HERITAGE VALLEY
Health System
Sewickley Valley Hospital • The Medical Center

1000 Dutch Ridge Rd
Beaver, Pennsylvania
15009-9700

K-8

MS-16

May 23, 2006

Sandy Gabriel CHP
Senior Health Physicist
Medical Branch
NRC Region I
475 Allendale Road
King of Prussia, Pa. 19406-1415

Re: Amendment to License # 37-11562-01
Docket # 03003143
Mail Control # 138655

Dear Ms. Gabriel,

Per your request, find enclosed the detailed emergency and spot check procedures that will be instituted to ensure compliance with 10 CFR 35.610 and 35.643 as part of the above referenced license amendment.

If there are any further questions regarding the described procedures, kindly let us know.

Sincerely,

Terry Biss

138655

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1000 Dutch Ridge Rd
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May 23, 2006

Licensee: Heritage Valley Health Systems
Licensee No: 37-11562-01
Docket No: 03003143
Mail Control No: 138655

To: Sandra Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

Fm: Tony Combine
Physicist
Heritage Valley Health Systems
Beaver, Pa.

The following is in response to your e-mail of 4/17/06 regarding an amendment request for the HDR program at Heritage Valley Health System, Beaver, Pa.

Below are the procedures that ensure compliance with 10 CFR 35.610 (4)

Emergency procedures are per attachment 1.
Names and telephone numbers of authorized users, authorized medical physicists, and Radiation Safety Officer are per attachment 2.

A copy of both the above attachments are posted at the HDR console along with NRC form 3 – Notice to Employees. Training is conducted yearly in both operating procedures as well as emergency procedures.

Below are the procedures to ensure compliance with 10 CFR 35.643

a-1 , d-1,2,3,4,5,6,7,8.

Daily unit checks shall be performed in accordance UPMC HealthSystem Cancer Centers Quality Assurance Daily Check on HDR Unit procedures. These tests include the 16 tests as listed on attachment 3 with the associated acceptance criteria also listed.

Test one (Current Date and Time on HDR Unit) is a comparison test of HDR date and time to actual date and time. Date must be correct and time should be correct to within 5 minutes.

Test two (Decayed Activity on HDR Unit) is a comparison of the HDR listed value of activity compared to a mathematically decayed activity of initial full calibration on current source. This should agree to within + or - 1 %.

Test three (Source Positioning) is a source positioning test and can be done using either a radiographic test against a standard measured dummy positioning strand or by using the distance check ruler and a visual check of positioning distance by remote viewing system. Standard is + or – 1 mm.

Test four (Timer Accuracy) is a timer accuracy test and is to be done for an accumulated time of 300 seconds on the timer. This is done with a stop watch and is to be within + or – 1 second of the set time.

Test five is the Room Radiation Monitor test. This is to be done visually by opening the door during a source out condition and noting the status of the monitor as the source retracts. Flashing indication of a source-on condition going to a not-flashing source not-on condition is considered satisfactory.

Test six (Door Interlock) is done in conjunction with test five. A source-on condition going to a source-off position on opening the door is considered satisfactory.

Tests seven through nine (Radiation Door Indicator, Source Indicator at Unit, and Source Indicator at Console) are visual checks of the various indicators during beam on conditions and following beam off. Test eight is to be performed using the remote viewing system. Correct indication of beam condition is considered satisfactory.

Test ten (Interrupt Button) is performed by interrupting a source-on situation with the interrupt key with satisfactory performance being a return to a source-off condition.

Test eleven (Emergency Stop/Reset) is performed on the console emergency-off by returning the source from a beam on condition to an off condition by depressing the console emergency off. Satisfactory performance is a source return to an off position along with a satisfactory reset of emergency off circuit. The remaining emergency offs (all in room) are checked by simply depressing the emergency off in a source off condition and noting if the switch is visibly tripped and satisfactorily reset. These switches are all in series with each other.

Tests twelve and thirteen (Patient Viewing and Intercommunication System) are visual and aural tests of the viewing and communication system. Both systems must show satisfactory performance.

