BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

February 6, 2008

USNRC
Steven A. Reynolds, Director
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: Response to An Apparent Violation in Inspection Report No. 03009376/2007-001(DNMS); EA-07-316
Karmanos Cancer Center, Detroit, MI

Dear Mr. Reynolds:

We would like to thank the NRC inspectors for their comprehensive review of our Gamma Knife program. We are not requesting a predecisional enforcement conference.

Our response to the requested information is attached. We would also like to take this opportunity to provide further clarification regarding the observations and findings pertaining to the medical incident. Based on the corrective actions implemented since the event, we believe that we are currently in full compliance with NRC regulations. Please do not hesitate to contact Dr. Jay Burmeister (313) 745-2483, if you need any additional information.

Sincerely,

Debra K. Herring

Debra Herring
Vice President, Ambulatory Operations

Enclosures:
1.Response letter
2.Clarification of the medical incident accompanied by original document with areas of clarification highlighted
3.Updated Gamma Knife Procedure Documentation Policy
4.Updated Gamma Knife forms
5.Images of intended and actual Gamma Knife plans from treatment planning system
6.Review of all Gamma Knife Cases from October 24, 2006 through October 22, 2007

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NCI A Comprehensive Cancer Center Designated by the National Cancer Institute
CCC

Response Letter

In response to the NRC inspection report, we have addressed the items listed in the inspection report letter both in the current document and in our previous report dated November 7, 2007.

Specifically, (1) the reason for the apparent violation is detailed in Section 4 of the November 7 report; (2) & (3) our corrective actions and steps taken to avoid further violations are described in Section 6 and Appendix A of our report dated November 7. In addition, we are attaching updated forms of the preliminary documents included in Appendix A from the November 7 report.

As part of our corrective actions, all Gamma Knife cases from October 24, 2006 through October 22, 2007 were reviewed with results attached. Our case review did not reveal any additional medical events.

Finally, (4) we believe that we are currently in full compliance with all actions specified in the November 7 report and in section 3 of the Executive Summary of the Inspection Report for this incident. In addition, we have detailed some clarifications to assure the accuracy of the inspection report. These clarifications are attached (enclosure 2).

Clarification of the Medical Incident

In the interest of accuracy, we would like to offer the following clarifications to the Executive Summary and Medical Consultant Report.

In both documents, there is repeated reference to the "left" cerebellum or the "wrong side" of the brain being treated. The radiation was in fact delivered to the right cerebellum with some overlap of the lesion, such that approximately 9% of the targeted volume received the prescribed dose. The prescription isodose line did not cross the midline into the left cerebellar hemisphere, i.e., the prescription dose of 18 Gray was contained entirely within the right cerebellum brain parenchyma and posterior fossa cerebrospinal fluid. Color printouts of the treatment plan are attached for your review.

The following statements in both the Executive Summary and Medical Consultant Report inaccurately indicate that the radiation treatment was administered to the left cerebellum. A copy of the original documents with highlighted areas requiring clarification is attached for your review.

Executive Summary:

1. Report Page 2, paragraph 1, final sentence
2. Report Page 2, paragraph 2, third sentence
3. Report Page 2, paragraph 3, final sentence
4. Report Page 3, paragraph 5 (2.2 Observations and Findings), final sentence
5. Report Page 4, paragraph 1 (2.2 Observations and Findings), second sentence
6. Report Page 4, paragraph 6 (2.3 Conclusions), first sentence
7. Report Page 6, paragraph 1 (4.2 Observations and Findings), first sentence

Medical Consultant Report:

1. Report Page 2, statement about estimated dose to unintended anatomic region
2. Report Page 2, statement of probable error associated with estimation
3. Report Page 2, paragraph 2 (Description of Incident), first sentence
4. Report Page 2, paragraph 2 (Description of Incident), third sentence
5. Report Page 3, paragraph 1 (Description of Incident), second sentence

We hope that these clarifications will provide additional insight into this medical event. We thank you in advance for your time and consideration.

EXECUTIVE SUMMARY

Karmanos Cancer Center
Detroit, Michigan
Inspection Report No. 030-09376/2007-001(DNMS)

This was a special, announced inspection to review the circumstances, root and contributing causes, and corrective actions associated with a reported medical event that occurred at the Karmanos Cancer Center, Detroit, Michigan. The reported event was associated with their stereotactic radiosurgery unit, a.k.a., "gamma knife." The patient was a 63-year-old female that was being treated for a metastatic brain tumor in the right cerebellum. Due to an error in the setup of the magnetic resonance imaging (MRI) unit, the MRI scan was reversed (right side of the head was on the left side and visa versa). Prior to the administration of the treatment the medical physicist, authorized user physician and neurosurgeon reviewed the MRI scan and treatment plan and all failed to notice the reversed MRI images. The reversed MRI image was scanned into the gamma knife treatment planning computer and a treatment plan was generated. The treatment plan was again reviewed and approved by the authorized user physician and neurosurgeon and again the reversed MRI images were not detected. The treatment was administered to the left side of the patient's brain rather than the right side.

After the treatment plan was generated the medical physicist was still concerned that the stereotactic head frame measurements and MRI images did not match and consulted with several colleagues including the gamma knife manufacturer (Elekta). Discussions were also held with the neurosurgeon, authorized user, neuroradiologist and chief physicist. After the treatment was administered it was subsequently discovered that the MRI scans were reversed and the left side of the patient's brain was treated rather than the right side. The licensee did not expect the patient to experience any major adverse medical effects as a result of the medical event other than possible mild edema. An NRC medical consultant reviewed this case to determine if any deterministic effects are expected. The medical consultant indicated that in his opinion he did not expect any significant deterministic effects to the patient.

The inspector identified one violation of NRC requirements involving the licensee's failure to ensure each administration is in accordance with the written directive prior to patient treatment. Specifically, the licensee's procedures for the implementation of treatment plans with its stereotactic radiosurgery unit as required by 10 CFR 35.41 did not require a check and verification of the treatment plan parameters prior to the treatment to ensure correct MRI scan orientation. The root cause of the apparent violation was the MRI technologist inadvertently performing the MRI scans in the "caudal" (jaw to top of the head) mode rather than the "cranial" (top of the head to the jaw) mode which caused the MRI scans to be reversed and the licensee's failure to identify that the images were reversed. As a result, the licensee administered a dose of 1,800 centigray to the wrong side of the patient's brain.

To reduce the likelihood of recurrence of a similar event, the licensee initiated several immediate and long-term corrective actions. The corrective actions included: (1) weekly meetings among the physics staff to discuss technical issues, focusing on the importance of good communications with other physics staff, and (2) new written procedures and policies were implemented for the MRI staff and gamma knife facility that required dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI image and the administered dose is in accordance with the written directive.

Report Details

1 Program Scope and Inspection History

The NRC License Number 21-04127-06 authorizes Karmanos Cancer Center (licensee) to use a variety of byproduct materials for medical therapy purposes, including sealed source therapy using a high dose rate (HDR) remote afterloading brachytherapy device, teletherapy and a stereotactic radiosurgical unit.

One Severity Level IV violation was identified during an Increased Controls inspection conducted on June 14, 2006. No violations were identified during routine inspections conducted on March 12, 2004 and June 13, 2006.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors reviewed the sequence of events that resulted in the medical event and the licensee's investigation of the event. In addition, the inspectors interviewed selected licensee personnel, reviewed patient treatment records, procedures, and equipment associated with the medical event, and toured related facilities.

