



STATE OF TENNESSEE

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

Megavoltage Radiation Therapy Services

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Megavoltage Radiation Therapy (MRT) Services. Rationale statements are provided for standards to explain the Division of Health Planning's (Division) underlying reasoning and are meant to assist stakeholders in responding to these Standards and to assist the HSDA in its assessment of certificate of need (CON) applications. Existing providers of MRT services are not affected by these Standards and Criteria unless they take an action that requires a new CON for such services.

These Standards and Criteria are effective immediately upon approval and adoption by the Governor. However, applications to provide MRT services that are deemed complete by the HSDA prior to the approval and adoption of these Standards and Criteria shall be considered under the 2011 Standards and Criteria for Megavoltage Radiation Therapy Services.

The Certificate of Need Standards and Criteria serve to uphold the Five Principles for Achieving Better Health set forth by the State Health Plan. Utilizing the Five Principles for Achieving Better Health during the development of the CON Standards and Criteria ensures the protection and promotion of the health of the people of Tennessee. The State Health Plan's Five Principles for Achieving Better Health are as follows:

1. **Healthy Lives:** The purpose of the State Health Plan is to improve the health of Tennesseans.
2. **Access:** Every citizen should have reasonable access to health care.
3. **Economic Efficiencies:** The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system.
4. **Quality of Care:** Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
5. **Workforce:** The state should support the development, recruitment and retention of a sufficient and quality health care workforce.

Definitions

External Beam Radiation Therapy (EBRT): Radiation therapy delivered by an MRT Unit from outside the body.

Image-Guided Radiation Therapy (IGRT): A procedure that uses a computer to create a picture of a tumor to help guide the radiation beam during radiation therapy. The pictures are made using CT, ultrasound, X-ray, or other imaging techniques. IGRT makes radiation therapy more accurate and causes less damage to healthy tissue.¹

Intensity-Modulated Radiation Therapy (IMRT): A type of 3-dimensional radiation therapy that uses computer-generated images to show the size and shape of the tumor. Thin beams of radiation of different intensities are aimed at the tumor from many angles. This type of radiation therapy reduces the damage to healthy tissue near the tumor, and can also called intensity-modulated radiation therapy.²

¹ National Cancer Institute Definition

² National Cancer Institute Definition

Linear Accelerator: A type of EBRT Unit that delivers a beam of high energy x-rays (photon or electron particles) from an external source to the location of the patient's tumor and/or other tissue being irradiated. Linear accelerators may deliver conventional EBRT, intensity modulated radiation therapy, image-guided radiation therapy, SBRT, and SRS services. Linear accelerators are the only MRT Unit type specifically listed in Tennessee Code Annotated Section 68-11-1607 (a)(4) as requiring a CON in order for services to be initiated. Select linear accelerators (hybrids) are capable of performing IGRT, IMRT, SRS, and SBRT services.

Select linear accelerators, hybrids, are capable of performing IGRT, IMRT, SRS, and SBRT services.

Megavoltage Radiation Therapy Procedure (MRT): Each discrete MRT treatment related to services performed on a single patient during a single visit, designated by CPT code. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes.

Megavoltage Radiation Therapy Unit (MRT): Medical equipment that performs radiation therapy using a linear accelerator.

On-Board Imaging (OBI): On-Board Imaging uses images obtained from the linear accelerator separate from patient delivery to confirm that a patient's therapy setup is accurate. Using these images, adjustments can be made to the patient's positioning on the treatment table or to the programmed settings on the linear accelerator.

Radiation Therapy: A medical procedure that allows non-invasive treatment of tumors and cancer cells using X-rays, gamma rays, and charged particles. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy). Radiation therapy delivered via high doses in five treatments or less is also known as Stereotactic Radiosurgery (SRS) when used to target lesions in the brain and as Stereotactic Body Radiotherapy (SBRT) or Stereotactic Ablative Radiotherapy (SABR) when used to target lesions in the body.

Standards and Criteria

1. Determination of Need: The following table outlines the utilization standards that should be used to determine need in the proposed service area.

a. These utilization standards were developed based on the following assumptions related to operating time:

- i. 8 hours per day,
- ii. 5 treatment days per week,
- iii. 52 weeks per year, and
- iv. 95% average up-time.

Type of Linear Accelerator	Estimated Patients Per Day	Capacity		
		Minimum (40%)	Optimal (80%)	Maximum (100%)
Non-IMRT, Non-IGRT	32	3162	6323	7904
IMRT only without OBI	32	3162	6323	7904
IMRT with OBI	38	3754	7509	9386
SRS only	14	1383	2766	3458
SBRT only	16	1581	3162	3952
Hybrid MRTs	32	3162	6323	7904

b. Applicants should use the treatment codes provided on the HSDA website to calculate utilization.

c. An applicant proposing a new Linear Accelerator should project a minimum of at least 3,162 MRT procedures in the first year of service in its proposed Service Area, building to a minimum of 6,323 procedures per year by the third year of service and for every year thereafter.

