MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an MRT service under Part 222 of the Code. MRT services and units are a covered clinical service pursuant to Part 222 of the Code. The Department shall use these in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan compiled Laws.

(c) ~~"Cyber knife" means a treatment device that is a frameless special stereotactic radiosurgery unit that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment and use this information to target the radiation beam emitted by the linear accelerator.~~

~~(d)~~ "DEDICATED STEREOTACTIC RADIOSURGERY UNIT" MEANS AN MRT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED WITH RADIOSURGERY.

(d) "Department" means the Michigan Department of Community Health (MDCH).

(e) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit.

(f) "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site; the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.

(g) "Existing MRT service" means a CON approved and operational facility and equipment used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all existing MRT units at a geographic location(s).

(~~g~~h)"Existing MRT unit" means a CON approved and operational equipment used to provide MRT services.

~~(h) "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.~~

(i) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.

(j) "High MRT unit" or "HMRT unit" means a heavy particle accelerator or any other MRT unit operating at an energy level equal to or greater than 30.0 million electron volts (megavolts or MEV).

(k) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(l) "Intraoperative MRT unit" or "IORT unit" means an MRT unit that is designed to emit only electrons, located in an operating room in the surgical department of a licensed hospital and available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(m) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(n) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, ~~or~~ cerebrovascular system abnormalities, OR CERTAIN BENIGN CONDITIONS are treated with radiation which is delivered by a MRT unit.

(o) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(p) "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.

(q) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(r) "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 or an HMRT unit.

(s) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube, MAGNETIC RESONANCE IMAGING DEVICE, OR COMPUTED TOMOGRAPHY SCANNER, WHICH IS USED IN REPRODUCING THE TWO-DIMENSIONAL OR THREE-DIMENSIONAL INTERNAL OR EXTERNAL GEOMETRY OF THE PATIENT, FOR USE IN TREATMENT PLANNING AND DELIVERY ~~and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties~~.

(t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) ~~gamma knife, (ii)~~ dedicated stereotactic radiosurgery unit, (ii~~i~~) dedicated total body irradiator (TBI), OR (~~iv~~iii) an OR-based IORT unit~~, or (v) cyber knife~~.

(u) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

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

(w) "Treatment visit" means one patient encounter during which MRT is administered AND BILLED. 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.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements to initiate an MRT service

Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently provided. The term does not include replacement of an existing MRT service. An applicant proposing to initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an MRT service shall demonstrate the following:
(a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.
(b) The proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):

(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.
(b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department, from the nearest MRT service.
(c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.
(d) The proposed MRT unit is not a special purpose MRT unit.

(3) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The applicant is a hospital licensed under part 215 of the Code.
(b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and located in planning area 8.
(c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department, from the nearest MRT service.
(d) The applicant provides comprehensive imaging services including at least the following:
(i) Fixed magnetic resonance imaging (MRI) services,
(ii) Fixed computed tomography (CT) services, and
(iii) Mobile positron emission tomography (PET) services.
(e) The proposed MRT unit is not a special purpose MRT unit.

(4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the following:
(a) The applicant is a single legal entity authorized to do business in the State of Michigan.
(b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT services with more than 30,000 equivalent treatment visits based on the most current data available to the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).
(c) The applicant shall include hospital MRT services from more than one planning area from one or both of the following:
(i) Hospital MRT services qualified under subsection (b).
(ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.
(d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual Survey.
(e) An application shall not be approved if it includes an MRT service described in subsection (i) or (ii) except as provided in subsections (iii) or (iv).
(i) An MRT service that was part of another application under this subsection.
(ii) An MRT service owned by, under common control of, or has a common parent, as an MRT service under subsection (i).
(iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.
(iv) The application includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.
(f) An application shall not be approved if it includes any of the following:
(i) An MRT service that is approved but not operational, or that has a pending application, for a heavy particle accelerator.
(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this subsection includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.
(g) An application shall not be approved if it includes any of the following:
(i) An MRT service that is approved for a heavy particle accelerator that is operational.
(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this section includes a commitment from the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.

(h) The applicant shall provide documentation of its process, policies and procedures, acceptable to the Department that allows any other interested entities to participate in the collaborative utilization of the HMRT unit.

(i) The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the MRT service utilizing an HMRT that includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

(j) The applicant shall indicate that its proposed HMRT unit will be available to both adult and pediatric patients.

(k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.

(5) Applicants under this section shall demonstrate the following staff will be provided:

(a) One (1) FTE board-certified or board-qualified physician trained in radiation oncology.

(b) One (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic physics.

(c) One (1) dosimetrist, a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(d) Two (2) FTE radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT).

(e) One (1) program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (5)(a).