2.2 Observations and Findings

On October 24, 2007, a patient was to be treated for a brain tumor in the right cerebellum with the stereotactic radiosurgical unit. A written directive was completed by the authorized user physician that called for a single treatment of 1,800 centigray (cGy) to the right cerebellum. On the morning of October 24, 2007, the neurosurgical team fitted the patient with a stereotactic head frame and the patient was sent to the magnetic resonance imaging (MRI) department for a stereotactic MRI brain scan. During the scanning process an error in the setup of the MRI unit occurred. This error in the setup resulted in the MRI scan being reversed (right side of the head was on the left side and visa versa). The reversed MRI image was scanned into the gamma knife treatment planning computer and a treatment plan was generated.

The authorized medical physicist (AMP) noticed a discrepancy between the contour of the patient's head when compared to the MRI image and the bubble helmet measurements (a device used to take precise measurements of the patient's head). The AMP contacted the gamma knife manufacturer (Elekta) by phone and discussed the discrepancy with the physics staff at Elekta. A decision was made to proceed with the treatment using the bubble helmet measurements. The neurosurgeon, authorized user physician and the medical physicist reviewed the treatment plan and all parties agreed with the treatment plan and to proceed with the treatment. However, none of these individuals realized that the MRI scan was reversed. The treatment was administered and the patient received a dose of 1,800 cGy to the left cerebellum of the brain rather than the right side.

After the treatment was administered the AMP discovered that the MRI images were acquired in an unconventional way. The AMP immediately contacted the authorized user physician, neurosurgeon and neuroradiologist and all parties reviewed the

treatment plan and again agreed that the treatment was administered appropriately. On the evening of October 24, 2007, the AMP discussed the discrepancy with the chief medical physicist and it was at that time that the AMP realized that the MRI images were reversed and the treatment was administered to the wrong side of the brain. On October 25, 2007, the licensee notified NRC that a medical event occurred involving the stereotactic radiosurgery unit, a.k.a, "gamma knife." The licensee concluded that the root cause of the medical event was due to an error in the setup of the MRI scan and the licensee's failure to recognize that the MRI images were reversed.

10 CFR 35.41(a) requires that for any administrations requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

The inspectors determined that prior to October 29, 2007, the licensee's written procedures did not provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for the implementation of treatment plans with its stereotactic radiosurgical unit did not require a check of the treatment plan parameters to ensure that the MRI brain scan was in the correct orientation. As a result, the licensee failed to administer a single treatment to the correct side of the patient's brain. This is an apparent violation of 10 CFR 35.41(a).

The authorized user physician did not expect any major adverse medical effects to the patient as a result of the medical event. The licensee immediately initiated an investigation of the medical event and determined that the root and contributing causes were: (1) inattention to detail, (2) an error in the setup of the MRI brain, and (3) a failure to identify that the MRI images were reversed.

As part of the licensee's investigation, the licensee reviewed all gamma knife treatment plans, including MRI scans, from October 2006 to October 2007 to determine if the same error occurred during previous treatments and none were identified. The inspectors reviewed approximately 50 random selected treatment plans to determine if the same error occurred and did not identify any additional errors in the administration of the gamma knife treatments.

2.3 Conclusions

A medical event occurred on October 24, 2007, when the licensee administered a gamma knife treatment of 1,800 cGy to the left cerebellum rather than the right cerebellum. The authorized user physician did not expect the error in the treatment to result in any major adverse medical effects.

The medical event was caused by an error in the setup of the MRI brain scan and the licensee's failure to identify that the MRI images were reversed. In addition, the licensee's written procedures for implementation of stereotactic radiosurgical treatment plans did not require a check of the treatment plan parameters to ensure that the MRI scan was in the correct orientation. The inspectors identified a violation of NRC requirements associated with the failure of the licensee's written procedures to provide

high confidence that each administration is in accordance with the written directive. The NRC inspectors determined that this event was an isolated event.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's November 6, 2007, written report regarding the medical event, interviews of selected licensee personnel, and the licensee's revised policies and procedures to ensure each administration is in accordance with the written directive prior to patient treatment.

3.2 Observations and Findings

The inspectors determined that the licensee initiated several immediate and long-term corrective actions to prevent recurrence of a similar event. The corrective actions included:

(1) Created a gamma knife procedure documentation policy;
(2) Created a gamma knife quality assurance form;
(3) Instituted a secondary check of treatment parameters by another physicist;
(4) Reviewed all patient charts of previous treatments (October 2006 to October 2007) to ensure that this event was an isolated event;
(5) Implemented a procedure that required the neurosurgeon and radiation oncologist to verify the number and orientation of the brain lesion;
(6) Implemented a procedure for requiring a "time out" before commencing with a treatment to allow an overall review of all details of the treatment prior to delivery;
(7) Held a meeting with all groups in the department including physicists, dosimetrists, therapists, and nurses to assure a proper environment existed that encouraged peer and supervisory consultation and openness in the reporting of incidents; and,
(8) Created a new written procedure for the MRI staff to ensure that the correct MRI scan orientation was used on all future gamma knife patients.

3.3 Conclusions

The inspectors determined that the licensee developed appropriate corrective actions to address the violation and prevent similar events.

4 Notifications and Reports

4.1 Inspection Scope

The inspectors interviewed selected licensee staff and reviewed the licensee's notification to the NRC Operations Center and the associated 15-day written report to ensure compliance with NRC reporting requirements.

4.2 Observations and Findings

On October 24, 2007, the licensee's Radiation Safety Officer determined that the patient's left side of the brain was treated rather than the right side which resulted in a medical event and notified the NRC's Operations Center of the event within 24 hours. The licensee provided its written report of the event within 15 days of the telephone report in a letter dated November 6, 2007. The inspectors determined that the written report included the information required by 10 CFR 35.3045(d).

The licensee notified the patient and patient's referring physician immediately after the event. The authorized user physician met with the patient and family and explained to them the possible side effects from the treatment.

4.3 Conclusions

The licensee made all of the notifications and submitted the reports required by 10 CFR 35.3045 within the specified time period. The inspectors determined that the licensee included all of the required information.

5 Exit Meeting

At the completion of the onsite inspection, the inspectors discussed the findings in this report with licensee management during an exit meeting. The inspectors discussed the sequence of events that led to the medical event, the root and contributing causes of the event, and the licensee's corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Partial List of Persons Contacted

* Debra Herring, Vice President Ambulatory Operations
* Clifford Crabtree, R.Ph., Vice President Operations
* Bridget Brambs, Administrative Director
  Joseph Rakowski, Ph.D, Radiation Safety Officer, Authorized Medical Physicist
  Sandeep Mittal, M.D., Neurosurgeon
  Jay Burmeister, Ph.D., Chief of Physics
  Maria Vlachaki, M.D., Radiation Oncologist
  Mara Jelich, Manager, Operations
  Zubin Bharucha, Medical Physicist
  Ron Marshall, Manager, Diagnostic Imaging, MRI
  Roland Gardner, Supervisor, MRI
  Mark Manders, R.T., MRI Technologist
  Steven Jackson, R.T., MRI Technologist

* Attended the October 30, 2007, exit meeting

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued in 1996.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as

required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

    - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

    - Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that

may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does

management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety
and Safeguards

Donald A. Cool, Director
Division of Industrial and Medical Nuclear
Office of Nuclear Material Safety and
and Safeguards

Technical contacts: (Updated as of November 22, 2005)

Sally Merchant, Office of Enforcement
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Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 12/4/2007

Signature Ronald E Goans MD 12/5/2007

Licensee Name: Karmanos Cancer Center

License No. 21-04127-06
Event No. 43746
Docket No. 030-09376

Facility Name: Karmanos Cancer Center

Incident Date: 10/24/2007

Date of Notification: 10/25/2007

Individuals' / Patient Physician Name and Address:

Maria T. Vlachaki, MD
Clinical Director, Radiation Oncology
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Detroit, Michigan 48201

Individuals Contacted During Investigation:

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Joe Rakowski, PhD
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Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. Draft document - Description of the event; NRC fax 10/25/2007
3. NRC Preliminary Notification of Event (Event # 43746)
4. NRC Medical Event - 15 day report from licensee
5. Karmanos Cancer Center correspondence to the NRC
6. Detailed review of patient records and photographs
7. Karmanos Cancer Center documents on event analysis and remediation efforts
8. Karmanos Cancer Center Gamma Knife planning form
9. Karmanos Cancer Center Gamma Knife Pre-procedure checklist
10. Karmanos Cancer Center Time-out draft document

Estimated Dose to Unintended Anatomic Region (see appendix A). By assessment of clinical signs:

18 Gy to left cerebellum (normal brain tissue); no adverse clinical signs or symptoms at this time.

Probable Error Associated with Estimation: < 10 %; the 18 Gy dose was planned but delivered to the wrong side of the cerebellum.

