

**Certificate of Need Standards for**  
**Megavoltage Radiation Therapy Services/Units**

I. **INTRODUCTION**

Radiation therapy (also called radiotherapy or x-ray therapy) is the use of a certain type of energy (called ionizing radiation) to treat cancer as well as a limited number of noncancerous conditions (e.g. arteriovenous malformations). Radiation therapy injures or destroys cells in the area being treated primarily by damaging their genetic material, making it impossible for those cells to continue to grow and divide. Although radiation damages both cancer cells and normal cells, most normal cells can recover from the effects of radiation and function properly. The goal of radiation therapy is to damage as many cancer cells as possible, while limiting harm to nearby healthy tissue.

Radiation may come from a machine (external radiation, teletherapy, beam radiation), may be placed inside or next to the body (internal radiation, brachytherapy), or may use unsealed radioactive materials that go throughout the body (systemic radiation therapy).

## II. DEFINITIONS

A. Acquisition of an existing MRT service or existing MRT unit(s) – The acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or MRT unit(s).

B. Brachytherapy/Internal radiation therapy – Use of a radioactive material that is placed very close to or inside the tumor. The radiation source is usually placed in a small holder called an implant (thin wires, catheters, ribbons, capsules, or seeds). Internal radiation therapy is of two types, Interstitial or Intracavitary implants or as surface applications.

C. Calibration Equipment – Is used to determine the accuracy of treatment equipment by measuring its variation from a standard to ascertain necessary correction factors.

D. Cancer – A malignant tumor or neoplasm, varying from highly curable local skin, oral and cervix cancers to rapidly fatal advanced cancers.

E. Cancer Incidence – The number of patients newly diagnosed with cancer in a specific calendar year within a defined population. This is often expressed as the ratio of new cases per unit of population per year.

F. Cancer Prevalence – Means the total number of patients (old or new) with cancer present during a specified time period within a defined population. This number excludes non-melanoma skin cancers.

G. Complete Comprehensive Cancer Center – A coordinated, multidisciplinary 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: (1) inpatient and outpatient radiation oncology; (2) inpatient and outpatient medical oncology services and chemotherapy suites; (3) surgical oncology; (4) high quality diagnostic and therapeutic equipment including, MRT, CT, and PET/CT; (5) hematology/oncology laboratory; (6) patient resource services and center; (7) advanced level experimental therapy programs and clinical trials with strict protocols; (8) intensive cancer research capabilities; (9) advanced treatment capabilities; (10) national and international studies participation; and, (11) recruitment of highly skilled physicians with advanced medical experience.

H. Computerized Treatment Planning – Is the use of a computer and dedicated software that are capable of calculating and displaying radiation dose distributions within a patient using clinical data from that patient and dosimetric data from the MRT machine to treat the patient.

I. Collimator – A mechanical element of a MRT machine, which defines the dimension, direction, or focus of the radiation beam by means of metal leaves, or diaphragms interposed in the path of the beam.

J. 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

does distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

K. Dosimetry Equipment – Is used to determine the amount, rate and distribution of ionizing radiation, including for example phantoms, film, ionization chambers and dosimeters. Such equipment permits accurate measurement of the dose of radiation delivered.

L. Driving miles – The number of miles from the address of the proposed MRT services to the address of the closest existing MRT unit. Driving miles is the number of miles from address to address.

M. External beam radiation therapy – The energy (source of radiation) used in external radiation therapy may come from the following:

1. X-rays are created by machines called linear accelerators. Depending on the amount of energy the x-rays have, they can be used to treat cancers more superficially or deep into tissues and organs.
2. Gamma rays are produced when isotopes of certain elements (such as iridium and Cobalt 60) release energy as they break down. Each element breaks down at a specific rate and emits radiation with specific energies, which affects how deeply it can penetrate into the body.
3. Proton beam therapy is a type of particle beam radiation therapy. Protons are generated by a heavy particle accelerator and deposit most of their

energy over a very small distance, which is called the Bragg peak. The Bragg peak can be exploited to deliver radiation to a tumor while depositing less radiation damage to surrounding normal tissues.

4. Intensity Modulated Radiation Therapy (IMRT) is a treatment delivery utilizing a radiation therapy plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or casted compensators.

N. Heavy particle accelerator – means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, or heavy ions with masses greater than that of an electron.

