of 1-131 sodium iodide greater than 30 microcuries.

Contrary to the above a written directive was not dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. Specifically, on February 28, 2005, the licensee administered 105.9 millcuries of 1-131 sodium iodide without a written directive dated and signed by an authorized user.

Corrective Action:

Written directive will be dated and signed by an authorized user prior to administration.

Correct Steps to Avoid Further Violations:

Education and constant audit prior to administration

Compliance Date:

December 1, 2005

B. 10 CFR 35.633(a) requires, in part, that a licensee authorized to use a remote afterloader unit for medical use perform full calibration measurements on each unit following replacement of the source.

T. 732.840.2200
Meridian Health Line 1.800.560.9990 · www.meridianhealth.com
425 Jack Martin Blvd. · Brick, NJ 08724

10 CFR 35.633(b) requires, in part, that full calibration measurements include determination of the length of the source transfer tubes, timer accuracy and linearity over the typical range of use, and length of the applicators.

Contrary to the above, as of November 8, 2005, the licensee's full calibration measurements of the remote afterloader unit following replacement of the source did not include determination of the length of the source transfer tubes, timer accuracy and linearity over the typical range of use, and length of the applicators. Specifically, the licensee's full calibration following replacement of the source of September 1, 2005 did not include determination of these measurements.

Corrective Action:

1. A form has been developed for time accuracy and linearity over the typical range.

2. A form has been developed to verify length of the source transfer tubes and applicators. This form will also be used for checking the functions of the source transfer tubes, applicators and transfer tub-applicator interfaces.
(See attachments)

Corrected Steps to Avoid Further Violations:

1. New policy and procedure to ensure compliance

2. Education and audits

Compliance Date:

December 1, 2005

If you have any further questions, please do not hesitate to contact me at (732) 840-3344.

Thank you.

Sincerely,

Richard Epstein, R.Ph., MBA
Vice President, Operations

Robert Monaco, M.D.
Robert Monaco, MD
Radiation Safety Officer

cc: P. Henderson – Region I Administrator

OCEAN MEDICAL CENTER
VARIAN HDR SAFETY SURVEY AND CALIBRATION

Date: 11/23/05 Name: Y. Lee Signature: YL

Source Receipt Survey and Inventory
(within 3 hours of receipt, if during business hours, or 3 hours from beginning of next day)

Meter: Victoreen 450B Calibration date: 9/30/05 Battery OK: ✓ Check source OK: ✓

mR/hr @ 1 meter: 1.0 mR/hr @ surface: 10.0 mR/hr

Source information entered in inventory form: ✓

Wipe test Signature: YL Date: 11/23/05

Net Count = 0 CPM

Varian Source Manufacturer Calibration Data
(Attach original calibration certificate)

Model #: VS-2000 Serial #: 02-01-1297-001 Activity: 9.836 Ci

112105-09836-36 on: 11/21/05 @12:00 PM CST

Safety Survey After Installation

Meter: Victoreen 450B Calibration date: 9/30/05 Battery OK: ✓ Check source OK: ✓

(Background: 0.03 mR/hr)

Exposure rate near treatment unit with source retracted

	Right	Left	Front	Rear	Above	Below	Tolerance
@ 1 m	0.05	0.05	0.05	0.05	0.09	0.04	< 0.25 mR/hr
@ 10 cm	0.12	0.25	0.10	0.04	0.55	0.04	< 25 mR/hr

Exposure rate outside treatment room with source exposed (Tolerance: 1 mR/hr)

Control console	North	West	South	East
0.03	0.03	0.03	0.03	0.03

12/8/05 Kenneth Lee

Source Calibration

Varian HDR Model #: VariSource 200 Serial #: VS-321 Source Model #: VS-2000 Serial #: 92-01-1299 42105-09836-31
Standard Imaging HDR-1000 Plus chamber S/N A023052 (4.691 x 10^{-4} Gy m^2 h^{-1} nA^{-1}; calibrated: 9/30/04)
Standard imaging electrometer Model CDX-2000B S/N J023104 (1.000 nA/Reading; calibrated: 9/24/04)
Activity conversion factor 248.1 Ci Gy^{-1} m^2 h
Run plastic tipped 100 cm catheter into bottom of chamber well
Settings: Applicator length 100 cm, Position 95 cm, dwell time 110 sec