Prescribed Dose (Medical Misadministration Only):

18 Gy to right cerebellar lesion.

Method Used to Calculate Dose: Radiation oncology clinical dose profile and physical dosimetry.

Description of Incident:

On October 24, 2007, a medical event occurred at the Leksell Gamma Knife facility at the Wayne State - Karmanos Cancer Center which resulted in the total dose delivered differing from the prescribed dose by more than 20%. The patient is a 64 year old female with a history of small cell lung cancer. She previously underwent chemotherapy and radiation therapy, along with 25 Gy to the whole brain in 10 fractions. The patient subsequently developed a metastatic lesion in the right cerebellum and was prescribed 18 Gy via gamma knife therapy to the nodule at the 50% isodose line.

Due to a left - right reversal of the treatment planning MRI images, the patient's left side was targeted and treated rather than the right side. The patient was treated with one shot of 18 mm at a gamma knife angle of 140 degrees. The error resulted in an 18 mm shift of isocenter across midline of the brain. The collimator diameter selected for the treatment was 18 mm, thus resulting in some overlap of the delivered 50% isodose volume with the correct intended target lesion volume. The event resulted in approximately 7% of the lesion volume receiving the prescribed dose of 18 Gy to the 50% isodose, rather than the preferred 95% of the lesion volume.

During the pre-treatment setup and simulation with MRI imaging, a caudal view was selected by the technician whereas the patient should have had a cranial view selected. This had the effect of reversing the axial images left to right. The standard of practice in gamma knife radiosurgery is to position the patient in the MRI scanner head first, and to use the cranial scan technique. The caudal MRI images were imported into the Gamma Knife treatment planning computer, and

subsequently registered as cranial. This resulted in the wrong side of the patient being targeted and treated, i.e. the left cerebellum was targeted and treated rather than the right cerebellar lesion.

Clinical Details (See Appendix 1 for planned and given dose profiles)

The patient is a 64 year old, right-handed female with a history of small cell lung cancer diagnosed in 2005. The past medical history is pertinent for a 40 pack-year smoking history and bilateral breast cancer diagnosed in 1992. The patient previously underwent chemotherapy and radiation therapy for the small cell tumor, along with 25 Gy to the whole brain in 10 fractions. She subsequently developed a metastatic lesion to the right cerebellum and was prescribed 18 Gy gamma knife stereotactic radiosurgery to the nodule at the 50% isodose line. The patient currently also has metastatic disease to the liver.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

Normal brain tissue is relatively radio-resistant. The tolerance dose with 5% severe complication rate in 5 years is referred to as the $TD_{5/5}$. For brain with complications of radiation necrosis and infarction, the $TD_{5/5}$ is approximately 50 Gy. The radiation dose in this case was given to a relatively silent portion of the brain and, therefore, I would not expect any significant deterministic effects.

Briefly describe the current medical condition of the exposed individual:

The patient is a 64 year old female with a history of small cell lung cancer diagnosed in 2005. She subsequently developed a metastatic lesion to the right cerebellum and was prescribed 18 Gy gamma knife stereotactic radiosurgery to the nodule at the 50% isodose line. The patient currently also has metastatic disease to the liver. Her long-term prognosis is not favorable due to her tumor burden.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams & Wilkins. 1980.

FA Mettler Jr, and AC Upton. Medical Effects of Ionizing Radiation. Second Edition. Saunders. 1995.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

Yes

If yes, would the individual like to be included in the program?

No

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes.

b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC.

d. Improvements needed to prevent recurrence - Yes.

This is a human factors issue, correctable by education and improved procedures. The issue was also addressed through the hospital Radiation Safety Committee and by physician management in the Karmanos Cancer Center. A time-out protocol is also currently in development to allow medical staff to review all aspects of the medical case prior to gamma knife treatment.

For all future gamma knife cases, left/right alignment of the MRI images will be inspected by the authorized medical physicist (AMP) by using the Leksel anterior face plate with fiducial markers visible in the MRI images. A Gamma Knife MRI protocol will also be written and posted in the MRI department and in the Gamma Knife suite. The protocol will clearly indicate the patient and scan orientation required for Gamma Knife planning and delivery, which are patient on table head first, with head first scanning protocol.

Appendix 2 illustrates the current pre-procedure gamma knife checklist, while appendix 3 presents the current gamma knife planning form. Appendix 4 presents the planned stereotactic imaging planning form. In this accident, prior to the therapy, the medical physicist noted that the stereotactic headset bubble readings did not match those in the pre-treatment planning form, he called the company representative and was told to proceed. This was quite unfortunate.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patients will be followed clinically by oncology physicians as indicated. I believe that the hospital system and, specifically, the oncology department, will institute an effective program to prevent a recurrence of this event. The information in the preliminary notification has also been reviewed with licensee management. Detailed checklists and policy statements are included in the appendices.

GAMMA KNIFE PROCEDURE DOCUMENTATION POLICY

Pertinent steps in the Gamma Knife procedure and of the role of the various members of the Gamma Knife multidisciplinary team are as follows:

a. After approval of Gamma Knife treatment by the Neuro-Oncology Muldisciplinary Team, the patient's chart and diagnostic films are secured by the radiation oncology and neurosurgery scheduling staff. A Gamma Knife Registration Checklist has been developed by the radiation oncology department to be signed off by the Gamma Knife Coordinator, patient services representative, radiation oncology medical records and Radiation Oncology nursing staff and be placed in the patient's radiotherapy chart. This will ensure that all relevant patient medical records including history and physical, pathology, imaging reports, radiation therapy consent form and radiation prescription sheet are available to the radiation oncologist and neurosurgeon at the time of the Gamma Knife procedure.
b. Neurosurgery staff completes the Stereotactic Frame Placement and Neuroimaging Form. This form identifies the dates of neurooncology tumor board approval and planned Gamma Knife procedure. In addition, the form outlines the location of the lesion(s), the resultant position of the stereotactic frame as well as the image acquisition protocol (i.e. specific MRI and/or CT sequences) required on the day of Gamma Knife treatment. The Stereotactic Frame Placement and Neuroimaging Form shall be signed off by the neurosurgery staff on the day of the frame placement. A copy of this document shall be placed in the patient's hospital chart.
c. Gamma Knife Preprocedure Checklist ensures that all relevant patient medical records and pre-procedure imaging and laboratory tests are available for review at the time of the procedure. In addition, this form includes the "MRI/CT Scanner Checklist". This ensures that MRI/CT image acquisition and transfer process is followed appropriately. It is signed off by the neurosurgery staff, stereotactic systems engineer and the MRI and/or CT technologist performing the scan(s). A copy of this document shall be placed in the patient's hospital chart.
d. During MRI/CT image import and registration, the AMP shall verify image left/right orientation by looking at the fiducial marker positions, the L/R notation and/or the CR notation on the hardcopy film and verifying correspondence between the film and the treatment planning system. The AMP will also qualitatively evaluate the agreement between the wire frame (from bubble measurements) and bony contours in the MRI/CT image. The AMP shall document this on the Gamma Knife Planning Form. The location of the lesion(s) shall be verified again and documented at the time of treatment planning by the treating radiation oncologist and neurosurgeon on the Gamma Knife Planning Form. The location and side of the lesion(s) have to be individually spelled out and the document needs to be signed by the radiation oncologist, neurosurgeon, and medical physicist.
e. If the frame placement is judged to be suboptimal, it needs to be repositioned or the procedure be aborted for that day. This will be evaluated and documented by both the neurosurgeon and the radiation oncologist on the Gamma Knife Planning Form.
f. A second AMP will review the MRI/CT images and treatment plan and then sign the Gamma Knife Planning Form.
g. At the completion of Gamma Knife planning process, the Gamma Knife plan shall be printed and signed by all involved including the radiation oncologist, neurosurgeon, and AMP.
h. Before the treatment is initiated, the "time-out" procedure will take place and will be documented in the Gamma Knife Time-Out Form. This process will reflect that the entire

