GAMMA KNIFE GUIDELINES

CREDENTIALING

For the purpose of these guidelines, treatment team members are defined as:

1. Radiation Oncologist - physician licensed to practice medicine in the state of Louisiana

2. Neurosurgeon - physician licensed to practice medicine in the state of Louisiana

3. Medical Physicist – Per the LSUHSC job description, the physicist must have an MS or Ph.D. in medical physics, physics, radiation biology, or a related discipline, and training in clinical medical physics. Clinical training may be obtained through a residency traineeship or a postdoctoral program of one or two years in a hospital. The Qualified Medical Physicist must be board certified or board eligible with the American Board of Radiology or American Board of Medical Physics. Two years of documented gamma knife treatment planning experience is desired. During the hiring process, if an applicant with less experience is selected, an experienced physicist (minimum of two years) will be contracted to evaluate clinical competency and provide a document indicating successful completion of the competency evaluation.

Neurosurgeons and Radiation Oncologists must be credentialed by the LSUHSC credentialing process in order to perform Gamma Knife procedures. Neurosurgeons, radiation oncologist, and Medical Physicist must be listed on the Facility Radioactive License in order to participate as a member of the gamma knife treatment team. A request to be added to the Facility Radioactive License will be presented to the Radiation Safety Committee only after credentials have been granted by the Credentials Committee (physicians). Upon approval, a written request to the Louisiana Department of Environmental Quality will be prepared and submitted by the LSUHSC Radiation Safety Officer. Individuals will be allowed to participate in clinical procedures once revised license is received.

DETAILS

1. All patients will be referred for Gamma Knife procedures to the Gamma Team, which consist of a neurosurgeon, a radiation oncologist, and a qualified medical physicist. All cases will be

reviewed in conference by the team; conferences will be scheduled weekly when cases are to be evaluated. All pertinent medical records and diagnostic images will be obtained by the nurse and presented at the conference. If medical records are not available, the case will be rescheduled for the weekly conference.

2. Once a decision has been made to provide Gamma Knife treatments, the nurse will contact and schedule the patient, provide patient education, send information of schedule to supporting staffing members and clinical services, obtain admit orders, and assure availability and sterilization of head frame.

3. The application of head frame for stereotactic localization for treatment of humans with the Gamma Knife Unit will be performed by the neurosurgeon. A nurse will be present to assist with placement and will be responsible for assuring that all items are available and have been properly sterilized.

4. The neurosurgeon will be available during diagnostic procedures (MRI, CT, or Interventional Radiography) to determine and localize treatment area for imaging. The neurosurgeon and radiation oncologist will together determine localization of tumor, vascular, non-tumor, and non-vascular lesion for planning and dose specifications.

5. The neurosurgeon and radiation oncologist are responsible for treatment plan evaluation for treatment of humans with the Gamma Knife Unit. Radiosurgery treatments shall be given according to the signed written prescription jointly agreed upon by the neurosurgeon and radiation oncologist. The written prescription must be signed by the physicians authorized on the Radioactive Materials License (LA – 0005-L01)

6. A qualified medical physicist is responsible for treatment planning and calibration of the unit. Non-human uses, involving calibration, testing and quality control, shall be performed by the licensed medical physicist. A standing order for a special physics consultation is required for each clinical procedure.

7. Radiosurgery shall be administered following the signed witnessed consent of the patient or legally responsible party.

8. Each treatment plan must be approved before the patient's treatment. The treatment plan dose distribution will be approved by

the qualified medical physicist, radiation oncologist and neurosurgeon.

9. Pregnant patients may require special attention by the radiation oncologist and the qualified medical physicist.

10. The radiation oncologist, medical physicist and appropriately trained nursing personnel must be present during patient treatment. The neurosurgeon must be present for treatment planning and available (in the facility) during patient treatment.

11. In the event of an emergency, a declared pregnant worker will not be allowed to participate in an emergency procedure in accordance with Hospital Policy 3.3. Another qualified individual will have to be present.

12. The Neurosurgeon, Radiation Oncologist and Physicist will review any situation that may be a medical event or misadministration of dose. Any unusual or medical event will be reported to Radiation Safety Officer. The Radiation Safety Officer will review the medical event and determine if the event is a reportable medical event in accordance with State Regulations LAC33:XV.712. If event is determined to be a reportable medical event, the Radiation Safety Officer will notify Hospital Administration and report medical event to the State of Louisiana Department of Environmental Quality. All medical events will be reported by the Radiation Safety Officer in accordance with state regulations. The following situations shall be reported to the Radiation Safety Officer immediately.

    a. An administration of dose to the wrong individual or human research subject

    b. An administration of dose to wrong treatment area

    c. When the dose differs from the prescribed dose;

    d. Leaking sealed source

13. Only licensed authorized personnel (Neurosurgeon or Radiation Oncologist) are allowed to operate the Gamma Knife Unit during treatment of a human subject. Authorized personnel are listed on the LSUHSC Radioactive Materials License LA-005-L01 that is kept in the Gamma Knife Suite. Individuals who are not on the license will not be allowed to participate in the operation of the unit for human use. A State Licensed Radiation Therapist will be allowed

to operate the Gamma Knife Unit under the direction of the Neurosurgeon or Radiation Oncologist, during treatment of a human subject and will be allowed to assist in changing helmets and adjusting X&Y coordinates. Nurses trained in Gamma Knife procedures will be allowed to assist in changing helmets and adjusting X & Y head frame coordinates during treatment of a human subject, under direct supervision of a Neurosurgeon or Radiation Oncologist.

