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. ~~(1)~~ These standards are requirements for approval TO INITIATE, REPLACE, EXPAND, OR ACQUIRE AN MRT SERVICE ~~and delivery of services for all projects approved and certificates of need issued~~ under Part 222 of the Code ~~that involve MRT services/units~~.

~~(2) An~~ MRT service~~S~~/ AND unit~~S~~ ~~is~~ ARE a covered clinical service ~~for purposes of~~PURSUANT TO Part 222 of the Code. ~~An MRT service/unit previously approved pursuant to Section 7 of these standards now seeking approval to operate pursuant to sections 4, 5, 6, 8, or 9 shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of an MRT service/unit. An MRT unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of a non-special MRT service/unit.~~

~~(3)~~ The Department shall use THESE ~~sections 4, 5, 6, 8, 9, and 10, as applicable,~~ in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~.~~

~~(4) The Department shall use Section 16, as applicable, in applying~~ 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) "Acquisition of an existing MRT service or existing MRT unit(s)" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or existing MRT unit(s).~~

~~(b) "Begin operation of an MRT service" means the establishment of a non-special MRT unit at a geographic location where an MRT service is not currently provided. The term does not include the acquisition or relocation of an existing MRT service and/or unit(s) or the renewal of a lease.~~

~~(c) "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, and Iridium-192.~~

~~(d) "Cancer treatment program" means 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: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) MRT capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.~~

~~(e~~A) ~~"Certificate of Need Commission" or~~ "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

~~(f~~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.

~~(g) "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.~~

~~(h) "Computer based treatment planning system" means a computer system capable of displaying radiation doses and dose distributions within a patient using anatomical data from that patient and using measured 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.~~

~~(i) "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.~~

(~~j~~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.

(~~k~~D) "Department" means the Michigan Department of Community Health (MDCH).

~~(l) "Dosimetrist" means 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.~~

~~(m) "Driving miles" means the number of miles from the address of the proposed MRT service to the address of the closest existing MRT unit. Driving miles is the number of miles from address to address as identified by use of mapping software that is verifiable by the Department.~~

~~(n) "Duplication factor" means the number derived by subtracting the duplication rate from 1.~~

~~(o) "Duplication rate" means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.~~

(~~p~~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. ~~Section 13 sets forth how ETVs shall be calculated.~~

(~~q~~F) "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).

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

~~(s) "Expand an existing MRT service" means adding one additional MRT unit to the number of existing MRT units.~~

~~(t) "Full time equivalent" or "FTE" means an individual(s) with normally scheduled working hours of 40 hours per week.~~

(~~u~~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.

~~(v) "Geographic location" means either (i) the geographic location of a licensed health facility as defined in the CON Review Standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location.~~

(~~w~~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.

(~~x~~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).

~~(y) "Hospital MRT service" means an MRT service owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).~~

~~(z) "Image guided radiation therapy" or "IGRT" means the use of in-room imaging to allow precise target localization using ultrasound, implanted fiducial markers or image reconstruction using kV or megavoltage beams. Two-dimensional port films using patient anatomy for localization do not constitute IGRT.~~

~~(aa) "Immediately available" means continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.~~

(~~bb~~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.

~~(cc) "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.~~

(~~dd~~L) "Intraoperative ~~treatment visit~~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 ~~visit where a dose~~ of A PATIENT UNDERGOING A SURGICALPROCEDURE WITH megavoltage radiation ~~is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit~~.

~~(ee) "Institutional review board" or "IRB" means an institutional review board, as defined by Public Law 93-348, that is regulated by Title 45 CFR 46.~~

~~(ff) "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.~~

~~(gg) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.~~

~~(hh) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission (NRC) or registered by the Michigan Department of Community Health, Division of Health Facilities and Services, Radiation Safety Section.~~

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

~~(jj) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board certified or board qualified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics.~~

(~~kk~~N) "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 a MRT unit.

~~(ll) "MRT program" means one or more MRT services operated at one or more geographic locations under the same administrative unit.~~

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

(~~nn~~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.

~~(oo) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

(~~pp~~Q) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department~~, Vital Records and Health Data Development Section,~~ mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

~~(qq) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~

~~the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(rr) "Multi-disciplinary cancer committee" means 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 (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.~~

(~~ss~~R) "New cancer case," means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.

(~~tt~~S) "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.

