

111-2-2-.42 Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units.

(1) Applicability.

(a) A certificate of need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A certificate of need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in 111-2-2-.42(3) in addition to the general review considerations of 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT certificate of need.

(d) A certificate of need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in 111-2-2-.42(4) in addition to the general review considerations of 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT certificate of need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of 111-2-2-.09(1).

(2) Definitions.

(a) “Brachytherapy” means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) “Complex treatment visit” means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) “Course of treatment” means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) “Gamma knife” means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia for use in planning for MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties:

Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties:

Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties:

Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties:

Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties:

Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) "Heavy particle Accelerator" means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron ($m \cdot c^2 = 0.511 \text{ MeV}$).

(g) "Horizon Year" means the last year of a five-year projection period for need determinations for MRT services.

(h) "Intensity modulated radiation therapy" or "IMRT" means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning

technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) “Intermediate treatment visit” means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) “Megavoltage radiation therapy” or “MRT” means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

(k) “MRT service” means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) “MRT unit” or “unit” means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(m) “Non-special MRT unit” or “non-special unit” means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) “Operating room based intraoperative MRT unit” or “OR-based IORT unit” means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(o) “Simple treatment visit” means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(p) “Simulation” is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient’s approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient’s clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.

(q) “Special purpose MRT unit” or “special purpose unit” or “special unit” means any of the following types of MRT units: (i) heavy particle accelerator, (ii) gamma knife, (iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife, or (iv) an OR-based IORT unit.

(r) “Stereotactic body radiation therapy (SBRT)” is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.

(s) “Stereotactic treatment visit” or “SRS treatment visit” means a visit involving SRS or SBRT treatment techniques.

(t) “Stereotactic Radiosurgery (SRS)” is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.

(u) “SRS LINAC” is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components: (i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a device which can point the linear accelerator from a wide variety of angles, and (iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator, SRS LINAC includes units such as CyberKnives.

(v) “Treatment site” means the anatomical location of the MRT treatment.

(w) “Treatment visit” means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(x) “Unit” means a single machine used for MRT services.

(y) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) Standards for Non-Special MRT.

(a) The need for the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this rule.

1. The numerical need for the addition of a non-special MRT unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by 50% to determine the number of projected cancer cases in each county that could be treated with a non-special MRT unit;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit within the Health Planning Area in the horizon year;

(iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

(v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area. Prior to the 2008 survey year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

(vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi) A. through step (vi) E.;

(vii) Calculate the number of needed non-special MRT units by dividing the number of projected equivalent visits obtained in step (iv) F. by 9,000, which represents the weighted equivalent capacity of a non-special MRT unit within a given year; and

(viii) Determine the net numerical unmet need for non-special MRT units by subtracting the total number of non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)(2) of this rule, from the number of needed non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit in a planning area, the aggregate utilization rate for all existing non-special MRT units, not including units approved pursuant to the exception in section (3)(b)(2) of this rule, in that planning area shall equal or exceed 80% of capacity based on 9,000 weighted equivalent visits. For those existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to non-special MRT services in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing or approved non-special MRT service; and

(iii) projected to serve a minimum of 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service, if the actual utilization of each radiation therapy unit within that service has exceeded 90% of optimal utilization over the most recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least 33% of capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor for each non-special MRT unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to non-special MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded non-special MRT service shall document the impact on existing and approved services which already provide non-special MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service, whose current utilization is at or above 80%, to a projected utilization of less than 70% within the first twenty-four months of the initial operation of the service or additional non-special MRT unit; or

2. decrease annual utilization of an existing service, whose current utilization is below 80%, by 10% or more within the first twenty-four months of the initial operation of the service or additional non-special MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit pursuant to the exceptions to need standards referenced in (3)(b)(2). shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded non-special MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the non-special MRT service;

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded non-special MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to stimulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the non-special MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system

must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;

3. Non-Special MRT capability including electron beam capability;
4. Capability to fabricate treatment aids;
5. Access to brachytherapy;

(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

- (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

- (ii) meets at least on a quarterly basis; and

- (iii) is responsible for the following:

- A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

- B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

- C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Human Resources, Division of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)(1); and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(i) An applicant for a new or expanded non-special MRT service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time frame and format requested by the Division.

(4) Standards for Special Purpose MRT.

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

Special MRT	Capacity	Minimum	Minimum
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Equipment		Aggregate Utilization	Projected Volume
Gamma Knife	500	80%	300 by 3 rd Year of Operation
Heavy Particle Accelerator	4,000 per Gantry	80%	2,400 per Gantry by 3 rd Year of Operation
Dedicated SRS LINAC (including CyberKnife)	850	80%	510 by 3 rd Year of Operation
OR-based IORT	250	80%	150 by 3 rd Year of Operation

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above 70%, to a projected utilization of less than 60% within the first twenty-four months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below 70%, by 10% or more within the first twenty-four months of the initial operation of the service or additional special purpose MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future

population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;
2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the special purpose MRT service;
3. providing a written commitment to participate in the Medicaid and PeachCare for Kids™ programs;
4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and
5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded special purpose MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the special purpose MRT service;
2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient;
3. Capability to fabricate treatment aids as applicable;

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Human Resources, Division of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available;

1. For applicants seeking the addition of a Gamma Knife:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

(iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time frame and format requested by the Division.

Authority O.C.G.A. Secs. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled "Specific Review Considerations for Radiation Therapy Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005. **Repealed:** New Rule entitled "Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units" adopted. F. May 13, 2008; eff. June 2, 2008.