Test fourteen (Emergency Response Kit) is visual inspection of the contents and location of the emergency response kit. Kit must be located in the standard in-room position and must contain long- handled forceps, wire cutters and suture removal kit.

Test fifteen (Survey Meter) is a test of the operation characteristics of the survey meter to be used in the implant procedure. Survey meter must have up-to-date calibration (within last year), must have satisfactory battery performance and must give a check source reading to within 10 % of the stated value on the meter.

Test sixteen (Source Retraction with Backup Battery Upon Power Failure) is accomplished by turning the power key to the unit, located at the unit console, to an off position during a source on condition. Satisfactory performance is a return of the source to an off position followed by a successful repowering of the system and one successful out-drive and return of the source.

The above tests are to be done by a trained physicist operator or authorized physicist and are to be checked by an authorized physicist in accord with 35.643 (c) should an authorized physicist not perform the test.

If the results of any tests are not satisfactory the unit shall be locked as per 35.643 (e). All individuals trained to perform spot checks are to be made aware of the criteria for the spot checks and also the conditions of 35.643 (e).

Checks done at Source Exchange are done as per 10 CFR 35.633 and as listed on attachment 4 and 5 are done in compliance with 10 CFR 35.633 a.(1) and (2) These tests are to be done by an authorized medical physicist.

Tests listed on Quality Assurance HDR General Check at Source Exchange are as follows:

Test one (Daily QA) includes a complete daily qa spot check test as described above.

Test two (Assess Radiation Survey Data from Service Engineer) is a review of unit leakage and a review of data on return source canister. This data is to agree with previous unit leakage surveys and transport regulations for containers.

Test three (Equipment and Area Survey) is to include an HDR leakage survey, and an area survey of the outside of the treatment room with the source in an on position. This is to agree with previous surveys on the unit and treatment room.

Test four (Source Output) is to be done with a valid (calibrated within the last two years) ADCL calibrated well chamber in conjunction with a valid ADCL calibrated electrometer. Calibration is to be done by ascertaining the maximum positional source reading in the well chamber and converting this reading to Ci per equations as listed on attachment #5. Comparison is done to stated source value on manufacturers certificate decayed to date of source output measurement. A satisfactory comparison is a an agreement of +/-5%.

Test five (Indexer and Dwell Position Test) and is to be done for all commonly used channels on the HDR using either a radiographic film comparison of a know measured standard dummy strand of by visual comparison using distance check ruler. This test will be done for indexer channels 1 through 9 at full calibration and shall be done one week prior to the use of the system for any channels beyond those that may be used in any non-common implant. (In thirteen years of use on the system we have yet to use any channel beyond #9.)

Test six (Source Retraction with Backup Battery Upon Power Failure) is to be done as listed in Test sixteen of the daily QA spot check procedures.

Test seven (Timer Accuracy and Linearity over Typical Range) will be tested using a stop watch and an ADCL calibrated ion chamber (either well or Farmer type .6cc chamber) used in conjunction with an ADCL calibrated electrometer. An integrated reading of the chamber shall be taken for the source for various times over the commonly used timer range. Values of integrated nanocoulombs/sec shall be calculated for times ranging from 5 seconds to 300 seconds correcting for source transit time error. This value should agree to within + or – 3 % of the 10 second nanocoulombs/sec value for uncorrected times and to within + or – 1% for times corrected for source transit time error.

Test eight through ten (Integrity, Function and Length of Source Transfer Tubes, Applicators, and Operation of Transfer Tubes, Applicators, and Tube-Applicator Interface) involves visual inspection of transfer tubes and their length, visual inspection of applicators and their length, and operability of transfer tubes and associated applicators. Visually measured length should be to within 1 mm against tape measure or meter stick. Tubes and applicators should show no visible signs of damage. Lastly all transfer mechanisms should function correctly.

Test eleven (Operating Manual at Console) is a visual inspection for the operating manual. It is kept in the cabinet below the HDR console.