~~(uu) "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.~~

~~(vv) "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. Examples of patient care evaluation studies include nationwide patient care evaluation studies; hospital wide quality assurance activities; and ongoing monitoring, evaluating, and action planning.~~

~~(ww) "Planning area" means the groups of counties shown in Section 17.~~

~~(xx) "Relocation of an existing MRT service and/or MRT unit(s)" means a change in the geographic location within the same planning area.~~

~~(yy) "Replace/upgrade an existing MRT unit" means an equipment change that results in an applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the equipment change.~~

~~(zz) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R., p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(aaa) "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.~~

(~~bbb~~T) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(~~ccc~~U) "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, (iii) dedicated total body irradiator (TBI), (iv) an OR-based IORT unit, or (v) cyber knife.

~~(ddd) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the destruction of a precisely defined intracranial and/or extracranial tumor or lesion.~~

(~~eee~~V) "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.

(~~fff~~W) "Treatment site" means the anatomical location of the MRT treatment.

(~~ggg~~X) "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.

~~(hhh) "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.~~

~~(iii) "Very complex treatment visit" means those visits listed in Section 13 that involve special techniques in the performance of the MRT.~~

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

Section 3. Modification of the Appendices

Sec. 3. ~~(1)~~ The Commission may modify the APPENDICES AS FOLLOWS.

(1) THE COMMISSION MAY MODIFY THE Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program AND presented ~~to the Commission~~ by the Department.

(2) The Commission may ~~periodically~~ modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data OBTAINED~~provided~~ FROM THE DEPARTMENT ANNUAL SURVEY ~~by~~ OF MRT providers ~~as part of a Department survey~~AND presented ~~to the Commission~~ by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) Modifications made by the Commission pursuant to subsections (1) or (2) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to ~~become~~ TAKE effect~~ive~~.

Section 4. Requirements ~~for approval - applicants proposing~~ to INITIATE ~~begin operation of a~~ AN MRT service ~~other than an MRT service utilizing an HMRT unit~~

Sec. 4. ~~(1)~~ INITIATE MEANS THE ESTABLISHMENT OF AN MRT SERVICE ~~An applicant proposing~~WHERE ~~to begin operation of a~~AN MRT service ~~,~~IS NOT CURRENTLY PROVIDED. ~~other than an~~THE TERM DOES NOT INCLUDE REPLACEMENT OF AN EXISTING~~-~~ MRT service. AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE ~~utilizing an HMRT unit,~~ shall demonstrate ~~that~~ 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 ~~a minimum of~~ 8,000 equivalent treatment visits ~~(ETVs)~~ for each proposed unit ~~results from application of the methodology described in Section 12, and~~.

(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 ~~proposed~~ APPLICANT ~~MRT service~~ projects ~~a minimum of~~ 5,500 equivalent treatment visits ~~(ETVs)~~ for each proposed unit ~~based on the application of the methodology described in Section 12~~.

(d) The proposed MRT unit is not a special purpose MRT unit.

(3) ~~All~~ AN applicant~~s~~ PROPOSING TO INITIATE AN MRT SERVICE WITH AN HMRT UNIT ~~under this section~~ shall demonstrate~~, at the time the application is submitted to the Department, that~~ the following~~ staff, at a minimum, will be provided~~:

(a) ~~An~~THE applicant is a single legal entity authorized to do business in the State of Michigan.

(b) ~~An~~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 ~~The participating services~~ under sub~~section~~DIVISION (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 ~~under this section~~ shall not be approved if it includes an MRT service described in ~~subsection~~subdivision (i) or (ii) except as provided in subsections (iii) or (iv).

(i) An MRT service that was part of another application under this ~~section~~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, ~~under this section~~ were subsequently disapproved~~,~~ OR withdrawn.

(iv) The application ~~under this section~~ includes a commitment from the MRT service described in ~~subsection~~SUBDIVISION (i) to surrender the CON, or application, described in ~~subsection~~SUBDIVISION (i) and that commitment is fulfilled at the time the application under this section is approved.

(f) An application ~~under this section~~ 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~~SUBDIVISION (i), unless the application under this SUBsection includes a commitment from the MRT service described in ~~subsection~~SUBDIVISION (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 ~~under this section~~ 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~~SUBDIVISION (i) to surrender the CON described in ~~subsection~~SUBDIVISION (i), and that commitment is fulfilled at the time the HMRT unit IS approved AND OPERATIONAL ~~is operational~~ under this SUBsection.

