WestVirginiaUniversityHospitals

May 4, 2012

Docket No. 030-20233 License No. 47-23066-02
Control No. 576453

Tara Weidner, Health Physicist
United States Nuclear Regulatory Commission-Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406

SUBJECT: Response to U.S. NRC E-mail request, on April 27, for additional information

Dear Ms. Weidner:

This packet is in reference to your e-mail request for additional information dated April 27, 2012.

If you have any further questions or concerns regarding our responses please feel free to contact Radiation Safety Department at 304-293-1554.

Sincerely,

Stephen D. Tancin
Vice President, Ancillary and Support Services

Nasser Razmianfar
Director and Radiation Safety Officer

Enclosure

Hospital Administration
Ruby Memorial Hospital
West Virginia University Children's Hospital
Jon Michael Moore Trauma Center
Chestnut Ridge Center
PO Box 8059
Morgantown, WV 26506-8059
Phone: 304-598-4200
www.health.wvu.edu

1. Submit your procedures for transfer and transportation of licensed material between authorized users at your facility, and your procedures for transfer and transportation of licensed material to other licensees. Describe your program to control such transfers, including update of material inventory and audits of users' procedures

The authorized user of radioactive material must notify the RSO of the proposed transfer. The radioactive material must be delivered to the RSO along with a description of the article, such as the nature of radionuclide's, the chemical form, the quantity (activity), the name, address, license number, and phone number of the addressee. The RSO will verify that the recipient is licensed by the NRC, an agreement state, and/or a relevant regulatory authority to receive the radioactive material and will prepare the shipment in accordance with all regulatory requirements.

Radioactive materials may be transferred between authorized users

I. If the recipient is authorized for that particular radionuclide.
II. Section 35.49(b) allows sealed sources or devices for medical use to be non-commercially transferred from a Part 35 licensee to another Part 35 licensee. Prior to transfer, the medical licensee receiving the sealed source or device must be authorized on its license to possess and use the device in accordance with applicable sections of Part 35 for which the sealed source or device will be used.
III. Shipments may be made only to persons who are licensed to receive radioactive materials and in accordance with procedures established by such persons.
IV. Prior to making a shipment of radioactive materials, a copy of the recipient's radioactive materials license must be on file in the Radiation Safety Office.
V. All aspects of the shipment (container, packaging, labeling, surveys, shipping papers, etc.) must be in accordance with U.S. DOT requirements.

For High Dose Rate Remote Afterloader (HDR):

2. Periodic spot-checks for remote afterloader units:

Response to this question addressed in number 1 of the attached letter Additional Information Request for IIDR Afterloader

3. Emergency procedures:

Response to this question addressed in number 2 of the attached letter Additional Information Request for HDR Afterloader

4. Console keys:

Response to this question addressed in number 3 of the attached letter Additional Information Request for HDR Afterloader

For Gamma Stereotactic Radiosurgery (GSR):

5. Licensing Guidance:

   We confirm that we will periodically review the Leksell Gamma Knife Perfexion – Licensing Guidance found on the NRC website and incorporate changes into your policies and procedures, as necessary.

6. Facilities and Equipment:

   Response to this question addressed in number 1 of the attached letter Additional Information Request for Gamma Stereotactic Radiosurgery

7. Periodic spot-checks for GSR units:

   Response to this question addressed in number 2 of the attached letter Additional Information Request for Gamma Stereotactic Radiosurgery

8. Spot-Checks:

   We confirm that your spot-checks will include: (a) monthly, location of radiation focal point with respect to table position, is within the specifications provided by the manufacturer, and (b) monthly, location of the table at a number of off-center positions is within the collision specifications provided by the manufacturer, and (c) approximately every six months, verification that each sector moves correctly to each position within appropriate tolerance limits.

   Response to this question addressed in number 3 of the attached letter Additional Information Request for Gamma Stereotactic Radiosurgery

9. Frame Adapter:

   We Confirm that our procedures include a check to ensure that all levers are turned and locked down and that the securing screw is in place prior to each patient procedure. In addition, we confirm that this check is part of our daily or patient checklist.

10. Wipe Test:

    We confirm that ELEKTA service engineers will remove the cap so that our personnel may conduct the wipe during routine maintenance.

11. LED lights:

    We confirm that we check the cabinet to confirm that all LED lights are lit to your daily checks.

12. Battery Backup:

    We confirm that our monthly checks include a test of the battery backup in the servo drive cabinet.

13. Sector Failures:

    We confirm that our emergency procedures include procedures for sector failures.

14. Frame Adaptor:

    We confirm that the frame adaptor will not be soaked in water since this may cause corrosion in the locking mechanisms in accordance with an Instruction for Use issued by Elekta.

WVUHealthcare
Radiation Oncology

May 4, 2012

Nasser Razmianfar, Ed.D.
Director and Radiation Safety Officer
Radiation Safety Department
One Medical Center Drive
P.O. Box 9006
Morgantown, W.V. 26506-9006

Subject: Additional Information Request for HDR Afterloader

This is a letter providing additional information you requested regarding the High Dose Rate Remote Afterloader (HDR).

1) Provided is a copy of our detailed spot check procedures. Please make note of procedures: #6 referencing (a.) source exposure indicators; #2 referencing (b.) viewing and intercom systems; #14 referencing (c.) emergency response equipment; #9 referencing (d.) timer accuracy; #8 referencing (e.) clock in unit's computer; and #13 referencing decayed source activity in the unit's computer. If any spot check results indicate the malfunction of any system, the control console will be locked in the off position and not used except as may be necessary to repair, replace, or check the malfunctioning system. Also, provided is a copy of the checklist used to document the results of the spot checks.