process has been performed accurately and according to the Gamma Knife Procedure Documentation Policy and that all forms included in the procedure have been signed by the appropriate professionals. The Gamma Knife Time-Out Form will include the following:

1. Verification of the name and medical record number of the patient by comparing the patients chart to his/her hospital wrist band.
2. Verification of the number and side of lesion(s) to be treated with Gamma Knife.
3. Verification of whether the patient had prior radiation therapy including WBRT, external beam radiotherapy, and/or stereotactic radiosurgery. The radiation doses as well as the location of the lesion(s) previously treated need to be individually spelled out and the document needs to be signed by the radiation oncologist, neurosurgeon and medical physicist.
4. Verification that the Gamma Knife plan has been reviewed and signed off by the radiation oncologist, neurosurgeon, and medical physicist.
5. If for any technical or medical reason the procedure needs to be aborted, this needs to be documented in the Gamma Knife Time-Out Form and signed off by the neurosurgeon and the radiation oncologist.

i. After the procedure is completed, the neurosurgery staff will remove the stereotactic head frame and the patient will return to his/her hospital room.

In summary, the documentation related to the Gamma Knife procedure shall include:

1. Gamma Knife Registration Checklist
2. Stereotactic Frame Placement and Neuroimaging Form
3. Gamma Knife Preprocedure Checklist
4. Gamma Knife Planning Form
5. Gamma Knife Time-Out Form

If any of the above documents is incomplete or missing, the medical physicist will assess and determine whether the procedure will continue as planned or be rescheduled. This assessment and action plan will be documented in the comment section of the Time-Out Form.

BARBARA ANN KARMANOS CANCER CENTER
At the Detroit Medical Center

Patient Label

GAMMA KNIFE

Registration Checklist

(Scheduling / Medical Record Preparation Checklist)

	Action	Signature	Date
Gamma Knife Coordinator	• Obtain copy of patient's CT, MRI and other appropriate radiologic films. • Coordinate presentation of patient's medical condition to Neuro-Oncology MDT Conference (Decision is made by MDT to treat patient with Gamma Knife).		
Gamma Knife Coordinator	• Give appointment information to Radiation Oncology PSR. • Give CT, MRI & other appropriate radiologic films to ROC RN.		
ROC- Patient Services Representative (PSR)	• Schedule patient's Gamma Knife appointment in "*IMPAC.*"		
Medical Records Personnel (MRP)	• Upon receipt of patient appointment information from PSR ("*IMPAC*"), MRP will locate existing radiation oncology treatment chart. • If patient is a "new" patient, MRP will create a "Radiation Oncology Treatment Chart" and give to ROC RN. • MRP will place this checklist on top of patient's treatment chart folder. • MRP will ensure that patient's treatment chart is given to ROC RN *at least two business days prior to the scheduled appointment*.		
ROC-RN	• Upon receipt of patients treatment chart (existing or new), ROC RN will verify that the following information is present: - Radiation Oncology Consult Report. If patient has not been seen by Radiation Oncologist, ROC RN will notify Gamma Knife Coordinator to reschedule. - History & Physical (electronic or paper) - Pathology Reports (electronic or paper) - MRI and CT Reports (written) - Appropriate diagnostic films - Completed / signed "Informed Consent for Radiation Therapy—Central Nervous System" (*Gamma Knife Consent*). Gamma Knife consent must include the site and side of the proposed Gamma Knife Surgery or it must indicate that there are multiple lesions in various locations.		

Patient Label

Stereotactic Frame Placement and Neuroimaging Form – BRAIN METASTASES

PATIENT NAME: _____ NEUROSURGEON: _____

DATE OF BIRTH: _____ RADIATION ONCOLOGIST: _____

TUMOR BOARD DATE: _____ GAMMA KNIFE DATE: _____

DATE OF LAST MRI/CT: _____ MRI/CT AVAILABLE: ☐ FILMS ☐ CD ☐ CIS

NUMBER OF LESIONS: _____ WHO HAS FILMS/CD: _____

LOCATION OF LESION(S) [PLEASE INDICATE RIGHT/LEFT]:

1- _____ 2- _____ 3- _____

4- _____ 5- _____ 6- _____

OPTIMAL FRAME PLACEMENT [BASED ON LOCATION OF LESION(S)]:

1-	☐ RIGHT	☐ LEFT	☐ NEUTRAL
2-	☐ SUPERIOR	☐ INFERIOR	☐ NEUTRAL
3-	☐ ANTERIOR	☐ POSTERIOR	☐ NEUTRAL

NEUROIMAGING PROTOCOL REQUIRED:

AXIAL T1	POST-GADOLINIUM	WHOLE HEAD	2 MM CUTS, NO GAPS
CORONAL T1	POST-GADOLINIUM	WHOLE HEAD	2 MM CUTS, NO GAPS

Comments: _____

_____ _____ _____

Neurosurgeon (Date) Neurosurgery RN (Date) GK Coordinator (Date)

DMC
Harper University Hospital

Patient Label

Gamma Knife Preprocedure Checklist

Date: _____

Pre-Procedure Checklist: *To be completed by Neurosurgery RN*	
☐	Stereotactic Frame Placement and Neuroimaging Form completed and placed in patient medical record
☐	History and Physical Exam completed and placed in patient medical record
☐	Radiation Oncology Consultation notes placed in patient medical record
☐	Neurosurgery Consultation notes placed in patient medical record
☐	*Consent for Surgery, Invasive Procedures and/or Diagnostic Procedures, Anesthesia, and/or Blood Transfusion* signed and placed in patient medical record
☐	Diagnostic films reviewed (prior MRI/CT images as hard copy, on CD, or in CIS)
☐	Pre-op tests (e.g. blood work, EKG, serum pregnancy test within last 14 days, x-rays) available in CIS or in patient medical record and do not preclude treatment
☐ Yes ☐ NA	Negative urine pregnancy test (done in the morning of procedure)
☐	MRI/CT images (hard copy printed/CD) taken to Gamma Knife suite

MRI/CT Scanner Checklist: *To be completed by MRI/CT Technologist*	
☐	MRI/CT scanner set up for patient in head first, supine position with "cranial" technique. *MRI/CT Technologist*
☐	MRI image "stacks" combined into one series and ready to export to Gamma Knife workstation. *MRI/CT Technologist*
☐	"H-SP-CR" is identified on the MRI/CT images. *MRI/CT Technologist*
☐	MRI/CT images successfully exported to the Gamma Knife workstation *MRI/CT Technologist*

Post frame placement: *To be completed by Stereotactic Systems Engineer*	
☐	Verified adequacy of frame placement and placed copy of calculations with images
☐	Bubble measurements obtained, confirmed and documented on Leksell Gamma Knife C Form by

Comments: _____

_____

_____

_____ _____

Signature Neurosurgery RN Signature Neurosurgeon / NP / Resident

_____ _____

Signature Stereotactic Systems Engineer Signature MRI Technologist

_____

Signature CT Technologist

This is not a permanent part of the medical record

BARBARA ANN KARMANOS CANCER CENTER

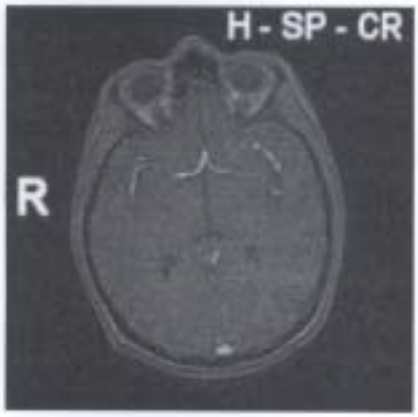
Patient Label

GAMMA KNIFE PLANNING FORM

☐ MRI Checklist completed.

