



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  
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 I-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 millicuries of I-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

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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

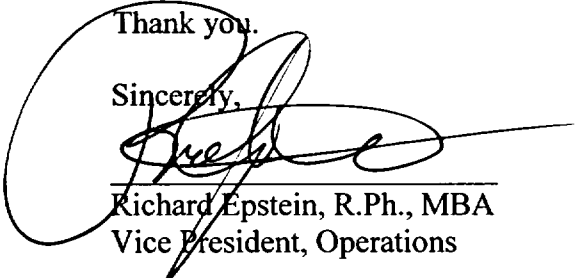
**Compliance Date:**

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, 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: [Signature]

**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: [Signature]

Date: 11/23/05

Net Count =  $\phi$  CPM

**Varian Source Manufacturer Calibration Data**  
(Attach original calibration certificate)

Model #: VS-2000 Serial #: 02-01-1297-001 Activity: 9.836 Ci  
112105-09836-3 Sn: 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

10/18/05

[Signature]

### Source Calibration

Varian HDR Model #: VariSource 200 Serial #: VS-321 Source Model #: VS-2000 Serial #: 02-01-1299  
112105-09836-31  
 Standard Imaging HDR-1000 Plus chamber S/N A023052 ( $4.691 \times 10^{-4} \text{ Gy m}^2 \text{ h}^{-1} \text{ nA}^{-1}$ ; calibrated: 9/30/04)  
 Standard imaging electrometer Model CDX-2000B S/N J023104 (1.000 nA/Reading; calibrated: 9/24/04)  
 Activity conversion factor  $248.1 \text{ Ci Gy}^{-1} \text{ m}^2 \text{ h}$   
 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: 176 mm Hg  $C_p =$  0.976

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

Average nA Reading \*  $C_p$  \* Decay Factor \*  $C_{\text{eff}} \times 10^{-4} * 1.000 * 248.1 = \text{Activity (Ci)}$

$$13.04 * 0.976 * 1.000 * 4.191 * 248.1 \times 10^{-4} = \boxed{0.296 \text{ Ci}}$$

See  
print out

$$\text{OMC Result} \div \text{Varian} = \frac{0.296}{8.385} = \boxed{0.0353} \quad \text{12/8/05}$$

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:

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**VariSource Source Activity Calibration**

SITE : OMC  
 DEPT: Radiation Oncology  
 R.S. OFFICER: Dr. Robert Monoco  
 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  
 Electrometer Serial Number : J023104  
 Electrometer Manufacturer : STANDARD IMAGING  
 Electrometer Model Number : CDX-2000B  
 Date Last Calibrated : 24-SEP-2004  
 Calibration Frequency : 24 months  
 Next Calibration Due : 24-SEP-2006

Chamber Calibration Factor :  $1.164 \times 10E+8$  Ci/Amp  
 Chamber Serial Number : A023052  
 Chamber Manufacturer : STANDARD IMAGING  
 Chamber Model Number : HDR 1000 PLUS  
 Date Last Calibrated : 30-SEP-2004  
 Calibration Frequency : 24 months  
 Next Calibration Due : 30-SEP-2006  
 Standard Temperature : 22.00 degrees Celcius  
 Standard Pressure : 760.0 mmHg

**Calibration Data**

Peak current reading :  $73.040 \times 10E-9$  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: Ku / kl

**OCEAN MEDICAL CENTER**  
**Varian HDR Timer Accuracy, Linearity Procedure**

Date: 12/8/05 Name: Keunchul Lee Signature: Keunchul Lee

**Timer Accuracy, Linearity, Reproducibility, Error**

Varian HDR Model #: VariSource 200 Serial #: YS-321 Source Model #: YS-2000 Serial #: 02-01-1299-001  
112105-09836-31  
 Standard Imaging HDR-1000 Plus chamber S/N A023052 ( $4.691 \times 10^{-4} \text{ Gy m}^2 \text{ h}^{-1} \text{ nA}^{-1}$ ; calibrated: 9/30/04)  
 Standard imaging electrometer Model CDX-2000B S/N J023104 (1.000 nA/Reading; calibrated: 9/24/04)  
 Activity conversion factor  $248.1 \text{ Ci Gy}^{-1} \text{ m}^2 \text{ h}$   
 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)	$(4412.5 - 4573.0) / (5 \times 4412.5 - 4573.0) = 0.0092$			
Measured time (w/ stopwatch) for 60 sec run = 60.1 sec. error (diff/60.0) = 0.002 (< 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" Sign on door
- ☒ Varian User Manual, System Log, Service Log present
- ☒ Emergency procedure posted
- ☒ NRC Form-3 posted

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**OCEAN MEDICAL CENTER**  
**Varian HDR Applicators Check Procedure**

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

**Ring and Tandem Applicators Check**

Length should be measured with rulers provided by Varian

	Angle	Without transfer tube			With transfer tube		
		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:

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[ 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 ✓