O. Megavoltage Radiation Therapy (MRT) – A clinical modality in which patients with cancer, other neoplasm, or cerebrovascular system abnormalities are treated with radiation which is delivered by a MRT unit.

P. Megavoltage Radiation Therapy (MRT) Machine – A linear accelerator, cobalt unit, particle accelerator 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. Non-special purpose MRT unit – A MRT unit that does not meet the definition of a special purpose MRT unit.

R. Operating room based intraoperative MRT unit (OR-based IORT unit) – A 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.

S. Special purpose MRT unit – Any of the following types of megavoltage radiation therapy units: (1) heavy particle accelerator; (2) stereotactic radiosurgery services consisting of multiple cobalt sources, including but not limited to GammaKnife®; (3) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including but not limited to CyberKnife®, Novalis® and X-Knife®; (4) dedicated total body irradiator; and, (5) OR based intraoperative radiation therapy (IORT) unit.

T. Stereotactic Radiation Therapy (SRT) – A procedure(s) performed in one (1) to five (5) treatment visits, using a stereotactic MRT machine to treat lesions in the brain (intracranial) or elsewhere in the body (extracranial).

U. Stereotactic Radiosurgery (SRS) – A form of radiation therapy for treating abnormalities, functional disorders, and tumors of the brain, neck, and tumors of the spine, lung, pancreas, prostate, bone, and liver. There are two basic methods in which SRS can be delivered to patients: (1) linear accelerator-based treatment; and, (2) multi-source photon-based treatment (often referred to as Cobalt 60, i.e. GammaKnife®). Furthermore, advances in technology have further distinguished linear

accelerator-based SRS therapy into two types: (1) image-guided robotic SRS systems, including but not limited to CyberKnife<sup>®</sup>, Novalis<sup>®</sup> and X-Knife<sup>®</sup>; and, (2) gantry-based systems. These two types of linear accelerator based SRS therapies may be delivered in a complete session or in a fractionated course of therapy up to a maximum of five sessions.

V. SRS LINAC – A dedicated linear accelerator stereotactic radio therapy unit that consists of three key components: (1) a linear accelerator used to produce a high energy megavoltage of radiation; (2) a device which can point the beam from a wide variety of angles; and, (3) an image-guidance patient positioning system using x-rays before or during treatment and uses this information to target the radiation beam emitted by the linear accelerator. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and uses this information to target the radiation beam emitted by the linear accelerator. SRS LINAC includes but is not limited to units such as CyberKnife<sup>®</sup>, Novalis<sup>®</sup> and X-Knife<sup>®</sup>.

W. Treatment Simulation – The process during which the patient is optimally positioned for treatment and all necessary data are collected to develop the radiation treatment plan. It can also permit a simulation or test of the chosen treatment parameters prior to actual treatment. Treatment simulation uses various imaging modalities including diagnostic x-ray and fluoroscopic units, CT, and MRI.

X. Treatment Visit – One patient encounter during which MRT is administered. One visit may involve one or more treatment ports or fields. Each

separate encounter by the same patient at different times during the same day shall be counted as a separate treatment visit.

### III. CURRENT INVENTORY

The Health Care Authority (Authority) shall provide to each applicant a current inventory of existing MRT units in the state.

### IV. NON-SPECIAL PURPOSE MRT UNITS

#### A. Need Methodology

Applicants proposing new or additional MRT services, that do not meet the definition of a “special purpose radiation therapy unit”, shall demonstrate that a proposed new radiation therapy facility will serve a population of 350 patients using the following methodology:

#### 1. Study Area/Service Area

The study area/service area for MRT services consists of the county of proposal and any contiguous county significantly impacted.<sup>1</sup> A significantly impacted county is a county:

- a. wherein at least 25% of the residents rely on acute care services in the county of proposal; or,

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<sup>1</sup> NOTE: The definition of a significantly impacted county may include contiguous counties outside West Virginia. Applicants shall document the location and description of all other MRT units in the proposed study area/service area.

- b. which generates or will generate at least 10% of the patient load in the county of proposal.