☐ Image orientation check (on film or PACS station):

1) Fiducial orientation matches orientation of head frame.
2) Check L/R notation on MR film (or image).
3) Check CA/CR notation on MR film (or image).
4) MRI film images (hard copy) agrees with image orientation in Gamma Plan
   ("R" on left side of image)
   ("H – SP – CR" in upper right corner)



☐ Qualitative agreement of wire frame (from bubble measurements) with MR image.

Largest measured deviation between wire frame contour and MR image surface: _____.

Lesion (1) Name: _____ Treatment Site: _____
Lesion (2) Name: _____ Treatment Site: _____
Lesion (3) Name: _____ Treatment Site: _____
Lesion (4) Name: _____ Treatment Site: _____
Lesion (5) Name: _____ Treatment Site: _____
Lesion (6) Name: _____ Treatment Site: _____
Lesion (7) Name: _____ Treatment Site: _____
Lesion (8) Name: _____ Treatment Site: _____
Lesion (9) Name: _____ Treatment Site: _____
Lesion (10) Name: _____ Treatment Site: _____

(If more than 10 lesions, please use second planning form)

_____ | _____

(Signature of Planning Physicist) Date (Signature of Physics Check) Date

☐ Identify number and orientation of lesions (to be checked by neurosurgeon and radiation oncologist)

_____ | _____

(Signature of Neurosurgeon) Date (Signature of Radiation Oncologist) Date

Comments: _____

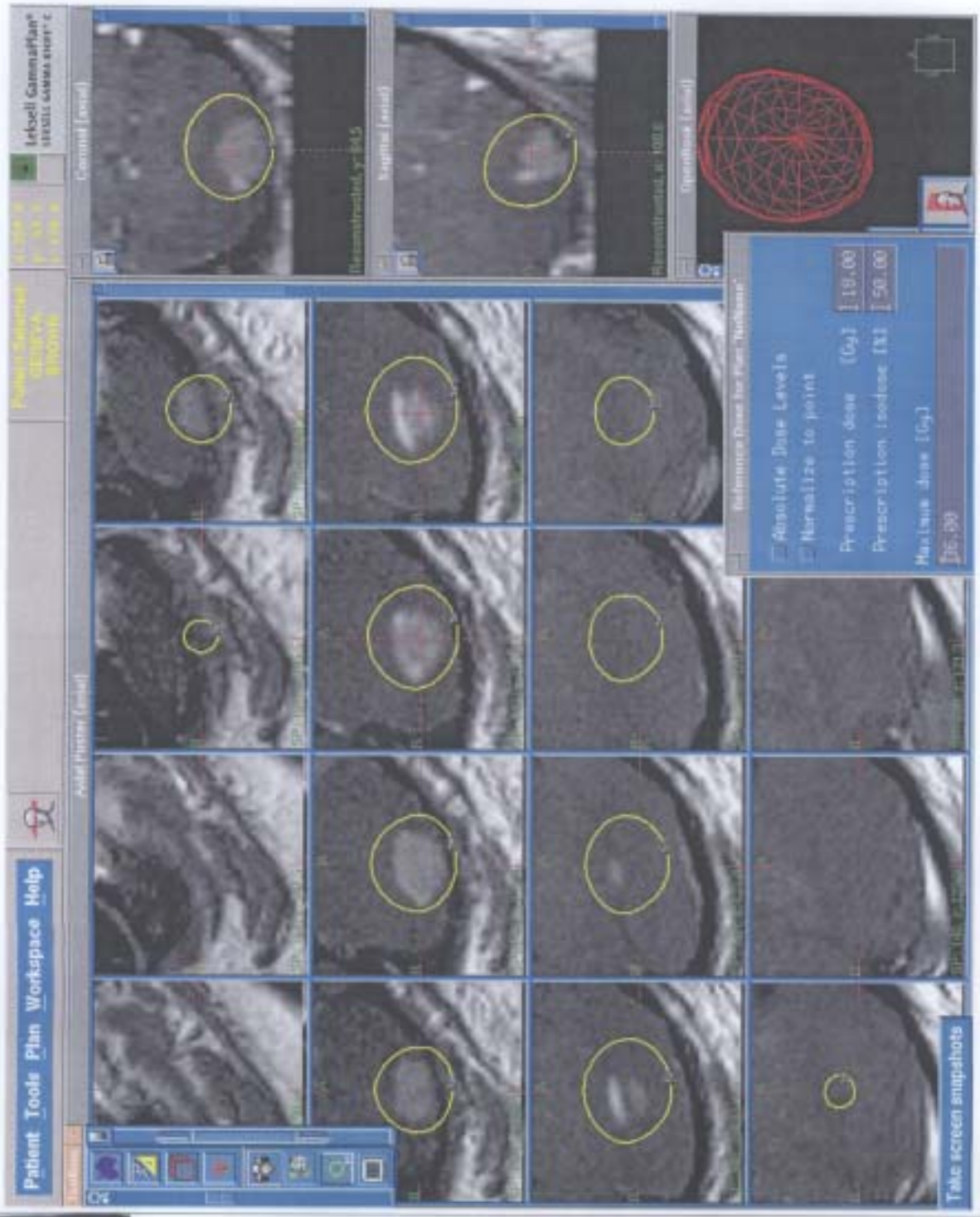
Key:

CR = Cranial
CA = Caudal
H = Head
SP = Supine
L/R = Left / Right
MR = Magnetic Resonance

INTENDED GAMMA KNIFE PLAN

Karmanos Cancer Center Snapshot *for the* *Leksell Gamma Knife C* *Leksell GammaPlan Wizard 5.34*	Patient: [redacted]
	Patient ID: [redacted]
	Diagnosis: *Metastasis Multiple*
	Treatment Date: *Feb 06, 2008*
	Operator: *zb*