(h) ~~An~~THE applicant shall provide documentation of its process, policies and procedures, acceptable to the Department~~, which will~~THAT allows any other interested entities to participate in the collaborative ~~utilizing~~UTILIZATION OF ~~an~~THE HMRT unit.

(i) ~~An~~THE applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the ~~proposed~~ MRT service utilizing an HMRT ~~unit~~THAT includ~~ing~~ES~~, but not limited to,~~ how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

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

(k) ~~An~~THE applicant shall demonstrate ~~that the MRT service utilizing an HMRT unit will have~~ simulation capabilities available for use in treatment planning.

(4) 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, ~~or physics assistant,~~ 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~~therapy technologists~~ [registered or eligible by the American Registry of Radiological Technologists (ARRT)~~], and~~.
(e) ONE (1) program director who is a board-certified physician trained in radiation oncology who may also be the physician required under ~~subsection~~ SUBDIVISION (~~3~~4)(a).

Section 5. Requirements ~~for approval - applicants proposing~~ to ~~expand~~ replace an existing MRT UNIT OR service ~~other than an MRT service utilizing an HMRT unit~~

Sec. 5. 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 A~~M~~N 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.
(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).

(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 4(2).
(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 4(4).
(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.

~~Sec. 5. (1) An applicant proposing to expand an existing MRT service, other than an MRT service utilizing an HMRT unit, with an additional non-special MRT unit shall demonstrate:~~
~~(a) an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units, and~~
~~(b) the additional unit shall be located at the same site, unless the requirements of section 9(2) also have been met.~~
~~(2) An applicant proposing to expand an existing MRT service, other than an MRT service utilizing an HMRT unit, with a special purpose MRT unit shall demonstrate each of the following, as applicable:~~
~~(a) An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units at the location where the special purpose unit is to be located.~~
~~(b) An applicant proposing to expand by adding a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.~~
~~(c) An applicant proposing to expand by adding and operating a dedicated stereotactic radiosurgery unit (including a gamma knife and cyber knife) shall demonstrate that (i) the applicant has, at the time the application is filed, a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.~~
~~(d) An applicant proposing to expand by adding an operating room based intraoperative MRT unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.~~

Section 6. Requirements ~~for approval - applicants proposing~~ to ~~replace/upgrade~~EXPAND an existing MRT ~~unit(s) other than an MRT~~ service ~~utilizing an HMRT unit~~

Sec. 6. 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~~:~~.

(~~a~~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.
(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.

~~Sec. 6. An applicant requesting to replace/upgrade an existing MRT unit(s), other than an HMRT unit, shall demonstrate each of the following, as applicable.~~

~~(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only unit at that geographic location, shall demonstrate each of the following:~~

~~(a) The unit performed at least 5,500 ETVs in the most recent 12-month period.~~

~~(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.~~

~~(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service which is the only MRT service in the planning area shall demonstrate each of the following:~~

~~(a) Each unit at the geographic location of the unit to be replaced operated at an average of at least 5,500 ETVs in the most recent 12-month period.~~

~~(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.~~

~~(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:~~

~~(a) Each non-special unit at the geographic location of the unit to be replaced operated at a total of at least 13,000 ETVs for two units and an additional 5,500 ETVs for each additional unit (i.e., 13,000 ETVs + 5,500 ETVs = 18,500 ETVs for three units, 13,000 ETVs + 5,500 etvs + 5,500 ETVs = 24,000 ETVs for four units, etc.) in the most recent 12-month period.~~

~~(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.~~

~~(4) An applicant requesting to replace/upgrade an existing special purpose unit shall demonstrate each of the following, as applicable:~~

~~(a) The special purpose unit to be replaced operated at an average of 1,000 ETVs for each OR-based IORT unit, gamma knife, cyber knife, dedicated stereotactic radiosurgery unit, or dedicated total body irradiator during the most recent 12-month period.~~

~~(b) The replacement special purpose unit will be located at the same geographic location as the special purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements of sections 5 and 9 have been met.~~

~~(c) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program.~~

~~(5) An applicant under this section shall demonstrate that the MRT unit proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles; that the existing unit clearly poses a threat to the safety of the public; or that the proposed replacement unit offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.~~

~~(6) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.~~

~~**Section 7. Requirements for approval - applicants proposing to use MRT units exclusively for research**~~

~~Sec. 7. (1) An applicant proposing a MRT unit to be used exclusively for research shall demonstrate each of the following:~~

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

~~(b) The MRT unit shall operate under a protocol approved by the applicant's IRB.~~

~~(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 16(1)(c)(v), (viii), (xiii); 16(2); 16(4); and 16(5).~~

~~(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 4, 5; 6; and 16(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of these standards.~~

~~(3) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.~~

Section ~~8~~7. Requirements ~~for approval - applicants proposing~~ to acquire an existing MRT service ~~or an existing MRT unit(s) other than an MRT service utilizing an HMRT unit~~

Sec. ~~8~~7. ~~(1)~~ 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 ~~existing~~ MRT service ~~and its MRT unit(s), other than an MRT service utilizing an HMRT unit,~~ shall demonstrate ~~that it meets all of~~ the following, AS APPLICABLE TO THE PROPOSED PROJECT~~:~~.

(1) FOR THE FIRST APPLICATION PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, OTHER THAN THE RENEWAL OF A LEASE, ON OR AFTER <INSERT EFFECTIVE DATE OF STANDARDS>, THE EXISTING MRT SERVICE SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THIS SECTION.

(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:~~The project is limited solely to the acquisition of an existing MRT service and its MRT unit(s).~~

~~(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.~~

~~(c) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~

(I) NON-SPECIAL MRT UNIT(S) AT 8,000 EQUIVALENT TREATMENT VISITS PER UNIT OR 5,500 FOR A UNIT APPROVED UNDER SUBDIVISION 4(2).

(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 RENEW A LEASE FOR AN EXISTING MRT UNIT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE THAN REPLACING THE EQUIPMENT.

~~(2) An applicant proposing to acquire an existing MRT unit(s) of an existing MRT service, other than an MRT service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~

~~(a) The project is limited solely to the acquisition of an existing MRT unit(s) of an existing MRT service.~~

~~(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.~~

~~(c) The project will not result in the replacement/upgrade of an existing MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.~~
~~(d) The requirements of Section 4(3) have been met.~~

Section 8. Requirements for A DEDICATED RESEARCH MRT unit(s)

Sec. 8. An applicant proposing TO ADD A DEDICATED RESEARCH MRT unit shall demonstrate the following:

(~~a~~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 9. Requirements for MEDICAID PARTICIPATION ~~approval - applicants proposing to relocate an existing MRT service and/or MRT unit(s) other than an MRT service utilizing an HMRT unit~~

Sec. 9. 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.
~~(1) An applicant proposing to relocate an existing MRT service and its MRT unit(s), other than an MRT service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~
~~(a) The relocation of the existing MRT service and its MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.~~
~~(b) The new geographic location will be in the same planning area as the existing geographic location.~~
~~(c) The project will not result in the replacement/upgrade of the existing MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~
~~(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.~~

~~(2) An applicant proposing to relocate an MRT unit(s) of an existing MRT service, other than an MRT service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~
~~(a) The relocation of the MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.~~
~~(b) The new geographic location will be in the same planning area as the existing geographic location.~~
~~(c) The project will not result in the replacement/upgrade of the existing MRT (unit)s to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~
~~(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.~~
~~(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.~~

~~(f) For a micropolitan statistical area or rural county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 5,500 ETVs in the most recent 12-month period. For a metropolitan statistical area county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 8,000 ETVs in the most recent 12-month period.~~

~~(g) The requirements of Section 4(3) have been met.~~

~~(h) A special purpose unit cannot be relocated to a site that does not have an existing non-special purpose unit.~~

Section 10. ~~Requirements for approval – applicants proposing to initiate an MRT service utilizing an HMRT unit~~ METHODOLOGY FOR PROJECTING EQUIVALENT TREATMENT VISITS

Sec. -10. ~~The~~AN applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits.

(1) Identify the number of new cancer cases ~~documented in accord with the requirements of~~UNDER Section ~~15~~13.

(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.

(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.

(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.

(5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.

(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.

(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.

(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.

(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5) by 2.~~5~~0.

(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of estimated EQUIVALENT TREATMENT VISITs.

~~The use of an HMRT unit represents emerging cancer treatment technology and consequently provides a mixture of both treatment and research uses. This section of the CON Review Standards for MRT Services/Units recognizes the unique nature of this technology.~~

~~(1) An applicant proposing to initiate an MRT service utilizing an HMRT unit shall demonstrate each of the following:~~

~~(a) An applicant is a single legal entity authorized to do business in the State of Michigan.~~

~~(b) An applicant is a collaborative that consists of at least 40% of all Michigan hospital MRT services with more than 30,000 ETVs.~~

~~(c) An applicant shall include hospital MRT services from more than one planning area from either or both of the following:~~

(i) The participating services under subsection (b).

(ii) Hospital MRT services with the highest number of ETVs in a planning area.

(d) For the purposes of this section, ETVs shall be those from the April 30, 2008 list (revised) published by the Department. The Department shall update the list every three years thereafter.

(e) An application under this section 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 section.

(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, under this section were subsequently disapproved, withdrawn.

(iv) The application under this section 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 under this section 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 section 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 under this section 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 approved under this section is operational.

(h) An applicant shall provide documentation of its process, policies and procedures, acceptable to the Department, which will allow any other interested entities to participate in the collaborative utilizing an HMRT unit.

(i) An applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the proposed MRT service utilizing an HMRT unit including, but not limited to, how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

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

(k) An applicant shall demonstrate that the MRT service utilizing an HMRT unit will have simulation capabilities available for use in treatment planning.

(2) An applicant proposing to initiate an mrt service utilizing an hmrt unit shall also demonstrate compliance with the requirements of section 4(3).

Section 11. Requirements for approval -- all applicants

Sec. 11. 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 12. Methodology for computing the projected number of equivalent treatment visits

Sec. 12. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).

(1) Identify the number of new cancer cases documented in accord with the requirements of Section 15.

~~(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.~~

~~(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.~~

~~(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.~~

~~(5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.~~

~~(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.~~

~~(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.~~

~~(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.~~

~~(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5) by 2.5.~~

~~(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of estimated ETVs.~~

Section ~~13~~11. Equivalent treatment visits

Sec. ~~13~~11. ~~For purposes of these standards, equivalent~~ Equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable section~~(s) of these standards~~, 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 ~~ETV~~ 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 section~~(s)~~ 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	~~2.50~~2.00	
~~Very Complex:~~		
Total Body Irradiation	8.00	~~5.00~~8.00
HMRT ~~Unit~~THERAPY		5.00
Stereotactic radio-surgery/radio-therapy* (non-gamma knife and cyber knife**)	8.00	8.00
Gamma Knife**		8.00
~~Dedicated OR-Based~~ IORT		20.00

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

*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 additional EQUIVALENT TREATMENT VISITs.

(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 ~~14~~12. Commitment of new cancer cases

Sec. ~~14~~12. ~~(1)~~ An applicant ~~proposing to use~~USING new cancer cases ~~shall~~ TO demonstrate NEED SHALL MEET ~~all of~~ the following:

(a1) Each entity contributing new cancer case data provides~~, as part of the application at the time it is submitted to the Department,~~ a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.

(b2) The ~~geographic~~ locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT service.

(23) An entity currently operating or approved to operate ~~a~~ AN MRT service shall not contribute new cancer cases to initiate any MRT service.

Section ~~15~~13. Documentation of new cancer case data

Sec. ~~15~~13. ~~(1)~~ An applicant ~~required to document volumes of new cancer cases~~ shall submit~~, as part of its application,~~ documentation from the MICHIGAN CANCER SURVEILLANCE PROGRAM, WITHIN THE Department~~, Vital Records and Health Data Development Section~~, verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available ~~from the State Registrar~~.

~~(2)~~ New cancer case data supporting an application ~~under these standards~~ shall be submitted to the Michigan Cancer Surveillance Program using a format and media specified in instructions from the ~~State Registrar~~DEPARTMENT.

Section ~~16~~14. Project delivery requirements ~~–~~terms of approval for all applicants

Sec. ~~16~~14. ~~(1)~~ An applicant shall agree that, if approved, THE MRT service~~s~~, INCLUDING ALL EXISTING AND APPROVED MRT UNITS, shall be delivered in compliance with the following ~~applicable terms of CON approval for each geographical location where the applicant operates an MRT unit~~:

(a1) Compliance with these standards.

~~(b) Compliance with applicable safety and operating standards.~~

(c2) Compliance with the following quality assurance standards:

~~(i)~~(A) An applicant shall assure that ~~the~~ 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 ~~therapy~~ 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,

(~~b~~II) ONE (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation,

(~~c~~III) ONE (1) dosimetrist ~~or physics assistant~~ for every 300 patients treated with MRT annually,

(~~d~~IV) TWO (2) ~~FTE~~ radiation ~~therapy technologists~~THERAPISTS ~~[~~registered or eligible by the American Registry of Radiological Technologists (ARRT)~~]~~, for every MRT unit per shift of operation (not including supervisory time), and

(~~e~~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 (~~iii~~II)~~(a)~~. ~~For purposes of evaluating this~~

subsection, tThe 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.

The non-special MRT units and HMRT units approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(B) The non-special MRT units and HMRT units approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(ii) An applicant shall establish a mechanism to assure that (a) the MRT service is staffed so that the MRT unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit 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 therapy technologist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established and operates a satisfactory quality assurance mechanism to assure that the MRT unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.

(iii) At a minimum, the following staff shall be provided: (a) 1 FTE board-certified or board- qualified physician trained in radiation oncology for each 250 patients treated with MRT annually, (b) 1 board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation, (c) 1 dosimetrist or physics assistant for every 300 patients treated with MRT annually, (d) 2 FTE radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)] for every MRT unit per shift of operation (not including supervisory time), and (e) 1 FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the departmentDepartment 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.

–(ivC) 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).

(vD) The AN applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. MRT facility staff 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 in or immediately available to the MRT unit at all times when patients are treated.

(viE) An applicant shall operate a cancer treatment program. For purposes of evaluating this subsection, tThe Department shall consider it prima facie evidence of meeting this requirement 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.

(~~vii~~F) ~~A~~ THE MRT service will have simulation capability at the same ~~l~~location.

(~~viii~~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:

~~(ix) An applicant required to document new cancer cases shall agree to pay the State Registrar's costs for verification of the new cancer case data.~~

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

(~~xi~~B) ~~The applicant, t~~To assure that the MRT SERVICE AND ITS unit(S) will be utilized by all segments of the Michigan population, THE APPLICANT shall:

(~~a~~I) ~~n~~not deny MRT services to any individual based on ability to pay or source of payment,

(~~b~~II) ~~p~~provide MRT services to an individual based on the clinical indications of need for the service, and

(~~c~~III) ~~m~~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) COMPLAINCE 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 ~~t~~treatments conducted ~~by~~ON A DEDICATED RESEARCH MRT unit.

(B) Non-special MRT units and HMRT units approved pursuant to Section 4(2) 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 SUBDIVISIONS (4)(A) OR (B) IF THE APPLICANT IS REPLACING AN MRT UNIT UNDER SUBSECTION 5(1).

(~~A~~D) ~~The~~ 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 ~~or its designee, and approved by the CON Commission~~. ~~The applicant shall provide the required data~~ Data ~~on a separate basis for each separate and distinct geographic location or unit, and separately for non-special MRT units and each~~ DATA SHALL BE PROVIDED BY EACH type of ~~special purpose~~ MRT unit~~, as required by the Department;~~ 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.

(~~B~~II) ~~If the applicant intends to include~~THE DEDICATED research ~~treatment visits conducted by a~~ MRT unit ~~other than an MRT unit approved exclusively for research pursuant to Section 7 in its utilization statistics, the applicant~~ shall NOT BE USED ~~submit to the Department a copy of the research protocol~~ FOR ANY PURPOSES OTHER THAN ~~with evidence of approval~~AS APPROVED by the IRB. ~~The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics.~~

(III) The ~~applicant shall not report to the Department any~~ treatments ON A DEDICATED ~~RESEARCH~~ RESEARCH ~~visits conducted by an~~ MRT UNIT SHALL NOT BE USED FOR ANY VOLUME PURPOSES~~unit approved pursuant to Section 7~~.

~~(xiii) The applicant shall provide the Department with a notice stating the first date on which the MRT service and its unit(s) became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.~~

~~(xiv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved and to seek approval under a separate CON application to operate the unit as a non-special MRT unit.~~

~~(xv) 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 as a total body irradiator. 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 Department, Division of Health Facilities and Services, Radiation Safety Section.~~

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

~~(2) An applicant for an MRT unit under Section 7 shall agree that the services provided by the MRT unit approved pursuant to Section 7 shall be delivered in compliance with the following terms of CON approval:~~

~~(a) The capital and operating costs relating to the research use of the MRT unit approved pursuant to Section 7 shall be charged only to a specific research account(s) and not to any patient or third-party payor.~~