Position	95 cm	95 cm	95 cm	Average
nA Reading	13.05	13.03	13.05	13.04

Temp: 20.9 °C Pressure: 776 mm Hg C_{tp}= 0.976

Date: 12/8/05 Time of day: 6:45 pm

Average nA Reading * C_{tp} * Decay Factor * C_{eff} x 10^{-4} * 1.000 * 248.1 = Activity (Ci)

13.04 * 0.976 * 1.000 * 4.691 * 248.1 x 10^{-4} = 8.296 Ci

See printout

OMC Result ÷ Varian = 8.296 / 8.385 = 0.989 ✓10

12/8/05 KEC

- ✓ Daily QA checks performed (attach sheet)
- ✓ Place sign on HDR unit stating radionuclide, S/N, activity, calibration date
- ✓ Place sign on HDR unit's console stating radionuclide, S/N, activity, calibration date
- ✓ Source inventory updated (files in HDR Service Binder)
- ✓ New activity and decay table in hand calculation check
- ✓ New activity entered in HDR treatment unit's control console
- ✓ New activity entered in Varian planning system (List version in use: 6.5)

Notes:

08 DEC 2005 19:22

VariSource Source Activity Calibration

SITE : OMC
DEPT: Radiation Oncology
R.S. OFFICER: Dr. Robert Moneco
PHYSICIST: Dr. Keunchul Lee

ADDRESS: 425 Jack Martin Boulevard
ADDRESS: Brick, NJ 08724

NOTES:
NOTES:
NOTES:

Varian Medical Systems Source Wire Information

Source Serial Number: 02-01-1299-001-112105-09836-31

Source Type Identification: 2
Source Intended Use: 1
Source Lot Information: 1299-001

Source Creation Date: 21 NOV 2005
Source Creation Strength: 09.836 Ci

Instrumentation Identification Information

Electrometer Correction Factor:	1.000	Chamber Calibration Factor	: 1.164 x 10E+8 Ci/Amp
Electrometer Serial Number :	J023104	Chamber Serial Number	: A023052
Electrometer Manufacturer :	STANDARD IMAGING	Chamber Manufacturer	: STANDARD IMAGING
Electrometer Model Number :	CDX-2000B	Chamber Model Number	: HDR 1000 PLUS
Date Last Calibrated :	24-SEP-2004	Date Last Calibrated	: 30-SEP-2004
Calibration Frequency :	24 months	Calibration Frequency	: 24 months
Next Calibration Due :	24-SEP-2006	Next Calibration Due	: 30-SEP-2006
		Standard Temperature	: 22.00 degrees Celcius
		Standard Pressure	: 760.0 mmHg

Calibration Data

Peak current reading : 73.040 x 10E-9 AMPs
Current Temperature : 20.90 degrees Celcius
Current Pressure : 776.0 mmHg

Source Activity Summary

	On 08 DEC 2005 (Today)	On 21 NOV 200 (CAL Day)
Site Measured	8.296 Ci	9.731 Ci
VariSource	8.385 Ci	9.836 Ci
% Difference	001.1 %	001.1 %

Based on 17 decay days and TP correction factor of 0.976.
AL Serial No.: VS321
Ocean Medical Center