2) With regards to our emergency procedures: (1) Provided is a copy of the emergency procedure flowchart. The chart is labeled with individual(s) responsible for each step of the plan. (2) We are restricting access to and posting of the treatment area by: posting a radioactive materials sign and a high radiation area sign at the treatment area; when the machine is on and sources are exposed the white (IN USE) sign above the entrance door is illuminated; if the entrance door is opened while the machine is IN USE the unit will terminate treatment and retract the source; provided is additional "High Dose Rate Brachytherapy Treatment in Progress. DO NOT ENTER" signage will be posted outside of the suite; yellow tape on the floor leading to the vault door designates restricted area during treatments. (3) Provided is a copy of the Emergency Contact List confirming names and telephone numbers of AU's, AMP's and the RSO. This list is posted next to the emergency response procedures.

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3) When the HDR is not in use or is unattended, the console keys will be either in procession of an AMP or locked in a lock box for which only the AMP's and RSO have access to.

Sincerely,

Joshua Hack, M.S.
Radiation Oncology Physicist

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Varian ^{192}Ir VariSource iX S/N H600398
Spot Check Procedures

Periodic spot checks of the remote afterloader are to be carried out before the first use of the unit on a given day and after each source installation. Satisfactory tests are indicated by a ✓.

Spot Check Procedures

1. Date: Record the date of the spot check on the spot check log.
2. Viewing / Intercom System: Turn on the viewing and intercom systems. Mark satisfactory if the afterloader can be viewed on the CCTV and the intercom can be heard in and out of the room.
3. Survey Meter / Batter Check: Turn on the survey meter to be used for the day. Check the constancy of the survey meter using a check source. Mark satisfactory if the meter turns on without low bat displayed and the constancy check is within 10% of nominal value.
4. Interlocks: Attempt to initiate the physics test "Spot Check – Interlocks" with the each of following interlocks: door open; last man out procedure not followed; afterloader key not turned; console key not turned. Mark satisfactory if each interlock prevents treatment from being initiated.
5. Emergency Stop: Initiate the physics test "Spot Check – Interlocks." During treatment press the console emergency stop. Clear the alarm and reinitiate treatment. During treatment press the door emergency stop button. Mark satisfactory if each emergency stop button stops treatment and retracts the source.
6. Radiation Monitors: Initiate the physics test "Spot Check – Interlocks." During treatment, view the Primalert radiation monitor in the room, the source exposure indicator on the remote afterloader, the source exposure indicator on the console. Mark satisfactory if each monitor indicates radiation present while the active source is dwelling.
7. Source Indicator – Console: Initiate the physics test "Spot Check – Interlocks." Mark satisfactory if the console indicates the proper status of the active source.
8. Clock (date and time): Verify the console date and time is within 2 min of the hospital date and time displayed on the phone. Mark satisfactory if the time and date are within 2 min. If greater than 2 min, adjust the console clock accordingly.

9. Timer Accuracy (30s): Initiate the physics test "Spot Check – Timer Accuracy." Pan and zoom the camera so that the dummy dwell position can be visualized. Start the stop watch when the active wire reaches this point and stops. Stop the stop watch when the active wire retracts. Write down the time measured. Test is satisfactory if the measured time is 30s ± 0.5s.

10. Catheter Misconnect: Attempt to initiate the physics test "Spot Check – Interlocks" with the quick connect not fully seated. Mark satisfactory if the system displays "guide tube loose"

11. Obstruction Test: Initiate the physics test "Spot Check – Obstruction." Mark satisfactory if the active wire hits the knot in the catheter and retracts.

12. Positional Accuracy: Initiate the treatment day PVT test. Record the distance of the wires displayed on the screen. Mark satisfactory if the active wire is within 1 mm of its intended position. Print the results and file in the afterloader binder.

13. Decayed Source Activity: Record the current source activity displayed on the console and the calculated decayed source activity. Test is satisfactory if the two activities are within 1%.

14. Emergency Response Equipment: Verify the emergency response equipment is available for use. The emergency response equipment includes: lead pig, long forceps, wire cutter, portable survey meter and stop watch. Mark satisfactory if the equipment is available.

15. Restricted Area Signage: Verify the "Restricted Area Signage" is available to be posted outside of the gamma knife suite during treatment. Mark satisfactory if the signage is available.

16. System OK to Treat: If all Spot Check tests are satisfactory, circle "Yes" to approve the system for use. If any of the Spot Check tests are not satisfactory, circle "No." If "No" is circled, no patients may be treated until all tests are again satisfactory.

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Radiation Oncology

Treatment Day / Source Exchange Spot Checks

Varian ^{192}Ir VariSource-iX S/N# H600398 Source S/N# 02-01-2651-001-041112-10594-62

Date									
Viewing / Intercom System									
Survey Meter / Battery Check									
Interlocks – Door – Last Man Out – Afterloader Key – Console Key									
Emergency Stop – Console – Door									
Radiation Monitors– Room – Afterloader – Console									
Source Indicator – Console									
Clock (date and time)									
Timer Accuracy (30s)									
Catheter Misconnect									
Obstruction Test									
Positional Accuracy (< 1mm)									
Decayed Source Activity – Computer (Ci)									
Decayed Source Activity – Calculated (Ci)									
Emergency Response Equipment									
Restricted Area Signage									
System OK to Treat	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Performed By:									