Test twelve (Emergency STOP in Treatment Room) is a test of the operational status of the two in-room emergency offs and is done in the same manner as the daily emergency stop tests.

Test thirteen (Radiation Monitor Battery Backup Test) is a test of the operational status of the Radiation Monitor using only the battery backup as a power source. This test is done by removing the radiation monitor and battery backup from the electrical power source. The source is then placed in a source-on position and the radiation monitor is checked visually to see if it indicates a source-on condition. (IE flashing lights) This is the criteria for satisfactory performance.

Remaining full calibration duties that have to be carried out include the entering of the new source activity into the HDR console unit and treatment planning system, printing out a new decay table, and making certain the old source is returned to vendor.

ATTACHMENT 1

Emergency Procedures
Microselectron HDR Iridium-192
If Source Fails to Return to the Safe

If the source would jam or decouple during a HDR treatment and fail to return to the safe after;

a) the preset time has lapsed, or
b) and interlock break, or
c) the interrupt or an emergency off button has been depressed

these emergency procedures shall be performed. An indication of a jammed or decoupled source would be any of the following occurring after a, b, or c above has occurred;

d) yellow control panel light remains lit, or
e) red light over entrance remains lit, or
f) radiation monitor inside treatment suite remains lit.

Procedures to Follow Once Emergency has Been Verified.

The source has retracted into its shielded position once the area monitor signals green flashing lights and the survey meter indicates radiation levels of less than 2 mR/hr at surface of Microselectron and the patient readings are background levels.

1. Depress interrupt (console) button. If source retracts into shielded position go to step #7, if not go to step #2.

2. Depress emergency button above console, if source retracts into shielded position to step #7, if not turn the emergency reset key and go to step #3.

3. Enter room with survey meter set to 1000 R/hr and depress emergency button at top of maze. If source retracts to shielded position go to step #7, if not turn emergency reset key and go to step #4.

4. Depress emergency button on Microselectron if source retracts to shielded position go to step #7, if not go to step #5.

5. Turn gold handled source crank, (following arrows) until it reaches its mechanical stop. If source is in shielded positions go to step #7 if not go to step #6.

6. With two (2) people pull the patient and the Microselectron with attached catheter(s) or guide tubes(s) away form each other until they are separated. If catheter(s) or guide tube(s) are sutured remove sutures with suture removal kit found in the HDR emergency kit.

7. Survey the patient for the radiation source and remove from room once it is certain that source is not inside patient. Lock entrance, post a warning sign, and secure the room from unauthorized entry. Call Nucletron at 1-800-336-2249.

ATTACHMENT 2

Emergency Call List – Nucletron HDR

In the event of a source emergency with the Nucletron HDR as defined in the emergency procedures, once all steps in the emergency procedures are completed contact one of the following, the RSO and Nucletron.

Authorized Users: Gerald Medwick DO x7616 or 724-728-2225
TK Dutta MD x7616 or 724-728-2225

Authorized Medical Physicists Tony Combine MS x7640 or 724-561-2210
Alphonse Loper MS x7642 or 412-478-0344
Dineli Alahakone MS 724-656-5870

Radiation Safety Officer Mark Perna MS 412-551-9259

Nucletron 800-336-2249

ATTACHMENT 3

UPMC Cancer Centers

Quality Assurance
Daily Check on HDR Unit

Manufacturer:	Nucletron B.V.	Date (mm/dd/yy):	
High Dose Rate Unit (Model/SN):	Nucletron Classic/	Facility Name: Town/City:	