2. Need Methodology

Applicants for MRT services that do not meet the definition of a “special purpose megavoltage radiation therapy unit” shall address the following:

- a. Applicants shall use the projected population for the proposed study area/service area for the third year of the project.
- b. Using the average of the number of new cancer cases for the last five (5) years, as compiled by the West Virginia Cancer Registry, the applicant shall calculate a crude rate for the incidence of cancer.
- c. The applicant shall apply this crude rate to the study area/service area population to arrive at an estimated number of cancer patients within the study area/service area.
- d. The applicant shall then calculate 60% (the number of cancer patients who may be expected to utilize radiation therapy) of the estimated number of cancer patients within the study area/service area.
- e. An applicant must conduct a written survey of all existing non-special purpose MRT providers in the applicant’s proposed study

area/service area. The survey must request that each of the existing non-special purpose MRT providers provide information regarding the counties in which they provide services and data regarding the number of patients served in each county during the most recent twelve month period. The return receipt along with all responses to the survey must be submitted to the Authority. The Authority may consider the applicant's survey when evaluating unmet need.

- f. The applicant shall then subtract the number of patients being treated by existing providers within the study area/service area. If the resulting number is 350 or greater and there is not an approved unit in the study area/service area, which had not become operational when the inventory and utilization data was published, the applicant has demonstrated a need for the new unit. The applicant shall deduct 350 patients from the estimated number of cancer patients within the study area/service area for each unit approved but not operational. However, if any other provider of MRT services in the study area/service area has failed to reach this threshold within four years of either receiving Certificate of Need (CON) approval or the initiation of MRT services, the presence of that provider shall not preclude the initiation of MRT services by the applicant.

The Authority may consider an application for a new radiation therapy facility if the applicant can demonstrate, using the above methodology, the unit would treat a population of 200 patients not within 60 minutes normal driving time of an existing radiation therapy provider.

B. Replacement of Non-special Purpose MRT Units

1. The replacement of an existing non-special purpose MRT unit shall not be subject to CON review if the capital expenditure is less than the expenditure minimum. However, the applicant must provide the following:
  - a. A minimum of thirty days notice to the Authority before implementation of the service; and,
  - b. Documentation that the proposed capital expenditure is less than the expenditure minimum.
2. The replacement of an existing non-special purpose MRT unit which capital expenditure is equal to or greater than the expenditure minimum shall meet the following:
  - a. A patient load where each unit at the facility is performing at least 6,000 treatments per year; and/or
  - b. Documentation that the existing MRT machine can no longer be expected to function appropriately because:

- i. maintenance and repair costs plus lost revenue as a result of excessive downtime becomes unreasonable;
- ii. treatment is impaired by irreparable mechanical wear (e.g., excessive collimator movements);
- iii. parts cannot be obtained for a discontinued unit; or,
- iv. the age of the equipment exceeds the useful life of the machine used in projecting the flow of revenue in the financial feasibility analysis submitted to support the CON for the machine to be replaced. If no CON was required, the age must exceed the AHA guidelines for useful life by more than one year.

C. An applicant may request that an existing MRT machine be declared obsolete, although retained and used as back-up for a replacement unit. An existing unit will only be determined to be a back-up unit and thus not counted as an existing unit as long as documentation is supplied to the effect that the back-up unit is subject to substantial down time, and the unit will only be used when the primary unit is not in operation. Further, it must be documented that a back-up unit will not substantially increase capital or operating costs.

D. The upgrade of an existing non-special purpose MRT unit shall not be subject to CON review if the capital expenditure is less than the expenditure minimum. However, regardless of the capital expenditure, all providers which propose to upgrade

an existing non-special purpose MRT unit must meet the criteria regarding quality contained in section VI.B. of these Standards. In addition, the applicant shall demonstrate the financial feasibility of the proposed upgrade.

E. Applicants proposing to provide a complete, comprehensive cancer center may provide alternative need methodologies to the Authority for its consideration. The proposal for the comprehensive cancer center must include, at a minimum, the following services:

1. Inpatient and outpatient radiation oncology;
2. Inpatient and outpatient medical oncology services and chemotherapy suites;
3. Surgical oncology;
4. High quality diagnostic and therapeutic equipment including, MRT, CT and SPECT/CT;
5. Hematology/oncology laboratory;
6. Patient resource services and center;
7. Advanced level experimental therapy programs and clinical trials with strict protocols;
8. Intensive cancer research capabilities;

9. Advanced treatment capabilities;
10. National and international studies participation; and,
11. Recruitment of highly skilled physicians with advanced medical experience.

V. SPECIAL PURPOSE MRT UNITS

A. Need Methodology

Applicants proposing to acquire a special purpose MRT unit must be an existing provider of MRT services. The need for the addition of a special purpose MRT unit shall be determined as follows:

1. Study Area/Service Area

The applicant shall delineate the study area/service area by documenting the expected areas from which the center can reasonably expect to draw patients. The applicant may submit testimony or documentation on the expected study area/service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services.