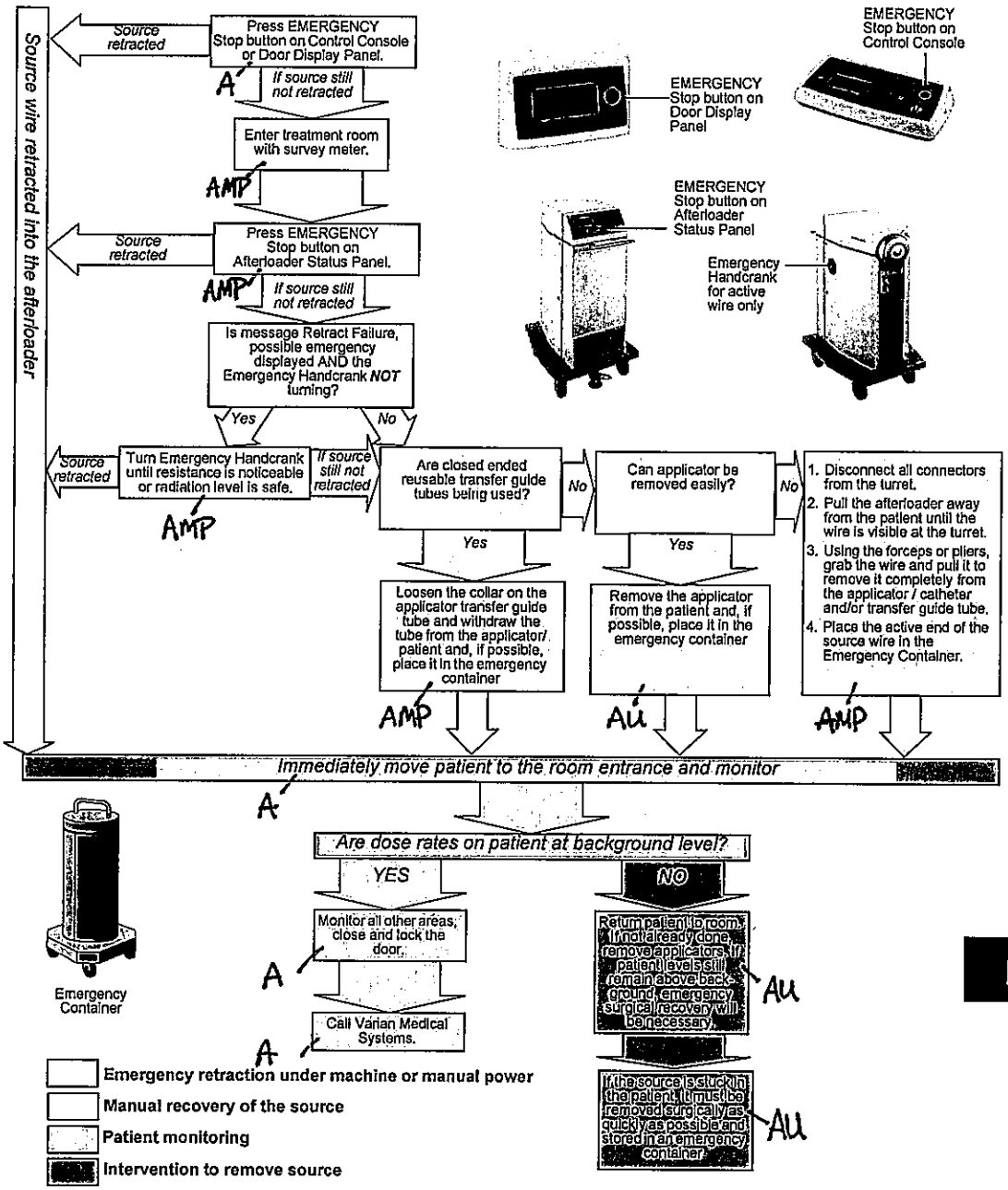


Figure D-1 Emergency Response Procedures

D

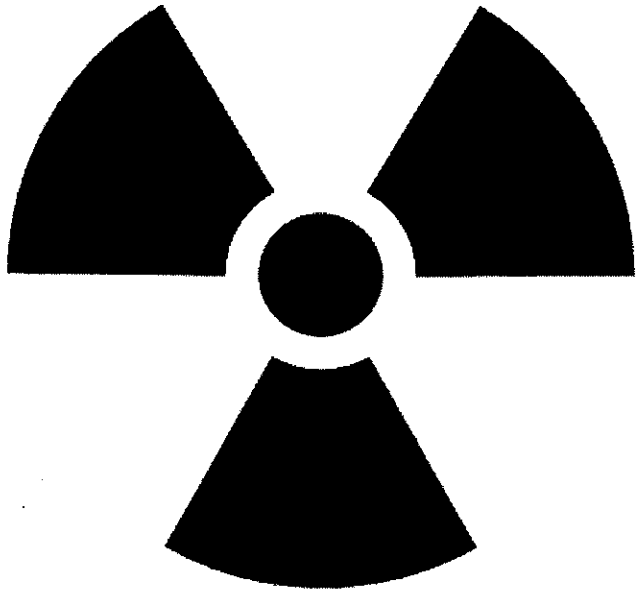
A: Any Personnel
AMP: Authorized Medical Physicist
AU: Authorized User

CAUTION

High Dose Rate
Brachytherapy

Treatment in Progress.

DO NOT ENTER



High Dose Rate Brachytherapy

EMERGENCY CONTACT NUMBERS

When paging within WVUH, dial 103 then the pager number. When paging outside WVUH, dial (304) 598-4789 then the pager number. Remember to include the whole number, including area code, when paging.