For **Nucletron Units**

	DATE [mm/dd]:							
No:	Items	MON	TUE	WED	THU	FRI	SAT	SUN
1.	Current Date & Time on HDR Unit [Correct]							
2.	Decayed Activity on HDR Unit [Correct]							
3.	Source Positioning [±1 mm]							
4.	Timer Accuracy [±1 sec]							
5.	Room Radiation Monitor [Operable]							
6.	Door Interlocks [Operable]							
7.	Radiation Door Indicator [Operable]							
8.	Source Indicator at Unit [Operable]							
9.	Source Indicator at Console [Operable]							
10.	Interrupt Button @ Console [Operable]							
11.	Emergency STOP/RESET [Operable]							
12.	TV Viewing System [Operable]							
13.	Inter-Communication System [Operable]							
14.	Emergency Response Kit [Present]							
15.	Survey Meter [Operable]							
16.	Source Retraction with Backup Battery Upon Power Failure [Operable]							
	Performed By [Initial]:							
	Reviewed By [Authorized Physicist - Initial]:							

Comments:

UPMC Cancer Centers

Quality Assurance
HDR General Check @ Source Exchange

Manufacturer:	Nucletron B.V.	Date (mm/dd/yy):	
High Dose Rate Unit (Model/SN):	Nucletron Classic/	Facility Name: Town/City:	

For **Nucletron Model Classic Units**

No:	Checks For Compliance	Check Here
1.	Include Daily QA Procedures [Acceptable]	
2.	Assess Radiation Survey Data from Service Engineer [Acceptable]	
3.	Equipment and Area Survey by Authorized Physicist [Acceptable}	
4.	Source Output [±5%]	
5.	Indexer and Dwell Position Check [Operable]	
6.	Source Retraction with backup battery upon power failure [Operable]	
7.	Timer Accuracy and Linearity over Typical Range [±1%]	
8.	Integrity of Source Transfer Tubes (Length, …) [Operable]	
9.	Integrity of Applicators (Length, …) [Operable]	
10.	Function of source transfer tubes; applicators; tube-applicator interface [Operable]	
11.	Operating Manuals at Console [Present]	
12.	Emergency STOP in Treatment Room [Operable]	
13.	Room Radiation Monitor Battery Backup Test [Operable]	
	Notes:	
14.	New source activity entered into HDR console unit	
15.	New source activity entered into treatment planning system	
16.	Print out new decay table	
17.	Make sure to return old source to vendor	

Comments:

Quality Assurance
HDR Output Check @ Source Exchange

Manufacturer:	Nucletron B.V.	Date (mm/dd/yy):	
High Dose Rate Unit (Model/SN):	Nucletron Classic/		

No:	ACTIVITY CALIBRATION					Calculations
	NOMINAL ACTIVITY:					
1.	Calibration Date:		Time:		Nominal Activity ($mGym^2h^{-1}$):	
2.	Nominal Activity (Ci) = Nominal Activity ($mGym^2h^{-1}$) /4.07 $mGym^2h^{-1}Ci^{-1}$:					
3.	Days Elapsed Between Calib Date and Today:				Decay Factor:	
	Half-life = 73.83/74.02 days	Decayed Activity (Ci) = Nominal Activity x Decay Factor:				
4.	**MEASURED ACTIVITY:**					
5.	Temperature:		Pressure:		C_{TP}:	
6.	Rdg (nA) [Calibration Position or Maximum Value]:					
7.	Calibration Factor - Electrometer and Chamber (Ci / nA):					
8.	Activity(Ci) = C_{TP} x Rdg x Calibration Factor:					
9.	Difference (%) = [(Measured Act - Decayed Act) / Decayed Act] x 100 [Tol: <5%]:					
10.	Use measured activity in the treatment planning system:					
	Performed By [Initial and Dated(dd/mm/yy)]:					

No:	Measuring Instrument		No:	Position (mm)	Reading (nA)
	Electrometer (Model/SN):		1.		
	Calibration Date:		2.		
	Ion chamber (Model/SN):		3.		
	Calibration Date:		4.		
	Scale:		5.		
	Bias Voltage:				

No:	Set Time (sec)	Measured Time (sec)	Reading (nC)	Timer Accuracy and Linearity
1.	5			Option: Either (1) use a watch to time when the source in and off
2.	10			position (use blinking source) or (2) measure the output when the
3.	50			Source in position (charge)
4.	150			Plot the graph and find the correlation using EXCEL formula
5.	300			