2. Need Methodology

The need may be demonstrated by using cancer prevalence and cancer incidence rates to show the number of persons within the study

area/service area that can be appropriately treated using the special purpose MRT unit, or by documenting the number of patients within the study area/service area transferred out of the study area/service area for special purpose radiation therapy services.

- a. Applicants shall use the projected population for the proposed study area/service area for the third year of the project.
- b. Using the average number of new cancer cases for the last five (5) years, as compiled by the West Virginia Cancer Registry, the applicant shall calculate a crude rate for the incidence of cancer.
- c. The applicant shall apply this crude rate to the study area/service area population to arrive at an estimated number of cancer patients within the study area/service area.
- d. The applicant shall then calculate 60% (the number of cancer patients who may be expected to utilize radiation therapy) of the estimated number of cancer patients within the study area/service area.
- e. An applicant must conduct a written survey of all existing special purpose MRT providers in the applicant's proposed study area/service area. The survey must request that each of the existing special purpose MRT providers provide information regarding the counties in which they provide services and data

regarding the number of patients served in each county during the most recent twelve month period. The return receipt along with all responses to the survey must be submitted to the Authority. The Authority may consider the applicant's survey when evaluating unmet need.

- f. The applicant shall then subtract the number of patients being treated by existing providers of the same or similar services within the study area/service area. If the resulting number is 350 or greater and there is not an approved unit in the study area/service area, which had not become operational when the inventory and utilization data was published, the applicant has demonstrated a need for the new unit. The applicant shall deduct 350 patients from the estimated number of cancer patients who are receiving the same or similar services within the study area/service area for each unit approved but not operational. However, if any other provider of MRT services in the study area/service area has failed to reach this threshold within four years of either receiving CON approval or the initiation of MRT services, the presence of that provider shall not preclude the initiation of MRT services by the applicant.

B. The replacement of an existing special purpose MRT unit shall not be subject to CON review if the capital expenditure is less than the expenditure minimum. However, the applicant must provide the following:

1. A minimum of thirty days notice to the Authority before implementation of the service; and,
2. Documentation that the proposed capital expenditure is less than the expenditure minimum.

C. Applicants seeking to replace special purpose MRT units, if the capital expenditure is greater than the expenditure minimum, shall establish the need for replacement based on:

1. A patient load where each unit at the facility is performing at least 500 treatment visits annually for cobalt based units; 850 treatment visits annually for linear accelerator based units; 250 treatment visits for OR-Based IORT; 4,000 treatment visits a for heavy particle accelerator; and/or,
2. Documentation that the existing unit can no longer be expected to function appropriately because:
  - a. maintenance and repair costs plus lost revenue as a result of excessive downtime become unreasonable;
  - b. treatment is impaired by irreparable mechanical wear (e.g., excessive collimator movements);
  - c. parts cannot be obtained for a discontinued unit; or,

- d. the age of the equipment exceeds the useful life of the machine used in projecting the flow of revenue in the financial feasibility analysis submitted to support the CON for the machine to be replaced. If no CON was required, the age must exceed the AHA guidelines for useful life by more than one year.

D. An applicant may request that an existing special purpose unit be declared obsolete, although retained and used as back-up for a replacement unit. An existing unit will only be determined to be a back-up unit and thus not counted as an existing unit as long as documentation is supplied to the effect that the back-up unit is subject to substantial down time, and the unit will only be used when the primary unit is not in operation. Further, it must be documented that a back-up unit will not substantially increase capital or operating costs.

## VI. QUALITY

A. Applicants seeking to provide new, additional or replacement non-special purpose MRT services shall demonstrate compliance with the following criteria:

1. One (1) board-certified or board-qualified physician trained in radiation oncology by the American Board of Radiology in Radiation Oncology must be on-site when services are being provided.
2. To assure the quality and safety of MRT equipment, a certified radiation physicist, trained in radiation therapy, shall be available for the calibration and maintenance of equipment as an employee of, or under contract to,

the provider of MRT services. The radiation physicist must be on-site when services are being provided.