Authorized Medical Physicist AMP	Joshua Hack (734) 645-9991 Pager # 2066
	Sudarshan Chamakuri, Phd DABR (702) 503-6830
Authorized User	Carl Jueng (304) 598-4706 (724) 880-3098
	Dr. Geraldine Jacobson (304) 598-4706 (319) 321-1891 Pager # 2438
Radiation Safety Officer (RSO)	Nasser Razmianfar (304) 376-7237 Pager # (304) 987-1586
Department Manager	Ken Drummond (304) 290-9964 Pager # 0584

WVUHealthcare
Radiation Oncology

May 4, 2012

Nasser Razmianfar, Ed.D.
Director and Radiation Safety Officer
Radiation Safety Department
One Medical Center Drive
P.O. Box 9006
Morgantown, W.V. 26506-9006

Subject: Additional Information Request for Gamma Stereotactic Radiosurgery

This is a letter providing additional information you requested regarding the Gamma Stereotactic Radiosurgery (GSR).

1. The following is a detailed facility and equipment list for GSR units.
    a. Warning systems and restricted area controls: The treatment area is posted with a radioactive materials sign and high radiation area sign; when the machine is on and sources are exposed the white (IN USE) sign above the entrance door is illuminated; if the entrance door is opened while the machine is IN USE, the unit will go into pause mode. An alarm will sound, the sources move to park position, table retracts and source doors close.
    b. Area radiation monitoring equipment: There is an independent Primalert radiation detector in the room with backup battery. There is a Primalarm remote located outside of the treatment doors.
    c. Viewing and intercom systems: There is an integrated viewing and intercom system within the Gamma Knife Perfexion unit. There is also an independent secondary viewing and intercom system located next to the Gamma Knife control console. The secondary viewing station has pan and zoom capabilities.
    d. Steps to ensure that no two units can be operated simultaneously: There is an AB switch connected to the door interlocks. This permits the door closed signal to go to either the Gamma Knife or the HDR system but not both.
    e. Methods to ensure console keys will be inaccessible: The console keys will be either in the possession of an AMP or locked in a lock box which only AMP's and the RSO have access to.
    f. Emergency response equipment: No additional equipment is needed to execute the emergency response procedures.

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2 Provided is a copy of our detailed daily spot check procedures. Please make note of procedures: #1 referencing (a.) stereotactic frames; #9 referencing (b.) electrical interlocks at room entrance and (g.) emergency off buttons; #10 and #11 referencing (c.) source exposure indicators and (f.) radiation monitors; #3 and #4 referencing (d.) viewing and intercom systems; and #14 referencing timer termination. If any spot check results indicate the malfunction of any system, the control console will be locked in the off position and not used except as may be necessary to repair, replace, or check the malfunctioning system. Also, provided is a copy of the checklist used to document the results of the spot checks.

3 Provided is a copy of our detailed monthly and semi-annual spot check procedures. Please make note of procedures: monthly #1 and daily#13 referencing (a) monthly focus precision test; monthly #7 referencing (b) clearance test tool check; semi-annual #3 referencing (c) vendors sector movement test. Also, provided is a copy of the checklists and reports used to document the results of the spot checks.

4 Provided is a copy of our Patient Treatment Log. The fifth column titled "Docking adapter" is where we document that we have ensured that all levers on the frame adapter are turned and locked down and that the securing screw is in place prior to each patient's treatment.

5 The wipe test of the convex, outer surface of the collimator cap is performed by the Radiation Safety Department semi-annually with the assistance of the ELEKTA service engineers.

6 Regarding the operation of the office cabinet backup batter, please make note of procedure #6 of our daily spot checks.

7 Regarding the operation of the backup battery in the servo drive cabinet, please make note of procedure #4 of our monthly spot checks.

8 Provided is a copy of the section of our posted emergency procedures regarding closing the radiation sectors manually in the event of sector retraction failure.

9 Regarding proper cleaning procedures of the frame adaptor, please make note of procedure #1 of our daily spot checks.

Sincerely,

Joshua Hack, M.S.
Radiation Oncology Physicist

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WEST VIRGINIA UNIVERSITY
Perfexion Gamma Knife
Pre-Treatment (Daily Spot) Check Procedures

1. Check Stereotactic Frames: Check the stereotactic frames by University of Pittsburgh Frame Check Test Tool. If any frame does not fit in to this test tool, (tolerance greater than 0.5 mm), take the frame out of service and return to Elekta. Alternatively, check the square of the frames by measuring distances between the holes used for registration of the frames with the docking adapter. The frame adaptor will be cleaned according to the instructions in the operator's manual. It will be cleaned using soft cloths and never be soaked to avoid corrosion. Prior to treatment, check that all frames used securely mount to the docking adapter. Each of the 3 latches should be able turned and locked. The securing screw for the most anterior latch should be able to be secured.
2. Time and date: Check that these are correct for the LGP and treatment units.
3. CCTV systems: Check for proper function.
4. Intercom systems: Check for proper function.
5. Check all of the postings (NRC, emergency procedures and emergency contacts and operating instructions). They must be located near the control console.
6. Check the proper function of the indicator lights on the office PC cabinet. The UPS panel should indicate AC IN – green, Battery power available (right column) – all green, PC power – green. The network switch panel should indicate the 16 light on the lowest row blinking yellow (proper speed, active).
7. Portable survey meter: Check proper function by noting the exposure reading against the GK treatment unit doors.
8. Perform the alarm test on the treatment console. Note proper auditory and visual signals.
9. Check all emergency off switches and door interlocks. For each emergency off button or door interlock, initiate the beam, activate the button or open the door. Assure that the beam is terminated, the table retracts and the gamma knife treatment unit doors close. Press the Pause button during an exposure and assure proper function of GK unit and table retraction.
10. Room area monitors: Check proper function of the area monitor in the treatment room by observing it with the CCTV system during an exposure. Also check the proper function of the external area monitor during an exposure.
11. Check all beam indicator lights at the treatment room door, control console, and on the unit during the dummy run for proper operation. The beam indicator light at the treatment room door should light when the beam is on. The control console should indicate radiation on and the treatment room indicator should indicate green and white LEDs lit when the beam if OFF; white and red LEDs lit when the shields are open and the table moves; only red LED lit once the sources are exposed.
12. Perform the sector positioning check run and note proper function of the sectors.