Section 4. Requirements to replace an existing MRT unit or service

Sec. 4. Replacement of an existing MRT unit means an equipment change that results in a new serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification of equipment or software; the replacement components; or change for the purpose of maintaining or improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:

(a) The replacement unit(s) is ~~the same type as the MRT unit(s) to be replaced~~ A NON-SPECIAL UNIT AND IS REPLACING A NON-SPECIAL UNIT, OR IS A SPECIAL PURPOSE UNIT AND IS REPLACING A NON-SPECIAL PURPOSE UNIT OR A SPECIAL PURPOSE UNIT.

(b) The MRT unit(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:

(i) The existing MRT unit(s) poses a threat to the safety of the patients.

(ii) The replacement MRT unit(s) offers technological improvements that enhance quality of care, increased efficiency, and a reduction in operating costs and patient charges.

(c) The applicant agrees that the unit(s) to be replaced will be removed from service on or before beginning operation of the replacement unit(s).

(d) THE SITE AT WHICH A SPECIAL PURPOSE UNIT IS REPLACED SHALL CONTINUE TO OPERATE A NON-SPECIAL PURPOSE UNIT.

(2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the following:

(a) The proposed site is within the same planning area as the existing MRT service site.

(b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:

(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section 3(2) or 3(3).

(ii) HMRT unit(s) AT 8,000 equivalent treatment visits per unit.

(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.

(3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall demonstrate the following:

(a) The applicant is the same legal entity as the existing MRT service.

(b) For volume purposes, the new site shall remain associated with the existing MRT service for a minimum of three years.

(c) The MRT unit(s) to be relocated is a non-special MRT unit(s).

(d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit.

(e) The proposed site meets the requirements of Section 3(~~4~~5).

(f) The proposed site is within the same planning area as the existing MRT service site.

(g) The existing MRT service has been in operation for at least 36 months as of the date the application was submitted to the Department.

Section 5. Requirements to expand an existing MRT service

Sec. 5. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to add a non-special MRT unit(s) shall demonstrate an average of 10,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.

(2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate the following, as applicable to the proposed project:

(a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units AND AN AVERAGE OF 1,000 EQUIVALENT TREATMENT VISITS WAS PERFORMED IN THE MOST RECENT 12-MONTH PERIOD ON EACH OF THE APPLICANT'S EXISTING AND APPROVED SPECIAL PURPOSE MRT UNITS.

(b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow transplantation program or have a written agreement to provide total body irradiation services to a hospital that operates a bone marrow transplantation program.

(c) ~~An applicant proposing to add a dedicated stereotactic radiosurgery unit such as a gamma knife or cyber knife, shall demonstrate that the applicant has a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.~~

~~(d)~~ An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

Section 6. Requirements to acquire an existing MRT service

Sec. 6. Acquiring an existing MRT service means obtaining possession and control by contract, ownership, lease, or another comparable arrangement and renewal of lease for an existing MRT unit(s). An applicant proposing to acquire an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) ~~For the first~~AN application ~~proposing to~~ FOR THE FIRST ~~acquire~~ acquisition OF an existing MRT service, other than the renewal of a lease, on or after November 21, 2011~~, the existing MRT service~~ shall not be required to be in compliance with the applicable volume requirements set forth in ~~this section~~Section 11. THE MRT SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

(2) ~~an applicant proposing to acquire an existing MRT service shall demonstrate the following:~~

~~(a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:~~

~~(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section 3(2) or 3(3).~~

~~(ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.~~

~~(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.~~ FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (1), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE MRT SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE VOLUME REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS APPLICABLE TO AN EXISTING MRT SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 7. Requirements for a dedicated research MRT unit(s)

Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the following:

(1) The applicant is an existing MRT service.

(2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more of treatments) for research purposes.

(3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant's Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

(4) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(5) The proposed site can have no more than two dedicated research MRT units.

Section 8. Requirements for Medicaid participation

Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services, if a CON is approved.

Section 9. Methodology for projecting equivalent treatment visits

Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits.

(1) An applicant shall demonstrate that the projection is based on the commitments of the treatments provided by the treating physician(s) for the most recent 12-month period immediately preceding the date of the application. The commitments of the treating physician(s) will be verified with the data maintained by the Department through its "CON Annual Survey."

(a) For the purposes of this section, treating physician means the staff physician of the MRT service directing and providing the MRT treatment, not the referring physician.

(2) An applicant shall demonstrate that the projected number of commitments to be performed at the proposed site under subsection (1) are from an existing MRT service that is in compliance with the

volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed MRT service by an applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) A written commitment from each treating physician that he or she will treat at least the volume of MRT treatments to be transferred to the proposed MRT service for no less than 3 years subsequent to the initiation of the MRT service proposed by an applicant.

(b) The number of treatments committed must have resulted in an actual treatment of the patient at the existing MRT service from which the treatment will be transferred. The committing physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its "CON Annual Survey."

(~~C~~c) The projected commitments are from an existing MRT service within the same planning area as the proposed MRT service.

Section 10. Equivalent treatment visits

Sec. 10. Equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable sections, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding equivalent treatment visits weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) The number of equivalent treatment visits for each category determined pursuant to subsection (2) shall be summed to determine the total equivalent treatment visits for the time period specified in the applicable sections of these standards.