3. A medical dosimetrist must be available on-site when services are rendered. The medical dosimetrist shall be a member of the radiation oncology team, who has knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, who is cognizant of procedures commonly used in brachytherapy, who has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists.
4. Radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site when services are being provided.
5. One (1) program director, who shall be a board-certified or board-qualified physician trained in radiation oncology, who shall be available by means of direct communication in person or by radio, telephone, or telecommunication.
6. There shall be a quality assurance program to monitor the quality and appropriateness of MRT services provided. In addition to the clinical quality assurance program, the applicant will document the following:

- a. Applicants providing or seeking to provide MRT services shall demonstrate that the facility in which the services are to be provided meets or will meet the equipment manufacturer's safety and operating standards as well as applicable state and federal standards.
- b. Applicants providing or seeking to provide MRT services shall document the development of policies and procedures for responding to equipment malfunction or operator error which minimize risk to the patient.
- c. Applicants providing or seeking to provide MRT services shall document that their policies and procedures are or will be responsive to patient requests for information and concerns regarding treatment.

B. In addition to the above mentioned criteria, an applicant for special purpose MRT services shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

- 1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or diagnostic X-ray, MRI, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to

define the area requiring treatment; and which must be at the defined location of the unit.

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, or PET/CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient.
3. The capability to fabricate treatment aids as applicable.
4. Existence of a multi-disciplinary cancer committee, which shall be a standing committee that:
  - a. Includes representatives from the medical specialties or subspecialties 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:
  - b. Meets at least on a quarterly basis; and,
  - c. Is responsible for the following:

- i. Establishing educational and problem oriented multi-disciplinary, facility wide cancer conferences that include the major anatomic locations of cancer seen at the facility;
  - ii. Monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and,
  - iii. Oversight of the applicant's tumor registry for quality control, staging and abstracting.
5. Participation in patient care evaluation studies, which shall include a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies, facility quality assurance activities, and ongoing monitoring, evaluating, and action planning.
6. Cancer prevention and education programs.
7. Consultation - The applicant must affirm that it has access to consultative services from all major disciplines needed to develop a comprehensive treatment plan.
8. An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

- a. For applicants seeking the addition of stereotactic radiosurgery services consisting of multiple cobalt sources:
  - i. One (1) board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a stereotactic radiosurgery unit consisting of multiple cobalt sources, and who shall be available on site when services are being provided; and,
  - ii. One (1) medical radiation physicist, who shall be on-site when services are being provided; and,
  - iii. One (1) board-certified or board-qualified Neurosurgeon.
  
- b. For applicants seeking the addition of Heavy Particle Accelerator services:
  - i. Two (2) radiation therapy technologists, who shall be registered or eligible by the ARRT or the ARCRT who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility.
  
- c. For applicants seeking the addition of a dedicated SRS LINAC:

- i. One (1) board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be on-site when services are provided; and,
  - ii. One (1) medical radiation physicist who shall be available on site when services are provided; and,
  - iii. One (1) radiation therapy technologist, who shall be registered or eligible by the ARRT or ARCRT, who shall have received special training in operating a SRS LINAC; and who shall be on-site when services are being provided.
- d. For applicants seeking the addition of an OR-Based IORT unit:
- i. One (1) board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an OR-Based IORT unit and who shall be available on-site when services are being rendered; and,
  - ii. One (1) medical radiation physicist who shall be available on-site when services are being provided.

## VII. CONTINUUM OF CARE

Organizations proposing MRT services shall document the development of procedures to ensure that the referring physician or the patient's primary care physician is apprised of treatment results in a timely fashion.

## VIII. COST

Applicants shall demonstrate the financial feasibility of a proposed MRT service by presenting projections which will show that revenues will equal expenses by the end of the third year of operation, or identify other sources of revenue or income which will subsidize the deficit.

## IX. ACCESSIBILITY

Applicants seeking to provide new, replacement, or additional MRT services shall demonstrate compliance with the following criteria:

- A. Written clinical criteria clearly specifying who is eligible for the service;
- B. Patient selection policies which provide that no person shall be denied appropriate services on account of age, sex, race, color, creed, national origin, physical or behavioral disability, type of payor, or ability to pay;
- C. A scheduling priority system based on patient need;
- D. Accessibility to the disabled in accordance with all applicable state and federal laws.

X. REPORTING

An applicant for new or expanded MRT services or special purpose MRT services shall agree to provide the Authority with all requested information and statistical data related to the operation and provision of services and to report that data to the Authority in the time frame and format requested.