13. Perform the Focus precision test with the diode test tool provided by Elekta. A result of "pass" indicates acceptable completion. The specification of 0.4mm is given in the Elekta acceptance test report.
14. Check that the timer terminates the planned exposure by doing a dummy run.

WEST VIRGINIA UNIVERSITY
Perfexion Gamma Knife Pre-Treatment Checks

Date										
1. Frames	Assembled square & clean									
	Docking adapter mounts securely									
2. Time and date	LGP									
	Treatment Unit									
3. CCTV	Elekta									
	Alternate									
4. Intercom	Elekta									
	Alternate									
5. Emergency procedures posted										
6. Office PC light indicators – UPS/network										
7. Exposure at shielding doors	(mR/hr)									
	Survey meter used									
8. Alarm test										
9. Interlock tests	Frame adapter docking									
	Side protection panels R & L									
	Door									
	Emergency button – Inside									
	Emergency button – console									
	Pause									
10. Area radiation monitors	Inside Tx room									
	Outside Tx room									
11. Beam status indicators	Treatment room									
	Door									
	Console									
12. Sector positioning check	Completed									
13. Focus precision test	Passed									
14. Timer termination of exposure										
	Physicist initials									

West Virginia University Hospitals
Gamma Knife Radiosurgery

Monthly Spot Check Procedure for Leksell Gamma Knife PERFEXION

1. Perform Daily QA

   Perform the daily QA procedure and make sure that all tests are satisfactory. This must be performed as part of the Monthly Spot Check, and the record sheet must be included.

2. Patient Treatment Couch Retraction

   Test the treatment table retraction by backup battery and manual pull-out as follows:

   (a) For backup battery retraction, follow the test as given in Item No. 5 below for the medical UPS battery test.
   (b) For manual retraction, follow the Emergency Procedures posted in the control console area. The manual retraction in Perfection unit can be applied in Z- direction as well as X-direction. The X-direction retraction is applied when there is any contact with the collimator cap. The Z-retraction is applied when patient is to be pulled out of the unit in an emergency situation when the patient couch does not pull out at its own at the end of treatment.

3. Simulated Control System Failure

   During treatment phase, turn console key OFF. By viewing TV monitor, confirm that the couch exits the unit, and the shielding doors close. Turn key back on, and verify that treatment can be continued.

4. Office UPS Battery Test

   The office UPS unit is located at the bottom of the office cabinet. (See page 143 of the Perfexion Manual version 018204 Rev.00, 2006/6).

   Press and hold the TEST button for a few seconds. During this time the UPS briefly operates the connected equipment on battery, which is indicated by the On Battery Power LED.

   If the test fails, the Replace Battery LED is turned on and short beeps are emitted during one minute. Allow the battery to recharge for 24 hours and then perform the test again. If the problem persists, contact Elekta service representative. The battery may require replacement.

5. Medical UPS Battery Test

   The medical UPS unit is located at the back of Perfexion unit in the treatment room. (See page 142 of the Perfexion Manual version 018204 Rev.00, 2006/6). Conduct this test at the end of working day as not to interfere with scheduled treatments.

   On the medical cabinet, switch off the mains button of the UPS unit. The charges are now turned off and the system is powered from the batteries as indicated by the indicator lamps of the output section.

   Let the mains button be switched off for 20 minutes. The output voltage is measured over that period of time and if it falls below a preset level, a system error is generated:
   - If an error is generated, contact Elekta service representative to arrange for the batteries to be exchanged.
   - If no error is generated, the batteries are in satisfactory condition.
   - After 20 minutes, switch on the mains button.
   - Perform the sector positioning checks using the file in the "Predefined" directory. Assure completion of all sector positioning for all 3 collimators. At six month intervals, attach the results of the Elekta service report for their positioning checks.
6. Perform the sector positioning checks using the file in the "Predefined" directory. Assure completion of all sector positioning for all 3 collimators. At six month intervals, attach the results of the Elekta service report for their positioning checks.
7. Perform Clearance Test Tool Check by selecting and executing QA clearance tool test. For each check position, check if the arm of the clearance check tool passes clear of the posts on the QA tool. The positions designated on the report as "CL" should clear and are indicated as Accepted. The positions designated on the report as "CO" should collide and are indicated as Rejected. Print the Operators report of the test and attach to monthly QA report.
8. Perform the collimator cap emergency stop test by touching the inner aluminum touch guard with the extended test tool provided by Elekta. The alarm should sound and necessitate releasing both table locks, manual retraction of the couch and the sources should have retracted to home position (In-room indicator light LED White).
9. Perform a 1 minute exposure to check the primary and redundant timers. Agreement should be within 1 second.
10. Measure the timer accuracy by using a stopwatch or an electronic clock. Note the time indicated by the radiation exposure timer.
11. Measure the timer linearity over the entire clinical range by taking radiation measurements for at least 3 time stations repetitively and calculating linearity ratio. Calculate constancy from repetitive measurements by calculating coefficient of variation. C.V. = Standard Deviation/mean value.

