

MEGAVOLTAGE RADIATION THERAPY SERVICES

I. INTRODUCTION

Radiation oncology assumes a significant role in the medical management and treatment of patients with cancer. A relatively high percentage of all cancer patients will be treated with radiation therapy as an integral component of their care. Optimal use of radiation therapy requires detailed attention to personnel, equipment, patient and personnel safety, education and quality assurance. These standards document the appropriate use of therapeutic ionizing radiation.¹

II. DEFINITIONS

A. Brachytherapy – A type of radiation therapy, which involves applying a radioactive material within or in close approximation to the patient. This material may be contained in various types of apparatus, e.g., tubes, needles, wire, seeds, and other small containers. Interstitial, intracavitary, and surface applications are forms of brachytherapy.

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.

¹American College of Radiology Standards for Radiation Oncology

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. 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.

I. 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.

J. 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.

K. 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 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.

NEED METHODOLOGY:

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 patient 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.

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 will 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 will 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.