14. A nurse will continuously monitor the patient during the entire treatment, including vital signs and administration of any medications. Nurses will monitor patients receiving conscious sedation according to Hospital Policy 5.26.

15. Safety training and review of safety procedures will be performed and documented annually by the Physicist. All staff participating in Gamma Knife procedures will attend annual training. If training is not in accordance with above, clinical privileges will be temporarily suspended until training is completed.

16. The outer convex surface of the collimator helmets and the exterior interface line between the hemispherical shield and the base shall be wiped for leak testing every six months. Leak Test procedures will be performed by a Qualified Medical Physicist and records are kept in the Gamma Knife Suite.

17. The ionization chamber and electrometer used for dose rate determination of the Gamma Knife unit shall be calibrated every two years or after any repair. Survey meters shall be calibrated annually. Barometers, thermometers and timers will be intercompared with appropriate equipment annually. Calibration equipment will be managed by a Qualified Medical Physicist and records are kept in the Gamma Knife Suite.

PERSONNEL MONITORING

1. All personnel participating in Gamma Knife procedures or working with the Gamma Knife unit shall be considered radiation workers and shall wear radiation monitors. Each person shall wear their assigned monitor while working and follow the procedures for use issued by the RSO. Hospital Policy 3.6. Radiation monitors shall be worn on the anterior torso between the neck and waist.

2. The Safety office is responsible for exchanging personnel monitoring devices issued by the hospital on a prearranged schedule. The current exchange interval is monthly. All badges will remain in employees assigned work area at a designated location. New badges will be delivered prior to the beginning of each month and used badges for the previous month will be collected and turned in to the Radiology Quality Management Manager by the 3rd day of each month. All workers will adhere to Hospital Policy 3.6; failure to comply will result in disciplinary actions.

3. Exposure records are kept by the Qualified Medical Physicist and Safety Office and are available for review by individuals that are monitored. Requests for review must be made directly to the Qualified Medical Physicist or Safety Office.

4. No adult employee (who is not pregnant) shall be allowed to receive radiation exposure in excess of 5000 millirems per year. ALARA (As Low As Reasonable Achievable) levels for therapeutic operation have been established by the RSO and will be used as guidelines for personnel exposure investigations.

5. The exposure to the fetus of a declared pregnant worker shall not exceed **500 millirems during the gestation period (nine-month term of pregnancy). In addition, an effort shall be made to avoid substantial variations above a uniform monthly exposure of 50 millirem . Hospital Policy 3.3**

6. If an excessive exposure is suspected, immediately notify the RSO, Safety Office, Radiation Physicist or Radiation Oncologist.

OPERATION OF THE GAMMA KNIFE UNIT

1. The treatment room has been established as a restricted area when the unit is in operation. The restricted area is identified by “CAUTION RADIATION AREA” signs at the entrances to the radiation area. Visitors may be allowed in the suite only when accompanied by authorized personnel.

2. Only persons whose presence is essential for completion of the treatment shall be allowed in the restricted area during operations.

3. The daily quality control checks shall be performed and documented prior to head frame placement. This quality control

check is to verify proper working condition of the Gamma Knife and can be performed by a physicist, nurse, radiation therapist, or licensed staff. If daily quality control check is not performed by a Qualified Medical Physicist, he/she must review and sign within 15 days of initiation of procedure.

4. Personnel shall remain at the control area during treatments.

5. Any apparent abnormal occurrence with a particular treatment shall be brought to the attention of the physicians and the medical physicists.

6. No individual other than the patient shall be in the treatment room during treatment.

7. If a patient must be held in position during treatment, mechanical supporting or immobilization devices shall be used.

8. When patients require restraints, use of restraints will be in accordance with Hospital Polices 5.15, 5.15.1, and 5.15.2.

9. Operation of the Gamma Knife treatment console will only be performed by a physician listed on the Facility Radioactive License or a Radiation Therapist under his/her direct supervision, in accordance with, Louisiana State Radiology Technologist Board of Examiners regulations.

10. At the control panel of the treatment unit, the patient will be kept under observation during treatment. A TV monitor is provided for patient observation. Multiple cameras are available. No treatments will be administered if the TV and camera system is not functioning.

MACHINE SAFETY PROCEDURES

1. Operation and service manuals for the Gamma Knife unit contain general descriptions of the equipment, the operating instructions, and guidelines to establish normal and proper operation of the therapy unit. These manuals are available at the unit or in a place designated by the medical physicist and should be consulted for information regarding normal operation.

2. Any suspected unusual machine operation should be brought to the attention of the medical physicist. Problems or suspected problems shall be reported to Elekta immediately. Treatments will be given only if the machine is operating properly.

3. The Gamma Knife unit was installed following the manufacturer's specifications; and the operational instructions (accompanying the equipment), shall be adhered to by all licensed personnel.

4. Only persons authorized by ELEKTA will perform service on the Gamma Knife unit.

5. Biomedical staff will be responsible for quarterly routine cleaning of helmet plugs and the replacement of switches located on the helmets, as needed.

6. The unit shall be secured against unauthorized use after patient treatment and all work by physics or engineering.

7. Documentation of policy and procedures and calibrations are located at the machine control area. These procedures will be performed by a Qualified Medical Physicist. [This includes; dates of the latest calibrations checks, results of the most recent spot checks conducted on the system, preventative maintenance inspections, and periodic physics quality assurance procedures].

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