12. Measure and calculate the timer-end-effect. Error = [3(R2 – R1)/3(R1) – R2]. R1 is the ionization chamber charge accumulated during a single 3 minute exposure, and R2 is the sum of charges for 3 consecutive 1 minute exposures. The timer error will be calculated from these ionization chamber measurements according to the standard method, with the equation listed in the monthly check data sheet.
13. Measure the output with a NIST/ADCL calibrated dosimetry system. Use the AAPM TG-21 calibration protocol. Insert the ADCL calibrated ionization chamber into the manufacturer supplied phantom. Using the16 mm collimator with all 8 sectors opened, measure the output, making sure to also correct for timer error. Make dose calculations using Perfexion Gamma Knife Monthly Spot Check form.
14. Expected output check: Calculate Expected output from original calibration by decaying ^{60}Co source (Half Life 5.26 Y). Compare measured value with expected value. If the % difference is greater than $\pm$3%, investigate and resolve. If the percent difference is greater than $\pm$5%, a full calibration is required. Enter calculations in Perfexion Gamma Knife Monthly Spot Check form
15. Check the treatment planning system output vs. the measured output.
16. Check the Relative Output Factors from the treatment planning system by comparing times required to deliver 20 Gy to the center of the 16 cm QC phantom.
17. Make the transportation measurements by comparing radiation measurements in phantom for 5Gy shots as indicated on the radiation measurements form. The tolerance is 5 cGy/shot the the 16 mm sectors.

GAMMA KNIFE PERFEXION
MONTHLY CHECKS
UNIVERSITY OF WEST VIRGINIA

Version: Oct 2011
(Monthly spot check procedure reference number)

Date	4/6/2012

FUNCTIONAL AND SAFETY CHECKS

Feature	Test OK	Test Failed	
Pre-treatment checks (1)	Y		
Check all stereotactic frames (1)	Y		
NRC postings (1)	Y		
Table retraction (2)	Y		Retracts on failure
Control system failure (3)	Y		
Office UPS test (4)	Y		
Medical UPS test (5)	Y		
Sector positioning (6)	Y		
Clearance test tool check (7)	Y		
Collimator cap emergency stop (8)	Y		
Redundant timer (9)	Y		

RADIATION BEAM MEASUREMENTS

Output at isocenter (+/- 3%)	Result	
Measured output (13)	3.19	Gy/min
Elekta output (14)	3.11	Gy/min
Computer output (15)	3.11	Gy/min
Measured / Elekta	1.025	
Computer / Expected	1.000	

Timer measurements	Measured	Nominal	Meas/Nom	Tolerance	
Timer accuracy (10)	179.856	180	0.999	0.01	min
Timer linearity (11)	1.002	1	1.002	2.00%	
Timer constancy (11)	0.0000	0	0.0000	0.10%	
Timer error (12)	0.002	-0.002	0.000	0.01	min

Relative Output Factors (+/- 5%)	LGP	Nominal	Meas/Nom
4 mm collimator (16)	0.809	0.814	0.994
8 mm collimator (16)	0.895	0.900	0.994
16 mm collimator (16)	1.000	1.000	1

Source transport measurements	Measured	Tolerance	
Transport dose (17)	-0.16	5	cGy

Measured / standard range	Minimum	Maximum	Criterion
Output * ROF (18)	1.02	1.03	0.95 - 1.05

Measurements by J Hack, MS

Date of measurements 4/6/2012

Instrument	Calib Factor	
PR05P	4.62E+10	R/C
Inovision 350	1.000E-09	nC/rdg

LGP Dose rate

Dose rate	3.799	Gy/min
Date	9/29/2010	

Pressure	736.9	mm Hg
Temperature	23	°C

ION CHAMBER READINGS and TIMER CHECKS (nC) **(16mm collimator)**

Time Set (min)	Time meas (sec)	Primary Timer (min)	Secondary Timer (min)	Electrometer readings: Leakage (pC)	Rdg1 (nC)	Rdg2 (nC)	Rdg3 (nC)	Net Avg Rdg
1	60.032	1.00	1.00	0.8	7	6.99	6.98	6.99
3	179.807	3.00	3.00	1.45	20.95	20.95	20.95	20.95
10	599.832	10.0	10.0	2.92	69.84	69.84	69.82	69.84
30	1799.932	30.0	30.0	8.09	209.31			209.30

Use physics file "Monthly Calibration"

RELATIVE OUTPUT FACTORS Time for 50 Gy, calculated from LGP for spherical phantom

Collimator	Standard	LGP time	ROF plan
4mm	0.814	19.77	0.809
8mm	0.9	17.88	0.895
16mm	1	16	1.000

Calculated 7/26/11

OUTPUT - TG21

N_X	4.62E+10	R/C
N_{elec}	1.00E-09	nC/rdg
N_{gas} / N_X	0.00861	Gy/R
C_{TP}	1.035	
Net rdg	20.94855	nC
P_{ion}	1.001	
L/p poly/air	1.113	
P_{wall}	0.967	
P_{repl}	0.9945	
uen/p H2O/pc	1.036	
net time	3.002	min

Dose rate 3.19 Gy/min

3 min rdg average used (O14)

TIMER CONSTANCY (StdDev) AND LINEARITY

Time Set	Meas/Set	Constancy	Linearity
1	1.001	0.0014	1.002
3	0.999	0.0000	1
10	1.000	0.0002	1.000
30	1.000	#DIV/0!	0.999

Note: 2nd line (3 min) is taken to be the standard
Linearity = (Avg Rdg / Time) / (Avg Rdg for 3min / 3 min)
Constancy = standard deviation / average reading

TIMER END EFFECT

alpha	0.002	min

Transport measurements for 16mm collimator

Time for 10Gy from LGP	3.2	min

Time set	Rdg (nC)	Corrected rdg
3	20.88	22.27
0.8	5.56	5.93
0.8	5.58	5.95
0.8	5.56	5.93
0.6	4.17	4.45

1.067 Time calc /set

Transport dose/shot = (Dose 4 shots-Dose1 shot)/3	-0.16	cGy

Use Physics file similar to "Source transport", but with updated times
Use 4 times that add up to the 10 Gy time
Time is calculated from LGP plan from patient "Physics, phantom"
Or: the way this is calculated, use the "source transport" file,
then correct the readings taken by the ratio of the current time calculated
to deliver 10 Gy by the time set on the first exposure.