- d. Applicants should utilize the publicly available Tennessee’s Cancer Registry (<https://www.tn.gov/health/health-program-areas/tcr.html>) data to estimate the need within the proposed service area. These data should then be compared to the data included in the HSDA’s Medical Equipment Registry for the defined market to determine the need.

To estimate the number of radiation treatment patients in its proposed service area, the applicant should multiply the number of cancer patients by 60%. A minimum of 600 cancer patients and 360 radiation patients should reside in the proposed service area. Data included in the HSDA’s Medical Equipment Registry may also be used to determine the need for radiation services in the proposed service area.

- e. An exception to the standard number of procedures may occur as new or improved technology and equipment or new treatment applications for Linear Accelerators develop. Any applications seeking an exception to the standards and criteria must include information on the projected impact on existing services in the proposed service area. Data reported in the HSDA’s Medical Equipment Registry should also be used to estimate the impact of the proposed project on existing services for the proposed service area.

2. Relationship to Existing Similar Services in the Proposed Service Area: Applicants should provide an inventory of and assess all available technologies and utilization in the service area. Additionally, the applicant should provide evidence that volumes in the proposed service area will support the introduction of new MRT services without causing existing providers to fall below the minimum thresholds outlined in the following table.

Type of Linear Accelerator	Minimum (40)%
Non-IMRT, Non-IGRT	3162
IMRT only	3162
IMRT with OBI	3754
SRS only	1383
SBRT only	1581
Hybrid MRTs	3162

- a. Applicants should use the treatment codes provided on the HSDA website to calculate utilization.
- b. Applicants should utilize the data included in the HSDA's Medical Equipment Registry along with the publicly available Tennessee's Cancer Registry (<http://tn.gov/health/health-program-areas/tcr.html>) to estimate the capacity for all existing units located within the applicant's proposed service area.
- c. An exception to the need standards may occur as new or improved technology and equipment or new treatment applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed service area.

3. Establishment of Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Applicants should utilize the publicly available Tennessee's Cancer Registry (<https://www.tn.gov/health/health-program-areas/tcr.html>) data to estimate the need within the proposed service area. These data should then be compared to the data included in the HSDA's Medical Equipment Registry for the defined market to determine the need.

To estimate the number of radiation treatment patients in its proposed service area, the applicant should multiply the number of cancer patients by 60%. A minimum of 600 cancer patients and 360 radiation patients should reside in the proposed service area. Data included in the HSDA's Medical Equipment Registry may also be used to determine the need for radiation services in the proposed service area.

Otherwise, a service area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Additionally, the applicant must demonstrate that the patient origin of the proposed site aligns with other existing cancer-related healthcare services provided within the defined service.

4. Access to MRT Units

- a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed service area.
- b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed service area's population.
- c. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if those data are available).

5. Economic Efficiencies: All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

6. Separate Inventories for Linear Accelerators and for other MRT Units: A separate inventory shall be maintained by the HSDA for Linear Accelerators, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.

7. Patient Safety and Quality of Care: The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.
- b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
- c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice.

- d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.
- e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (NCI). Applicants should provide evidence of accreditation by ASTRO, ACR, or other similar accrediting authority either as a stand-alone facility or through that of a parent organization with oversight capabilities.
- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject's transfer agreement hospital medical staff.
- g. All applicants should demonstrate the ability to provide simulations and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.
- h. Applicants should provide evidence of plans for the radiation oncology physician treating patients to participate in consultative services and a multi-disciplinary cancer committee to ensure high quality treatment for the patients. Additionally, each center should have a dedicated radiation oncologist to serve as medical director with defined responsibilities overseeing quality assurance for the site.
- i. Treatment planning at off-site centers should be coordinated with a multi-disciplinary cancer center.

8. Data Requirements: Applicants shall agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

- 9. Services to High-Need and Underserved Populations:** Special consideration should be given to applicants providing services fulfilling the unique needs and requirements of certain high-need populations, including uninsured, low-income, and underserved geographic regions, as well as to other underserved population groups. This includes any applicant:
- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration,
 - b. Who is a “safety net hospital” or a “children’s hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program, and/or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.
- 10. Access:** An applicant should demonstrate an ability and willingness to serve equally all of the service area in which it seeks certification.
- 11. Adequate Staffing:** An applicant shall document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and that such personnel are available in the proposed service area.
- 12. Assurance of Resources:** The applicant shall document that it will provide the resources necessary to properly support the applicable level of services. Included in such documentation shall be a letter of support from the applicant’s governing board of directors, Chief Executive Officer, or Chief Financial Officer documenting the full commitment of the applicant to develop and maintain the facility resources, equipment, and staffing to provide the appropriate services. The applicant shall also document the financial costs of maintaining these resources and its ability to sustain them.
- 13. Quality Control and Monitoring:** The applicant shall identify and document its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring system.

14. Licensure and Quality Considerations: Any existing applicant for this CON service category shall be in compliance with the appropriate rules of TDH. The applicant shall also demonstrate its accreditation status with the Joint Commission or other applicable accrediting agency.