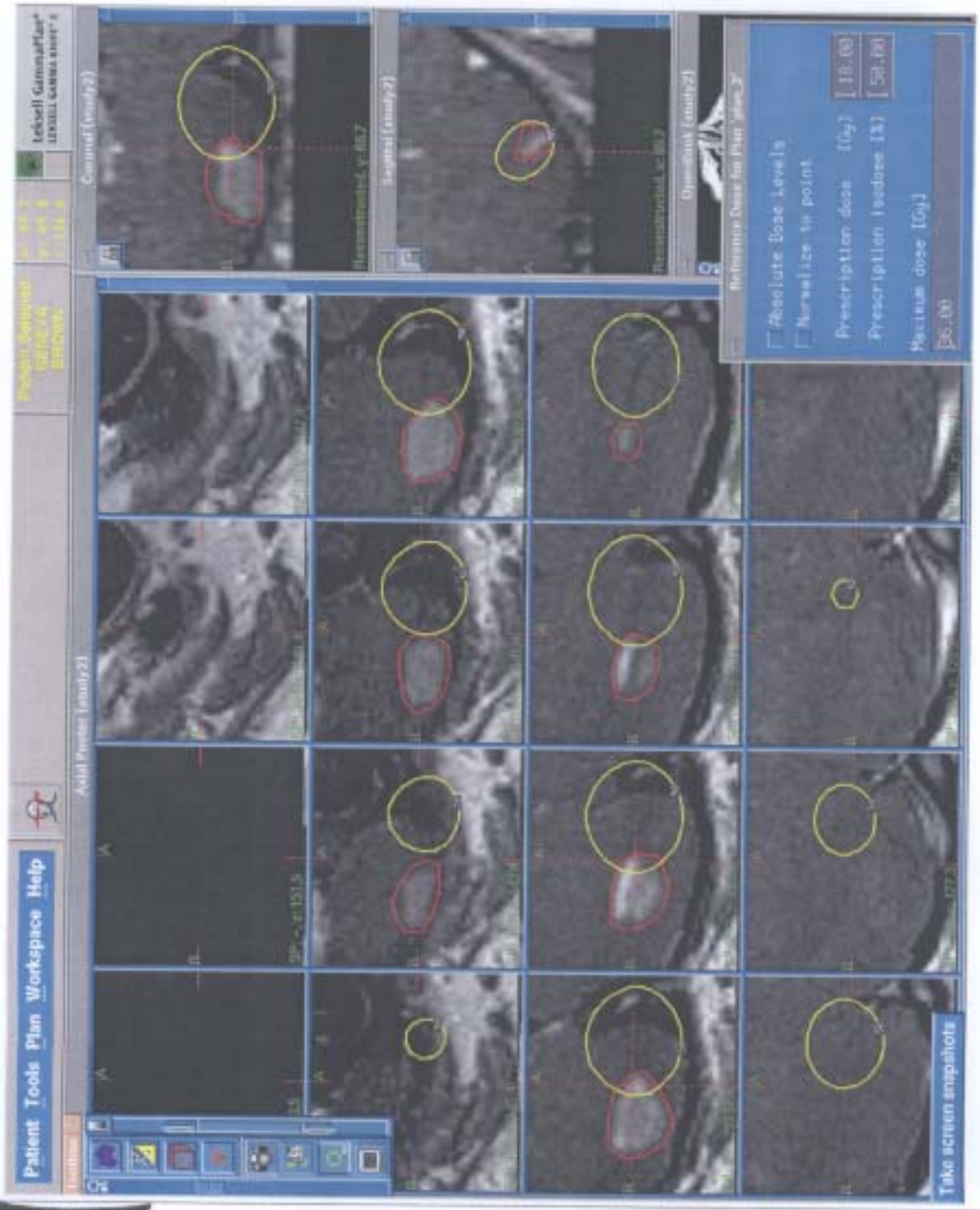
Snapshot: Wed–Oct–24–13:56:41–2007



ACTUAL GAMMA KNIFE PLAN

Karmanos Cancer Center Snapshot *for the* *Leksell Gamma Knife C* *Leksell GammaPlan Wizard 5.34*	Patient: [redacted]
	Patient ID: [redacted]
	Diagnosis: *Metastasis Multiple*
	Treatment Date: *Feb 06, 2008*
	Operator: *zb*

Snapshot: Wed–Feb–06–12:08:50–2008



[redacted]

12:09:17 Feb 6, 2008

BARBARA ANN KARMANOS CANCER CENTER

Gamma Knife Time-Out Form

(Time-Out to be performed ***immediately*** before starting the procedure)

Patient Label

Date: _____

Check Yes/No/NA. ***If "No" selected, please explain in comments section below.***

Correct patient, correct procedure, correct site and correct side: *To be completed by Medical Physicist and Radiation Oncology Nurse*	
☐ Yes	Verify patient name, date of birth and medical record number from hospital chart and wrist band.
☐ Yes	Verify name and date of birth with the patient or patient's representative (ask patient / representative to state name and DOB).
☐ Yes	Verify the **correct procedure, the correct site and the correct side** (as appropriate) with the patient or patient's representative (individual who signed the consent forms).

Pre-Treatment Checklist: *To be completed by Medical Physicist, Radiation Oncologist and Neurosurgeon*	
☐ Yes ☐ No	Stereotactic Frame Placement and Neuroimaging Form reviewed and consistent with proposed treatment plan
☐ Yes ☐ No	History and Physical Exam reviewed and consistent with proposed treatment plan (Physician)
☐ Yes ☐ No	Radiation Oncology Consultation reviewed and consistent with proposed treatment plan (Physician)
☐ Yes ☐ No	Neurosurgery Consultation notes reviewed and consistent with proposed treatment plan (Physician)
☐ Yes ☐ No	*Informed Consent for Radiation Therapy* is signed and placed in patient's Radiation Treatment Record. *Consent must include site and side of surgery as appropriate.* (Physician)
☐ Yes ☐ No	*Consent for Surgery, Invasive Procedures and/or Diagnostic Procedures, Anesthesia, and/or Blood Transfusion* is signed and placed in patient medical record. *Consent must include site and side of surgery as appropriate.* (Physician)
☐ Yes ☐ No	Prior diagnostic films reviewed and number/location of each lesion consistent with proposed treatment plan (Physician)
☐ Yes ☐ No	Current MRI/CT reviewed and number/location of each lesion consistent with proposed treatment plan (Physician)
☐ Yes ☐ No	Verification of prior radiation therapy (WBRT, EBRT, SRS)
☐ Yes ☐ No ☐ NA	Verification of dosage and location of previously treated lesion(s)
☐ Yes ☐ No	Verification of the number and location of each lesion to be treated on the Gamma Knife Planning Form and final Gamma Knife Treatment Plan (Physician)
☐ Yes ☐ No	Gamma Knife Treatment Plan signed off by Radiation Oncologist, Neurosurgeon, and Medical Physicist