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.00	
Total Body Irradiation	8.00	8.00
HMRT Therapy		5.00
Stereotactic radio-surgery/radio-therapy*~~*~~	8.00	8.00
IORT~~ (non-gamma knife and cyber knife**)~~		20.00
~~Gamma Knife**~~		~~8.00~~
~~IORT~~		~~20.00~~

All patients under 5 years of age receive a 2.00 additive factor.

GATING RECEIVES A 1.00 ADDITIVE FACTOR. GATING IS THE CAPTURING AND MONITORING OF THE TARGET'S OR FIDUCIAL'S MOTION DURING RADIATION TREATMENT AND THE MODULATION OF THE RADIATION BEAM IN ORDER TO MORE PRECISELY DELIVER RADIATION TO THE TARGET AND/OR DECREASE THE RADIATION DOSE TO THE SURROUNDING NORMAL TISSUE.

~~* After the first visit, each additional visit receives 2.5 additional equivalent treatment visits with a maximum of five visits per course of therapy.~~

~~**~~

~~**~~After the first isocenter, each additional isocenter receives ~~4~~ 6 ~~additional~~ equivalent treatment visits. THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF THERAPY.

(4) “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.

(5) "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.

(6) "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.

(7) "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(8) “Stereotactic treatment visit” means a visit involving the use of a stereotactic guiding device with radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.

(9) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(10) “Isocenter” means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(11) "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.

Section 11. Project delivery requirements terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and approved MRT units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or radiation therapists qualified by training and experience to operate the unit safely and effectively. The Department shall consider it prima facie evidence if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may also submit, and the Department may accept, other evidence. ~~An applicant approved to operate a dedicated stereotactic radiosurgery unit or a gamma knife has on the active medical staff a neurosurgeon(s) trained in the special type of MRT unit being operated.~~

(b) An applicant shall have the following staff:

(i) One (1) full-time equivalent (FTE) board-certified or board- qualified physician trained in radiation oncology for each 250 patients treated with MRT annually.

(ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation.

(iii) One (1) dosimetrist for every 300 patients treated with MRT annually.

(iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).

(v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (i). The Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one radiation oncologist will be immediately available during the operation of the unit(s).

(d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur. Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to the MRT unit at all times when patients are treated.

(e) An applicant shall operate a cancer treatment program. The Department shall consider it prima facie evidence if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability, and, either on-site or through written agreements with other providers, all of the following services: access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, a computer-based treatment planning system, medical radiation physicist involvement, MRT capability including electron beam capability, treatment aid fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care evaluation studies, and cancer prevention and education programs. The applicant may also submit, and the Department may accept, other evidence. Patient care evaluation studies means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Tumor registry means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

(i) An applicant shall submit evidence of accreditation by the American College of Surgeons Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and continue to participate annually thereafter.

(ii) An applicant shall submit evidence of accreditation by the American College of Radiology (ACR), ~~/~~American Society for Radiation Oncology (~~ACR/~~ASTRO) or the American College of Radiation Oncology (ACRO) within the first three years of operation and continue to participate annually thereafter.

(f) The MRT service will have simulation capability at the same location.

(g) An applicant shall participate in the Michigan Cancer Surveillance Program.

(h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved.

(i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.

(j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer conditions. The number of patients treated, number enrolled in research studies, and the types of cancer conditions involved shall be provided to the Department as part of the CON Annual Survey.

(k) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) Compliance with the following access to care requirements:

(a) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.

(b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan population, the applicant shall:

(i) not deny MRT services to any individual based on ability to pay or source of payment,

(ii) provide MRT services to an individual based on the clinical indications of need for the service, and

(iii) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(4) Compliance with the following monitoring and reporting requirements:

(a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(b) Non-special MRT units and HMRT units approved pursuant to Section 3(2) or 3(3) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is replacing an MRT unit under section 4(1).

(d) An applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department. Data shall be provided by each type of MRT unit in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(e) Services provided on a dedicated research MRT unit shall be delivered in compliance with the following terms:

(i) Capital and operating costs for research treatment visits shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(ii) The dedicated research MRT unit shall not be used for any purposes other than as approved by the IRB.

(iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.

(5) The applicable agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 12. Effect on prior CON review standards; comparative reviews

Sec. 12. proposed projects reviewed under these standards shall not be subject to comparative review. These standards supersede and replace the CON Review Standards for MRT Services/Units approved by the CON Commission on ~~September 22, 2011~~MARCH 28, 2013 and effective ~~November 21, 2011~~MAY 24, 2013.

APPENDIX A

PLANNING AREAS BY COUNTY

1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

APPENDIX B

Rural Michigan counties are as follows:

Alcona	~~Hillsdale~~	Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford	~~Mason~~	Sanilac
Emmet	~~Montcalm~~	Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	~~Newaygo~~MONTCALM
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget