

**Technology and Equipment Committee
Agency Report
Adjusted Need Petition for a
Demonstration Project for Linear Accelerator Equipment in the
2026 State Medical Facilities Plan**

Petitioner:

Raleigh Neurology
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Contact:

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Request:

Raleigh Neurosurgical Clinic (RNC) requests an adjusted statewide need determination for one linear accelerator (LINAC) demonstration project, specifically for a self-shielded stereotactic radiosurgery (SS-SRS)-dedicated LINAC in the *2026 State Medical Facilities Plan (SMFP or “Plan”)*.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that “involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies.” Any person may submit a certificate of need (CON) application for a need determination in the *Plan*. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

Analysis/Implications:

Demonstrations are multi-year projects that address questions regarding a health care modality for which the utility or value is not yet known and/or that the current *SMFP* methodologies or policies do not address. Typically, projects compare the demonstration modality or approach to the current modality or approach. This allows Agency staff to assess whether the strategy being demonstrated can achieve outcomes aligned with the *SMFP*’s basic principles, such as reaching more patients in need of the service (i.e., underserved populations) or providing more timely access to the service. An examination of clinical effectiveness is beyond the scope of demonstration projects in Healthcare Planning.

The Petitioner does not clearly articulate the goals of the proposed demonstration project. Instead, they assert that the current methodology is geared toward traditional “vault-based” LINACs, and highlight the merits of SS-SRS LINACs over traditional units. The Petitioner also writes, “[c]urrently, self-shielded, SRS-dedicated linear accelerators are designed specifically for SRS focused on tumors, lesions, and conditions in the brain, head, and neck. This limited radiation patient population requires a larger service area, as compared to traditional linear accelerators” (Petition, page 6). Thus, the Petitioner appears to seek a new methodology or policy for specialized equipment or equipment for use only in specific settings rather than a request for a demonstration project.

The Agency receives petitions for the addition of policies and revisions of need determination methodologies during the Spring petition process. Precedents include the *SMFP*’s “Policy TE-2: Intraoperative Magnetic Resonance Imaging [MRI] Scanners”, and “Policy TE-4: Plan Exemption for Dual-Functioning Fixed PET Scanners in Mid-Size-Cancer Centers” which were developed from petitions that showed that the relevant need determination methodologies did not consider specialized equipment. