

CERTIFICATE OF NEED STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY SERVICES/UNITS

I. INTRODUCTION

Radiation therapy (also called radiotherapy, x-ray therapy, or irradiation) is the use of a certain type of energy (called ionizing radiation) to kill cancer cells and shrink tumors. Radiation therapy injures or destroys cells in the area being treated 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), may be placed inside the body (internal radiation), or may use unsealed radioactive materials that go throughout the body (systemic radiation therapy).

II. DEFINITIONS

A. Brachytherapy/Internal radiation therapy: Uses radiation 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/intraluminal.

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

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

D. Cancer Incidence – Means the number of patients newly diagnosed 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.

E. Cancer Prevalence – Means the total number of patients (old or new) with cancer present during a specified time period within a defined population.

F. Computerized Treatment Planning – Is the use of a computer to analyze different treatment options. While treatment planning may be done manually using dosimetry and simulation equipment to determine isodose curves, speed and accuracy are improved via computerization.

G. Collimator – Is a mechanical element of an MRT machine, which defines the dimension, direction, or focus of the radiation beam by means of metal tubes, cones or diaphragms interposed in the path of the beam.

H. 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 oncologists.

I. Dosimetry Equipment – Is used to determine the amount, rate and distribution of ionizing radiation, including phantoms and dosimeters. Such equipment permits accurate measurement of the patient's contour, and localization of internal organs and bony structures to identify the precise isodose curves needed for effective treatment.

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

- X-rays are created by machines called linear accelerators. Depending on the amount of energy the x-rays have, they can be used to destroy cancer cells on the surface of the body (lower energy) or deeper into tissues and organs (higher energy). Compared with other types of radiation, x-rays can deliver radiation to a relatively large area.
- 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 gives off a different amount of energy, which affects how deeply it can penetrate into the body.
- Proton beam therapy is a type of Particle beam radiation therapy. Protons deposit their energy over a very small area, which is called the Bragg peak. The Bragg peak can be used to target high doses of proton beam therapy to a tumor while doing less damage to normal tissue in front of and behind the tumor.

K. 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.

L. 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.

M. Megavoltage Radiation Therapy (MRT)/ Intensity Modulated Radiation Therapy (IMRT) – Is the application of ionizing radiation, used in the treatment of individuals with cancer and other neoplastic diseases.

N. Megavoltage Radiation Therapy (MRT) Machine – Is a machine or energy source, used to generate a high energy radiation beam of at least one million electron volts, to treat cancer and other neoplastic diseases. MRT machines include Cobalt 60 units, linear accelerators and other particle accelerators.

O. Special purpose megavoltage radiation therapy unit – Means any of the following types of megavoltage radiation therapy units: (1) heavy particle accelerator; (2) gamma knife; (3) dedicated stereotactic radiosurgery unit; (4) dedicated total body irradiator; (5) OR based intraoperative radiation therapy (IORT) unit.

P. Stereotactic Radiosurgery (SRS) – Means a procedure performed in a limited number of treatment visits, using a rigidly attached stereotactic guiding device, other immobilizing technology, and/or a stereotactic image-guided system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multisource Cobalt 60 units.

Q. SRS LINAC – Means a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components: (1) an advanced linear accelerator used to produce a high energy megavoltage of radiation; (2) a device which can point the linear accelerator from a wide variety of angles, and (3) an image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator. SRS LINAC includes units such as Cyberknives.

R. Treatment Simulation – Allows the therapist to determine positioning of the patient, shielding of adjacent body areas, and optimum radiation dosage. It permits a simulation or test of the chosen treatment parameters prior to actual treatment. Treatment simulation uses various modalities including diagnostic x-ray and fluoroscopic units, CT, and MRI.

III. CURRENT INVENTORY

HCA shall provide to each applicant a current inventory of existing MRT units in the state.

IV. NEED METHODOLOGY

A. Entities 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:

STUDY AREA/SERVICE AREA:

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

1. wherein at least 25% of the residents rely on acute care services in the county of proposal; and
2. which generates or will generate at least 10% of the patient load in the county of proposal.

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.

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

1. Applicants shall use the projected population for the proposed study area/service area for the third year of the project.
2. 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.
3. 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.
4. 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.

5. 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.

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. Entities seeking to replace MRT machines shall establish the need for replacement based on:

1. A patient load where each unit at the facility is performing at least 6,000 treatments per year; and/or
2. Documentation that the existing MRT machine can no longer be expected to function appropriately because:
 - a. maintenance and repair costs plus lost revenue as a result of excessive downtime becomes 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.

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. Entities 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.

E. Need Methodology Special Purpose Radiation Therapy Units - Applicants proposing to acquire a special purpose radiation therapy unit shall:

- Define the proposed service area by demonstrating that the facility can reasonably expect to serve persons from that area.
- For Gamma Knife units, document that 130 procedures will be performed by the end of the third year of operation. The need may be demonstrated by using cancer prevalence and cancer incidence rates to show the number of persons within the service area that can be appropriately treated using the special purpose radiation therapy unit, or by documenting the number of patients within the service area transferred out of the service area for special purpose radiation therapy services.

- For SRS LINAC units, document that 520 procedures will be performed by the end of the third year of operation. The need may be demonstrated by using cancer prevalence and cancer incidence rates to show the number of persons within the service area that can be appropriately treated using the special purpose radiation therapy unit, or by documenting the number of patients within the service area transferred out of the service area for special purpose radiation therapy services.
- Demonstrate that the proposed new service will not have an adverse impact on existing providers of the same service.
- Demonstrate the financial feasibility of the new service by the end of the third year of operation.

V. QUALITY

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

1. 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;
2. MRT services will be provided under the direction of an on-site licensed physician who is board-eligible or board-certified by The American Board of Radiology in Radiation Oncology. These personnel must be on-site, when services are being provided;
3. Applicants shall document that radiation oncology services will be provided by qualified professional personnel including a radiation oncologist and support personnel such as radiation therapists, medical radiation physicists, treatment planning staff, simulation staff, nursing, and ancillary personnel. These personnel must be on-site, when services are being provided; and,
4. 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 shall document the following:
 - a. Entities 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. Entities 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. Entities 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. Providers of MRT services shall provide directly or through contractual arrangements access to the following services:

- 1. Diagnostic - Services should include, but not be limited to, imaging (radiology, nuclear medicine, fluoroscopy, CT, MRI, ultrasound), hematology, and clinical and surgical pathology;
- 2. Consultation - Consultative services should include, at a minimum, internal medicine, surgery, oncology, pathology, radiology;
- 3. Social Services - Services provided should include those of a social worker, psychologist, or psychiatrist;
- 4. Rehabilitative/Supportive Services - Services should include social rehabilitation, occupational and physical therapy, nutrition counseling;
- 5. Treatment Services - Services should include treatment planning, dosimetry, teletherapy, local irradiation (surface, intracavitary, interstitial, and internal or systemic); and,
- 6. Tumor Registry - Each institution shall be affiliated with the West Virginia Cancer Registry.

VI. 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.

VII. 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.

VIII. ACCESSIBILITY

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

1. Written clinical criteria clearly specifying who is eligible for the service;
2. 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;
3. A scheduling priority system based on patient need; and,
4. Accessibility to the disabled in accordance with all applicable state and federal laws.