Tested by Keunchul Lee
Signature: KCL / KJ

OCEAN MEDICAL CENTER
Varian HDR Timer Accuracy, Linearity Procedure

Date: 12/8 105 Name: Keunchul Lee Signature: Keunchul Lee

Timer Accuracy, Linearity, Reproducibility, Error

Varian HDR Model #: VariSource 200 Serial #: VS-321 Source Model #: VS-2000 Serial #: 02-01-1299-001 112105-09836-31
Standard Imaging HDR-1000 Plus chamber S/N A023052 (4.691×10^{-4} Gy m^2 h^{-1} nA^{-1}; calibrated: 9/30/04)
Standard imaging electrometer Model CDX-2000B S/N J023104 (1.000 nA/Reading; calibrated: 9/24/04)
Activity conversion factor 248.1 Ci Gy^{-1} m^2 h
Run plastic tipped 100 cm catheter into bottom of chamber well
Settings: Applicator length 100 cm, Position 95 cm, dwell time 110 sec

Time Set	Charge (nC)	Net Time*	Net Reading (nC)**	Current (nA)	Ratio
5.0 sec	402.20	0.0 sec	—	—	—
10.0 sec	768.46	5.0 sec	366.26	73.25	1.003
15.0 sec	1133.0	10.0 sec	730.80	73.08	1.001
25.0 sec	1862.5	20.0 sec	1460.3	73.02	1.000
35.0 sec	2591.5	30.0 sec	2189.3	72.98	0.999

- Net Time = Time set – 5.0 seconds
- Net Reading = Charge at a time set – Charge at 5.0 sec Time set

Time Set	Charge (nC)				
60.0 sec w/four interruptions (A)	4573.0				
60 sec w/o interruptions (B)	4414.1	4411.4	4412.0	Mean = 4412.5	Max/Min = 1.0006
Timer error = (A-B)/(5B-A)	(4412.5 - 4573.0)/(5x4412.5 - 4573.0) = 0.0092				
Measured time (w/ stopwatch) for 60 sec run = 60.1 sec. error (diff/60.0) = 0.002 (< 2%) (0.2%)					

Applicator Inspection

✓ All transfer tubes and quick connects inspected
✓ Vaginal cylinder applicators and transfer tubes inspected
✓ Ring and tandem applicators and transfer tubes inspected
✓ Bronchial catheters inspected

- ✓ Daily QA checks performed (attach sheet)
- ✓ Place sign on HDR unit stating radionuclide, S/N, activity, calibration date
- ✓ Place sign on HDR unit's console stating radionuclide, S/N, activity, calibration date
- ✓ Source inventory form updated
- ✓ New activity and decay table in calculation and daily QA books
- ✓ New activity entered in HDR treatment unit's control console
- ✓ New activity entered in Varian planning system (List version in use: 6.5)
- ✓ Two survey meters present and calibrated within past 12 months
- ✓ GM counters' battery check and constancy check
- ✓ Door interlock switch for selecting HDR and Linac
- ✓ "Caution – Radioactive Material" Sign on door, HDR unit, and cabinet
- ✓ "Caution – High Energy Area" Sing on door
- ✓ Varian User Manual, System Log, Service Log present
- ✓ Emergency procedure posted
- ✓ NRC Form-3 posted

Notes:

OCEAN MEDICAL CENTER
Varian HDR Applicators Check Procedure

Date: 12/8/2005 Name: Kwanchul Lee Signature: Kwanchul Lee

Ring and Tandem Applicators Check

Length should be measured with rulers provided by Varian

		Without transfer tube			With transfer tube		
	Angle	2 cm	4 cm	6 cm	2 cm	4 cm	6 cm
Tandem	30°	30.0	30.0	30.0	121.4	121.4	121.4
	45°	30.0	30.0	30.0	121.4	121.4	121.4
	60°	30.0	30.0	30.0	121.4	121.4	121.4
Ring		30°	45°	60°	30°	45°	60°
		30.0	30.0	30.0	121.4	121.4	121.4

Cylinder Applicators Check

Cylinder

Diameter	2.0cm	2.3 cm	2.6 cm	3.0 cm	3.5 cm	4.0 cm
Tip Distance	2.0 mm	3.0 mm	4.0 mm	6.0 mm	8.0 mm	11.0 mm
Check	✓	✓	✓	✓	✓	✓

