MEMORANDUM

To: Gamma Knife Physicians

Date: July 6, 2009

From: Maurice W. Nicholson M.D., Gamma Knife Center of the Pacific

Regarding: SRS Procedures

Dear Gamma Knife Physicians,

An incident occurred last week when a wrong sized collimator was used while treating a patient. Fortunately, this error was recognized before any critical area was irradiated. This is the first time that this error has occurred in over ten years of operation and we want to be certain that it never happens again.

It is imperative that in addition to verifying the X, Y, and Z co-ordinates that the size of the collimator also be verified and double checked.

We will be making some adjustments to current protocol to insure that this type of error does not ever happen again.

If you have any input or comments that you would like to make please call feel free to call us at the office.

Regards,

Maurice W. Nicholson M.D.
Medical Director
Gamma Knife Center of the Pacific

Quality Management Program

Purpose:

The Quality Management Program is intended to provide high confidence that: (1) the patient's identity is verified before each administration; and (2) each administration is in accordance with the written directive.

Written Directive, Definition:

A written directive contains the patient's name, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site. It must be signed and dated by the authorized user prior to treatment.

Policy:

1. The treatment plan will be prepared and signed by the Authorized User physician (radiation oncologist), the Authorized Medical Physicist, and the Neurosurgeon prior to administration of any Gamma Knife treatment. This treatment plan serves as the required Written Directive.

2. Prior to the administration of any radiation dose covered by this policy, the person administering the dose will confirm that the treatment plan has been signed by the Radiation Oncologist, Medical Physicist, and Neurosurgeon.

3. Prior to the administration of radiation dose covered by this policy, the person responsible for the administration will confirm the identity of the patient by two methods. Acceptable methods include verification of patient's name, birthdate, social security number, medical record number, hospital ID bracelet, photograph, or patient's address. In the event the patient is non-responsive, consent and identification will be confirmed by the presence of the patient's legal guardian prior to administration of any radiation dose covered by this policy. Patient identity confirmation will be recorded in the Treatment Record.

4. Prior to administering the gamma knife treatment, the computer generated treatment plan will be examined to verify that correct input data for the patient was used in the calculations (e.g., source strength and frame measurements).

5. Any questions, conflicts or discrepancies must be resolved with the authorized user prior to administration of the dose.

6. Before each shot is delivered, all treatment settings will be verified independently by two individuals who did not make the adjustment. This double-check process applies to all settings, including collimator helmet size, plug position(s), x/y/z coordinates, angle, and treatment time. The individuals setting or confirming the settings must be include the radiation oncologist and the medical physicist.

7. After all settings are confirmed, the medical physicist and radiation oncologist will initial the appropriate line of the treatment record indicating that the settings match the treatment plan. The radiation oncologist will also initial next to the collimator size on the treatment plan to indicate that the correct collimator size is being used.

8. After each shot is successfully completed, the radiation oncologist will initial the appropriate line on the treatment record.

9. After all targets have been treated, the Radiation Oncologist and Medical Physicist will verify that the treatment was administered according to the approved treatment plan and sign the bottom of the Treatment Record.

Medical Events

1. A medical event is an event which results in:

   a. An administered dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin, AND

      i. The total dose delivered differs from the prescribed dose by 20 percent or more; OR
      ii. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

   b. A dose that exceeds 5 rem effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin from an administration of a dose to the wrong individual.

2. The NRC Operations Center must be notified by telephone no later than the next calendar day after discovery of the medical event.

3. A written report must be submitted to the appropriate NRC Regional Office within 15 days after discovery of the medical event. The written report must contain:

   a. The licensees name;
   b. The name of the prescribing physician;
   c. A brief description of the event;
   d. Why the event occurred;
   e. The effect, if any, on the individuals who received the administration;
   f. What actions, if any, have been taken or are planned to prevent recurrence; and
   g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

The report may not contain the individual's name or any other information that could lead to identification of the individual.

4. The referring physician and the patient shall be notified no later than 24 hours after the medical event is discovered, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful.

Annual Review

1. Scope:

A program review of administrations covered by the requirements of this Quality Management policy will be reviewed annually. The review will include all information required on the written directive / prescription and the verification and confirmation processes described above. The review will:

a. Include an evaluation of a representative sample of patient treatments. The review will be done on 20 patients or 20%, which ever is greater.

b. Evaluate the effectiveness of the Quality Management Program, and make changes to meet the objectives of this program.

c. Be conducted annually, not to exceed 12 months.

2. Reporting and Problem Resolution:

In the event that an unintended use or other incidents covered by this Quality Management policy is detected, a complete report of the incident will be made by the person administering the dose. The report will be presented to the authorized user or the medical physicist.

3. Maintenance of Records

a. Copies of the written directive/prescription and Treatment Record will be maintained in the patient's medical record.

b. The completed written directive and Treatment Record will be maintained in the patient's record for a minimum of three years.

c. All records required by this Quality Management Program policy will be available for audit by the Nuclear Regulatory Commission and other accrediting agencies as appropriate.

Gamma Knife Center of the Pacific

Patient Name:
Patient #:

Gamma Knife Treatment Record

Site:	Date:
Total Dose Prescribed:	Isodose Line Prescribed To:

Patient Identity Confirmation (2 methods)

Name	Patient ID #	D.O.B.	SSN	Other

Setting Confirmation

Shot #	Initial confirming all settings match treatment plan		Shot completed successfully (Rad Onc. initial)
	Radiation Oncologist	Medical Physicist	

Treatment Verification

Date	Total Dose	Physicist Signature	Rad. Oncologist Signature