Prepared: T. Kirby, PhD
1/24/2011

Leksell Gamma Knife® PERFEXION™

Operator's report

Patient name: QA Clearance tool test
Patient ID: -
Diagnosis: QA Test treatment
Plan ID: 0
Treatment date: 2005-12-08
Planning time: 2005-12-08 09:00:00
Plan operator: -
Max dose [Gy]: 0.0

Overview

Treatment status: Opened
Number of runs: 1
Number of shots: 16
Start time:
End time:

Comment:

-

Run index	Frame adapter	Gamma	Number of shots
1	Standard G	90	16

Treatment results

Run index: 1

Shot	X[mm]	Y[mm]	Z[mm]	Planned[min]	Elapsed[min]	Collimators	Clearance
CL1	39.3	39.3	25.0	0.08		4,B,B,B,B,B,B,B	Accepted
CO1	37.9	37.9	25.0	0.08		B,4,B,B,B,B,B,B	Rejected
CL2	47.4	152.6	50.0	0.08		B,B,4,B,B,B,B,B	Accepted
CO2	46.0	154.0	50.0	0.08		B,B,B,4,B,B,B,B	Rejected
CL3	152.6	152.6	75.0	0.08		B,B,B,B,4,B,B,B	Accepted
CO3	154.0	154.0	75.0	0.08		B,B,B,B,B,4,B,B	Rejected
CL4	160.8	39.3	100.0	0.08		B,B,B,B,B,B,4,B	Accepted
CO4	162.2	37.9	100.0	0.08		B,B,B,B,B,B,B,4	Rejected
CL5	30.8	30.8	1.5	0.08		B,B,B,B,B,B,4,B	Accepted
CO5	30.8	30.8	3.5	0.08		B,B,B,B,B,B,B,4	Rejected
CL6	38.9	161.1	1.5	0.08		B,B,B,B,B,4,B,B	Accepted
CO6	38.9	161.1	3.5	0.08		B,B,B,B,B,B,4,B	Rejected
CL7	161.1	161.1	1.5	0.08		B,B,B,B,B,B,B,4	Accepted
CO7	161.1	161.1	3.5	0.08		B,B,B,B,B,B,4,B	Rejected
CL8	169.3	30.8	1.5	0.08		B,B,B,B,B,B,B,4	Accepted
CO8	169.3	30.8	3.5	0.08		B,B,B,B,B,B,B,4	Rejected

West Virginia University Hospitals
Gamma Knife Radiosurgery
Version: January 2011
Semi-Annual Spot Check Procedure for Leksell Gamma Knife PERFEXION

1. Perform Daily QA

   Perform the daily QA procedure and make sure that all tests are satisfactory. This must be performed as part of the Monthly Spot Check, and the record sheet must be included.

2. Perform Monthly QA

   Perform the monthly QA procedure and make sure that all tests are satisfactory. This must be performed as part of the Semi-Annual Spot Check, and the record sheet must be included.

3. Review and confirm results of Vendors Sector Movement test. Attach a copy to the Semi-Annual spot check report.

GAMMA KNIFE PERFEXION
Semi-Annual CHECKS
UNIVERSITY OF WEST VIRGINIA

Version: 10/2010

FUNCTIONAL AND SAFETY CHECKS

Feature	**Test OK**	**Test Failed**
1. Daily QA procedures (attached)		
2. Monthly QA procedures (attached)		
3. Vendors Sector Movement test (attached)		

Authorized Medical Physicist: _____ ____/____/____

Component checked	Pass	Fail	Fault ID
If changed, new value, Sector 3: ..... (µm)		N/A	
If changed, new value, Sector 4: ..... (µm)		N/A	
If changed, new value, Sector 5: ..... (µm)		N/A	
If changed, new value, Sector 6: ..... (µm)		N/A	
If changed, new value, Sector 7: ..... (µm)		N/A	
If changed, new value, Sector 8: ..... (µm)		N/A	

8.10 Sector positions check

8.10.1 Position 8 mm

Component checked	Pass	Fail	Fault ID
Difference between measured and configured value, Sector 1: 006 (µm)			
Difference between measured and configured value, Sector 2: 005 (µm)			
Difference between measured and configured value, Sector 3: 3 (µm)			
Difference between measured and configured value, Sector 4: 7 (µm)			
Difference between measured and configured value, Sector 5: 2 (µm)			
Difference between measured and configured value, Sector 6: 2 (µm)			
Difference between measured and configured value, Sector 7: 4 (µm)			
Difference between measured and configured value, Sector 8: 1 (µm)			

39 mm
39
39
39.2
39.5
39
39.5
38

All of the checks on this page are done:	Initials:	Date:
		4/20/12

8.9 Mechanical stop validation

Component checked	Pass	Fail	Fault ID
Difference between measured and configured value, X: 002 (µm)			
Difference between measured and configured value, Y: 005 (µm)			
Difference between measured and configured value, Z: 015 (µm)			
Difference between measured and configured value, Sector 1: 012 (µm)			
Difference between measured and configured value, Sector 2: 011 (µm)			
Difference between measured and configured value, Sector 3: 001 (µm)			
Difference between measured and configured value, Sector 4: 002 (µm)			
Difference between measured and configured value, Sector 5: 000 (µm)			
Difference between measured and configured value, Sector 6: 002 (µm)			
Difference between measured and configured value, Sector 7: 027 (µm)			
Difference between measured and configured value, Sector 8: 002 (µm)			