~~Tandems and transfer tubes~~

Tandems		Transfer Tubes			
Tandem #1	Tandem #2	Channel 1	Channel 2	Channel 3	Channel 4
25.7	25.7	121.4	121.4	121.4	121.4

Notes:

[Treatment Verification and Personal Information for Patient File SOURCE01]

NAME: Source Change
PATIENT ID: Source Change AGE: 100 SEX: M
RECORD NUMBER: Source 001
DOCTOR: UNKNOWN
DOSIMETRIST: UNKNOWN
TREATMENT SITE: UNKNOWN
PLAN CREATED ON AFTERLOADER CONTROL CONSOLE.
CREATION: 08 DEC 2005 LAST DELIVERED: NONE
PLAN DWELL TIMES BASED ON 10.000 CURIES SOURCE STRENGTH.
(Source isotope IR-192)

DWELL TIMES HERE ARE COMPUTED BASED ON CURRENT SOURCE WIRE ACTIVITY
ON 08 DEC 2005 OF 8.385 CURIES, DECAYED 17 DAYS FROM CALIBRATION DATE 21 NOV 200
USING A HALF LIFE OF 73.83 DAYS.
AFTERLOADER SOURCE WIRE SERIAL NUMBER: 02-01-1299-001-112105-09836-31
SCALE FACTOR APPLIED TO INITIAL PLAN DWELL TIMES: 1.193.
PRESCRIPTION: 5.00 GY in 1 FRACTIONS
ATTEMPTED FRACTION #: 01. PREVIOUSLY COMPLETED FRACTIONS: 00.

TOTAL DWELL TIME REQUIRED FOR TREATMENT: 131.2 SECONDS.

*CHANNEL: 1 CATHETER: Source CATHETER LENGTH: 100.0 CHANNEL DWELL TIME: 131.2 CHANNEL Ci*Secs: 1100.1*

	POS 01	POS 02	POS 03	POS 04	POS 05	POS 06	POS 07	POS 08	POS 09	POS 10	POS 11	POS 12	POS 13	POS 14	POS 15	POS 16	POS 17	POS 18	POS 19	POS 20
POINT (cm)	95.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
DWELL (secs)	131.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

The Treatment Delivery Password is 03073. Plan Approved by _____ Date:_____ Dosimetrist: _____ Date:_____

[Continued Print Out of Treatment Delivery Record for Patient File SOURCE01]

08 DEC 2005 19:01:36 -- VariSource Remote Afterloader Treatment halted.
ERROR CLASS 2: Error can be reset by console operator
ERROR CODE A8: Door opened while treat active
08 DEC 2005 19:01:51 -- VariSource Remote Afterloader Treatment halted.
ERROR CLASS 2: Error can be reset by console operator
ERROR CODE 6E: Last Man Out Sequence not followed
08 DEC 2005 19:03:08 -- Resuming Treatment for Channel 1.
08 DEC 2005 19:03:08 -- Performing Dummy Wire Check on All Remaining Channels.
08 DEC 2005 19:03:17 -- Dummy Wire check on Channel 1 completed.
08 DEC 2005 19:03:17 -- Completed Dummy Wire Check on All Remaining Channels.
08 DEC 2005 19:03:17 -- Selected Channel 1.
CHANNEL: 1 *CATHETER: Source* *CATHETER LENGTH: 100.0*

	POS 01	POS 02	POS 03	POS 04	POS 05	POS 06	POS 07	POS 08	POS 09	POS 10	POS 11	POS 12	POS 13	POS 14	POS 15	POS 16	POS 17	POS 18	POS 19	POS 20
POINT (cm)	95.0																			
DWELL (secs)	131.2																			

08 DEC 2005 19:05:35 -- Active Wire Treatment on Channel 1 completed.
08 DEC 2005 19:05:35 -- Completed Delivering Treatment for Channel 1.
Actual Dwell Time Delivered by Treatment: 131.2 seconds. ✓
Completed VariSource Treatment Sequence.

Stopwatch 131.28 sec ✓