~~(b) The MRT unit approved pursuant to Section 7 shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRT unit pursuant to Part 222 and these standards, other than Section 7.~~

~~(3) An applicant for an MRT service utilizing an HMRT unit approved under Section 10 shall agree to deliver the service in compliance with the following additional terms:~~

~~(a) All patients treated 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.~~

~~(b) Upon completion of any study, and authorization by study sponsor, the findings and summary of any research studies, consistent with patient confidentiality, shall be provided to the Department by the applicant.~~

~~(c) The MRT service utilizing an HMRT unit shall provide the Department, on an annual basis, following the initiation of the service, with updates to the information provided and approved by the Department pursuant to subsections 10(1)(h), (i), (j), (k), and 10(2).~~

~~(d) On an annual basis, following the initiation of the service, the Department will assess the affordability of the project by evaluating the "Hospital Cost Report" and any other applicable information supplied to the Centers of Medicare and Medicaid Services (CMS) and the Michigan Medical Services Administration (MSA).~~

~~(e) Upon review, by the Department, of the information submitted under subsections (c) and (d) above, and the Department's finding that the service has not fulfilled project delivery requirements, the Department may order changes with regard to the provision of the HMRT service to assure fulfillment of project delivery requirements. The Department may elect to verify the information and data through on-site review of appropriate records.~~

~~(4) 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).~~

(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 15. Effect on prior CON review standards; comparative reviews

Sec. 15. PROPOSED PROJECTS reviewed UNDER THESE standards SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW. THESE STANDARDS supersede and replace the CON Review Standards for ~~Megavoltage Radiation Therapy (~~MRT~~)~~ Services/Units approved by the CON Commission on ~~December 13, 2005~~SEPTEMBER 16, 2008 and effective ~~January 30, 2006~~NOVEMBER 13, 2008.

~~Section 17. Planning areas~~
APPENDIX A

DUPLICATION RATES AND FACTORS

The following Duplication Rates and Factors are effective <INSERT EFFECTIVE DATE> and remain in effect until otherwise changed by the Commission. Duplication factor means the number derived by subtracting the duplication rate from 1. Duplication rate means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.123~~.21085~~	0.877~~.78915~~
2	0.152~~.23517~~	0.848~~.76483~~
3	0.113~~.11219~~	0.887~~.74336~~
4	0.162~~.25664~~	0.838~~.74336~~
5	0.167~~.21849~~	0.833~~0.78151~~
6	0.270~~.34615~~	0.730~~.65385~~
7	0.126~~.21865~~	0.874~~.78135~~
8	0.193~~.12314~~	0.807~~.87686~~

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective <INSERT EFFECTIVE DATE> ~~December 11, 2007~~ and remains in effect until otherwise changed by the Commission.

Treatment Visit Category	Statewide Percent
Simple	0.7~~1.6~~%
Intermediate	0.1~~8~~%
Complex	52.2~~73.4~~%
IMRT	47.0~~24.2~~%

Source: 200~~6~~10 Annual ~~Hospital Statistical~~CON Survey

APPENDIX C

~~Sec. 17. Counties assigned to each planning area are as follows:~~

PLANNING AREA	**COUNTIES**		
~~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~~

~~Section 18. Effect on prior CON review standards; comparative reviews~~

~~Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units approved by the CON Commission on December 13, 2005 and effective January 30, 2006.~~

~~(2) Projects reviewed under these standards shall not be subject to comparative review.~~

APPENDIX A

DUPLICATION RATES AND FACTORS

The following Duplication Rates and Factors are effective December 11, 2007 <INSERT EFFECTIVE DATE>and remain in effect until otherwise changed by the Commission.

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.210850.123	0.789150.877
2	0.235170.152	0.764830.848
3	0.112190.113	0.887810.887
4	0.256640.162	0.743360.838
5	0.218490.167	0.781510.8330
6	0.346150.270	0.653850.730
7	0.218650.126	0.781350.874
8	0.123140.193	0.876860.807

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective December 11, 2007 and remains in effect until otherwise changed by the Commission.

Treatment Visit Category	Statewide Percent
Simple	1.60.7%
Intermediate	.80.1%
Complex	73.452.2%
IMRT	24.247.0%

Source: 2006 Annual Hospital Statistical Survey

~~APPENDIX C~~

~~CON REVIEW STANDARDS~~ ~~FOR MRT SERVICES~~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 D

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information And Regulatory Affairs
United States Office of Management And Budget