Comments: _____

_____

_____

_____ _____

Signature – Radiation Oncologist Signature – Neurosurgeon

_____ _____

Signature – Medical Physicist Signature – Radiation Oncology Nurse

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
KG	[redacted]		Rt. Post Cerebellum 18Gy	Yes
KG	[redacted]		Lt. Temporal 18Gy Lt. Frontal 18 Gy Rt. Midbrain 15 Gy Rt. Amt. Cerebellum 15 Gy	Yes
EL	[redacted]		Rt. Parietal 18 Gy	Yes
EL	[redacted]		Lt Lat. Parietal 18 GY Lt. Medial Parietal 20 Gy Rt. Med. Parietal 20 Gy Rt. Occipital 20 Gy	Yes
NR	[redacted]		Rt. Post Frontal 18 Gy	Yes
NR	[redacted]		Lt. Occipital 13 Gy Lt. Periventricular 15 Gy Rt. Cerebellar 18 Gy Rt. Amt. Frontal 18 Gy Lt. Frontal 18 Gy	Yes
SD	[redacted]		Lt. Post Frontal 20 Gy Lt. Amt. Frontal 20 Gy Lt. Occipital 20 Gy Lt. Inferior Occipital 20 Gy	Yes
MK	[redacted]		Lt. Temporal 18 Gy	Yes
MK	[redacted]		Rt. Internal Capsule 20 Gy Lt. Parieta 20 Gy	Yes
AG	[redacted]		Lt. Mid Parietal 20 Gy Lt. Mid Post Parietal 20 Gy Rt. Mid Parietal 20 Gy	Yes
QY	[redacted]		Lt. Paravintricular/Parietal 16 Gy	Yes
JW	[redacted]		Rt. Cerebellar 18 Gy Lt. Parietal 18 Gy Rt. Temporal 18 Gy	Yes
KE	[redacted]		Rt. Acoustic 12 Gy	Yes
RS	[redacted]		Rt. Cerebellar 20 Gy Lt. Cerebellar 20 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
JR	[redacted]		Lt. Frontal 20 Gy	Yes
LB	[redacted]		Lt. Occiputal 20 Gy	Yes
TS	[redacted]		Lt. Acoustic Neuroma 12.5Gy	Yes
RT	[redacted]		Rt. Front Temporal 18 Gy Lt. Frontal 18 Gy Lt. Corpus Callosum 18 Gy	Yes
RT	[redacted]		Rt. Temporal 20 Gy Rt. Cerebellar 20 Gy	Yes
RT	[redacted]		Lt. Temporal 20 Gy Lt. Post Frontal 20 Gy Lt. Lat. Frontal 20 Gy Lt. Occipital 20 Gy Lt. Mid. Frontal 20 Gy Lt.	Yes
CC	[redacted]		Lt. Frontal 20 Gy Rt. Frontal 20 Gy Rt. Paraventricular 20 Gy	Yes
DE	[redacted]		Rt. Post Parietal 15 Gy Rt. Dural 18 Gy	Yes
SA	[redacted]		Rt. Medial Occys 20 Gy Lt. Medial Frontal 20 Gy Lt. Lateral Frontal 20 Gy Rt. Frontal 20 Gy	Yes
BG	[redacted]		Rt. Trigeminal 35 Gy	Yes
SC	[redacted]		Rt. Frontal 20 Gy Rt. Temporal 20 Gy Rt. Med. Parietal 20 Gy Rt. Lat. Parietal 20 Gy	Yes
SC	[redacted]		Rt. Frontal 20 Gy	Yes
LM	[redacted]		Lt. Cerebellar 20 Gy Rt. Cerebellar 20 Gy	Yes
JL	[redacted]		Lt. Cerebellar 17 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
KF	[redacted]	[redacted]	Lt. Frontal 20 Gy Lt. Capsule 20 Gy Rt. Med Frontal 20 Gy Rt. Lat. Frontal 20 Gy Rt. Post Occipital 20 Gy Lt. Cerebellar 20 Gy Rt. Parietal 20 Gy Rt. Med. Occipit 20 Gy	Yes
ER	[redacted]	[redacted]	Lt. Temporal 16 Gy Lt. Inf. Temporal 16 Gy	Yes
ER	[redacted]	[redacted]	Rt. Cerebellar 18 Gy Rt. Temporal 18 Gy Rt. Ant. Occip. 18 Gy Rt. Occipital 18 Gy Lt. Ant. Frontal 18 Gy Rt. Med. Frontal 18 Gy Rt. Lat. Frontal 18 Gy Lt. Occipital 18 Gy Rt. Parietal 18 Gy Lt. Paraventricular 18 Gy Lt. Cerebellar 18 Gy Lt. Parietal 18 Gy	Yes
BB	[redacted]	[redacted]	Rt. Med Parietal 20 Gy Lt. Med Cerebellar 12.5 Gy Lt. Lat. Cerebellar 20 Gy	Yes
SM	[redacted]	[redacted]	Lt. Temporal Lobe 20 Gy	Yes
JJ	[redacted]	[redacted]	Rt. Cerebellar 17 Gy Lt. Cerebellar 17 Gy Lt. Temporal 17 Gy	Yes
CA	[redacted]	[redacted]	Rt. Postenor Fossa 17 Gy	Yes
AG	[redacted]	[redacted]	Rt. Paraventricular 20 Gy	Yes
AG	[redacted]	[redacted]	Lt. Paraventricular 20 Gy	Yes
AM	[redacted]	[redacted]	Rt. Parietal 18 Gy Rt. Frontal 18 Gy	Yes
RC	[redacted]	[redacted]	Rt. Corpus Callosin 16 Gy	Yes
SK	[redacted]	[redacted]	Lt. Parietal 16 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
DF	[redacted]		Rt. Frontal 18 Gy Rt. Parietal 18 Gy Lt. Medial Frontal 18 Gy Lt. Lat. Frontal 18 Gy Lt. Inf. Frontal 18 Gy Lt. P-Occipital 18 Gy Rt. P-Occipital 18 Gy Rt. Occipital 18 Gy	Yes
YS	[redacted]		Rt. Acoustic 12 Gy	Yes
SC	[redacted]		Lt. Cerebellar 22 Gy	Yes
JK	[redacted]		Amt. Crainal Fossa 17 Gy	Yes
MM	[redacted]		Lt. Cerebellum 18 Gy Lt. Vermis 18 Gy	Yes
JT	[redacted]		Rt. Temporal 18 Gy	Yes
JG	[redacted]		CP Angle 12 Gy	Yes
RP	[redacted]		Lt. Acoustic 12 Gy	Yes
MS	[redacted]		Brainstem 13.5 Gy	Yes
AM	[redacted]		Lt Rontal 20 Gy Lt. Temporal 20 Gy	Yes
EC	[redacted]		Lt. Temporal 18 Gy	Yes
CN	[redacted]		Rt. Cerebellar 16 Gy	Yes
AM	[redacted]		Rt. Parietal 12.5 Gy	Yes
AM	[redacted]		Rt. Temporal 15 Gy Rt. Frontal 18 Gy	Yes
AM	[redacted]		Rt. Frontal 20 Gy	Yes
DD	[redacted]		Rt. Occipital 15 Gy	Yes
DD	[redacted]		Lt. Temporal 20 Gy	Yes
JH	[redacted]		Lt. Cerebellar 20 Gy	Yes
RM	[redacted]		Pituitary 22 Gy	Yes
KK	[redacted]		Lt. Parietal 17 Gy	Yes
BR	[redacted]		Lt. Parietal Occipital 18 Gy Rt. Parietal 18 Gy (Temporal)	Yes
CR	[redacted]		Rt. Cerellum 20 Gy	Yes
PD	[redacted]		Rt. Frontal 17 Gy Lt. Cerebellum 17 Gy	Yes
KM	[redacted]		Lt. Lat. Cerebellum 20 Gy Lt. Med. Cerebellum 20 Gy Lt. Temporal 20 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
KM	[redacted]		Rt. Temporal 20 Gy	Yes
KM	[redacted]		Rt. Sup. Frontal 20 Gy Lt. Post. Central 20 Gy Rt. Inf. Frontal 20 Gy Rt. Periorbital 20 Gy Lt. Precentral 20 Gy	Yes
RH	[redacted]		AVM Lt. Occipital 12.3 Gy	Yes
DH	[redacted]		Rt. Corpus 20 Gy	Yes