Only applicable if the mechanical stop values are changed:

Component checked	Pass	Fail	Fault ID
If changed, new value, X: ..... (µm)		N/A	
If changed, new value, Y: ..... (µm)		N/A	
If changed, new value, Z: ..... (µm)		N/A	
If changed, new value, Sector 1: ..... (µm)		N/A	
If changed, new value, Sector 2: ..... (µm)		N/A	

All of the checks on this page are done:	Initials:	Date:

Component checked	Pass	Fail	Fault ID	
Difference between measured and configured value, Sector 7: 12 (µm)				110
Difference between measured and configured value, Sector 8: 12 (µm)				109

8.10.4 Position 16 mm

Component checked	Pass	Fail	Fault ID	
Difference between measured and configured value, Sector 1: 4 (µm)				80.5
Difference between measured and configured value, Sector 2: 7 (µm)				81
Difference between measured and configured value, Sector 3: 1 (µm)				80
Difference between measured and configured value, Sector 4: 5 (µm)				81
Difference between measured and configured value, Sector 5: 1 (µm)				81
Difference between measured and configured value, Sector 6: 1 (µm)				80
Difference between measured and configured value, Sector 7: 9 (µm)				80.5
Difference between measured and configured value, Sector 8: 2 (µm)				71.1

All of the checks on this page are done:	Initials:	Date: 4/21/17

8.10.2 Position Off

Component checked	Pass	Fail	Fault ID	
Difference between measured and configured value, Sector 1: 4 (µm)				124
Difference between measured and configured value, Sector 2: 3 (µm)				125
Difference between measured and configured value, Sector 3: 2 (µm)				124
Difference between measured and configured value, Sector 4: 7 (µm)				125
Difference between measured and configured value, Sector 5: 1 (µm)				124.5
Difference between measured and configured value, Sector 6: 0 (µm)				124.5
Difference between measured and configured value, Sector 7: 3 (µm)				125
Difference between measured and configured value, Sector 8: 1 (µm)				124.5

8.10.3 Position 4 mm

Component checked	Pass	Fail	Fault ID	
Difference between measured and configured value, Sector 1: 15 (µm)				109.5
Difference between measured and configured value, Sector 2: 35 (µm)				110
Difference between measured and configured value, Sector 3: 82 (µm)				109.5
Difference between measured and configured value, Sector 4: 25 (µm)				110
Difference between measured and configured value, Sector 5: 41 (µm)				110
Difference between measured and configured value, Sector 6: 02 (µm)				109.5

All of the checks on this page are done:	Initials:	Date: 4/21/17

8.13 Comments

Section	Comment

8.11 PPS precision check

Component checked	Pass	Fail	Fault ID
Part number of Installation Diode Tool:		N/A	
Serial number of Installation Diode Tool: Bost		N/A	
Radial diff on center diode for 4 mm collimator: -135 (µm)			
Radial diff on center diode for 8 mm collimator: 150 (µm)			
Radial diff on center diode for 16 mm collimator: 184 (µm)			
Radial diff on short diode for 4 mm collimator: 119 (µm)			
Radial diff on long diode for 4 mm collimator: 131 (µm)			

8.12 Focus precision check

Component checked	Pass	Fail	Fault ID
QA focus precision check result			
Calculated deviation in focus position, X: 0 (mm)			
Calculated deviation in focus position, Y: -1 (mm)			
Calculated deviation in focus position, Z: 0 (mm)			

All of the checks on this page are done:	Initials:	Date: 4/19/12

WEST VIRGINIA UNIVERSITY
Perfexion Gamma Knife Patient Treatment Log

Date	Patient Name and WVU ID Number	Diagnosis	Time Out / Pt ID verif	Docking adapter	Authorized User (MD)	Authorized Medical Physicist	Notes
			☐ Name ☐ DOB ☐ MRN	☐ Latched	☐ J. Frich, MD	☐ J Hack, MS	
			☐ Name ☐ DOB ☐ MRN	☐ Latched	☐ J. Frich, MD	☐ J Hack, MS	
			☐ Name ☐ DOB ☐ MRN	☐ Latched	☐ J. Frich, MD	☐ J Hack, MS	
			☐ Name ☐ DOB ☐ MRN	☐ Latched	☐ J. Frich, MD	☐ J Hack, MS	
			☐ Name ☐ DOB ☐ MRN	☐ Latched	☐ J. Frich, MD	☐ J Hack, MS	

CLOSING THE RADIATION SECTORS MANUALLY

If the radiation sectors have not returned to the sector home position, the sectors must be closed manually. The sectors' position is indicated by the white lamp on the wall-mounted radiation warning lamp. If the white lamp is not lit, close the sectors manually as follows

- Remove the rear section of the radiation unit cover
- In the ECU unit of the medical cabinet, turn off the power to the Sector Drive Unit (SDU) by using the **1** labeled **24V SDU**
- At the rear of the radiation unit, the sector drive mechanics can be found. Each sector has a red handle **2** which can be used to pull the sector outwards to the end position
- Inspect the position of each red handle. Manually pull each sector that is not in the sector home position outwards to the end position by pulling the red handle hard. When all sectors are in the sector home position, the white lamp on the wall-mounted radiation warning lamp is lit.
- In the ECU unit of the medical cabinet, use the switch labeled 24V SDU to turn on the power to the Sector Drive Unit again