DH	[redacted]		Rt. Cerebellar – 20 Gy	Yes
BB	[redacted]		Rt. Mid Brain 17 Gy	Yes
GT	[redacted]		Lt. Parietal 20 Gy	Yes
AI	[redacted]		Rt. Trigenimal 40 Gy	Yes
SG	[redacted]		Lt. Frontal 18 Gy Rt. Paraventricular 20 Gy Lt. Paraventricular 20 Gy Lt. Occipital 20 Gy	Yes
LL	[redacted]		Rt. Jugular Foramen 15 Gy	Yes
PA	[redacted]		Rt. Parietal 18 Gy Rt. Periventricular 18 Gy	Yes
RS	[redacted]		Rt. Mid Fossa Lesion 15 Gy	Yes
SL	[redacted]		Lt. Med. Frontal Lesion 20Gy	Yes
LA	[redacted]		Rt. Occipital Lesion – 18 Gy	Yes
ET	[redacted]		Rt. Cavenous Sinus 13 - Gy	Yes
JB	[redacted]		Rt. Parietal Lesion 18 Gy Lt. Frontal Lesion 20 Gy	Yes
CA	[redacted]		Rt. Insula 20 Gy Rt. Putamen 20 Gy Rt. Pos. Sup. Frontal 20 Gy Rt. Corp. Call 20 Gy Lt. Ant Sup. Frontal 20 Gy Lt. Par. Occipital 20 Gy Lt. Incular 20 Gy Lt. Gyrectus 20 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
CA	[redacted]	[redacted]	Lt. Sup. Frontal 22 Gy Lt. Mid. Post. Frontal 22 Gy Lt. Mid Post Frontal 22 Gy Rt. Post. Par 22 Gy Rt. Ant. Sup. Frontal 22 Gy Lt. Post Par 22 Gy Lt. Frontal 22 Gy Rt. Cerebell Lesion 22 Gy Lt. Parietal 22 Gy	Yes
KS	[redacted]	[redacted]	Rt. & Lt. Cerebell 20 Gy Rt. Corona Rad 20 Gy Lt. Med. Occipital 20 Gy	Yes
KS	[redacted]	[redacted]	Rt. Temporal 20 Gy Rt. Cerebellum 20 Gy Lt. Cerebellum 20 Gy	Yes
GG	[redacted]	[redacted]	Rt. Acoustic Neu 12 Gy	Yes
NR	[redacted]	[redacted]	Frontal Horn of Lt. Lat. Ventricle 18 Gy Rt. Frontal Cerebellum 20 Gy	Yes
VS	[redacted]	[redacted]	4th Vent. Ependymora 12 Gy Rt. Acoustic 12 Gy	Yes
DW	[redacted]	[redacted]	Lt. Occipital 20 Gy Lt. Cerebellum 20 Gy	Yes
DW	[redacted]	[redacted]	Rt. Parietal 20 Gy Rt. Ant. Frontal 20 Gy Rt. Post. Frontal 20 Gy Rt. Cerebellum 20 Gy	Yes
DB	[redacted]	[redacted]	Lt. Inf. Frontal 15 Gy Rt. Parietal 20 Gy Lt. Sup. Frontal 20 Gy Rt. Sup Frontal 20 Gy Rt. Frontal 18 Gy Lt. Occipital 20 Gy	Yes
DB	[redacted]	[redacted]	Lt. Parietal 18 Gy Rt. Sup. Frontal 18 Gy Rt. Paraventricular 18 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
SH	[redacted]		Lt. Cerebellar 20 Gy	Yes
LA	[redacted]		Rt. Temporal 20 Gy	Yes
MW	[redacted]		Rt. Cerebellum 20 Gy	Yes
JS	[redacted]		Lt. Post Frontal 20 Gy	Yes
JC	[redacted]		Lt. Parietal 18 Gy	Yes
AL	[redacted]		Rt. Parietal 20 Gy Lt. Para Occipital 20 Gy	Yes
DR	[redacted]		Rt. Temp Occipital 22 Gy to 60% Rt. Parietal 22 Gy Rt. Font Parietal 22 Gy Rt. Ant. Temporal 22 Gy Lt. Temp Occipital 22 Gy	Yes
AM	[redacted]		Lt. Cerebellar 18 Gy	Yes
DH	[redacted]		Rt. Lat. Ventricle 18 Gy 4th Ventricle 18 Gy	Yes
DR	[redacted]		Rt. Retra Clival 13 Gy	Yes
RF	[redacted]		Rt. Parietal 18 Gy	Yes
CH	[redacted]		Lt. Pituitary 15 Gy	Yes
JD	[redacted]		Rt. Cavernous Sinus 12.5 Gy	Yes
DD	[redacted]		Lt. Frontal 18 Gy	Yes
EB	[redacted]		Rt. Inf. Calliculus 15 Gy Rt. Cerebellar 20 Gy	Yes
BR	[redacted]		Rt. Frontal 18 Gy Lt. Parietal 18 Gy	Yes
JM	[redacted]		Rt. Cavernous Sinus 14 Gy	Yes
ME	[redacted]		Lt. Pri. Frontal 22 Gy Lt. Frontal 22 Gy Rt. Frontal 22 Gy Lt. Posterior Frontal 22 Gy	Yes
MW	[redacted]		Rt. Mid Parietal 20 Gy Rt. Post Frontal 20 Gy	Yes
CS	[redacted]		Lt. Intraventricular 18 Gy	Yes
TS	[redacted]		Rt. Parietal 20 Gy	Yes
AL	[redacted]		Rt. Temporal 18 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
RA	[redacted]		Rt. Parietal 15 Gy	Yes
RB	[redacted]		Rt. Temporal 24 Gy Rt. Frontal 24 Gy Lt. Parietal 24 Gy Rt. Mid 24 Gy	Yes
SF	[redacted]		Rt. Cerebellum 15 Gy Rt. Occipital 15 Gy	Yes
ED	[redacted]		Rt. Acoustic 12.5 Gy	Yes
MW	[redacted]		Lt. Frontal Parietal 20 Gy Thalavous 20 Gy Mid Front Posterior 20 Gy Rt. Precentral 20 Gy Mid Front Lat 20 Gy	Yes
MK	[redacted]		Rt. Anterior 15 Gy - 40%	Yes
JK	[redacted]		Rt. Frontal 24 Gy Lt. Frontal 24 Gy	Yes
MC	[redacted]		Rt. Occipital 32 Gy – 100%	Yes
SF	[redacted]		Corpus Callosum 15 Gy Lt. Paraventricular 15 Gy Lt. Frontal 15 Gy	Yes
SF	[redacted]		Rt. Cerebellar 15 Gy Rt. Occipital 15 Gy	Yes
DF	[redacted]		Lt. Cerebellar 16 Gy	Yes
RB	[redacted]		Lt. Sphenoid 14 Gy	Yes
JW	[redacted]		Lt. Brain Stem 15 Gy	Yes
JT	[redacted]		Rt. Cerebellar 15 Gy	Yes
MF	[redacted]		Rt. Trigeminal 40 Gy	Yes
JM	[redacted]		Lt. Cerebellum 20 Gy	Yes
BS	[redacted]		Lt. Cerebellar Inf 20 Gy Lt. Cerebellar Sup 20 Gy	Yes
DG	[redacted]		Lt. Occipital 20 Gy Rt. Paravintricular 20 Gy Lt. Frontal 20 Gy Lt. Post Central 20 Gy	Yes
MS	[redacted]		Rt. Cerebellar 18 Gy Lt. Parietal 18 Gy Lt. Posterior 18 Gy	Yes

Gamma Knife Case Review
October 24, 2006 - October 24, 2007

Patient Name	ROC ID	Date Treated	Prescribed Lesions and Doses	Correct Doses Delivered to Correct Locations?
EC	[redacted]		Lt. Temporal 18 Gy	Yes
JG	[redacted]		CP Angle 12 Gy	Yes
BE	[redacted]		Lt. Frontal 15 Gy Corpus Callosum 18 Gy	Yes
BJ	[redacted]		Lt. Frontal AVM 20 Gy	Yes
BW	[redacted]		Lt. Parietal AVM 18 Gy	Yes
ES	[redacted]		Rt. Prec Gyrus 22 Gy Rt. Insular 22 Gy	Yes
JR	[redacted]		Lt. Occipital AVM 18 Gy	Yes
DL	[redacted]		Rt. Cavenous Sinus 13 Gy	Yes
MB	[redacted]		Lt. Cerebellar 14 Gy	Yes
CM	[redacted]		Rt. Temporal AVM 18 Gy	Yes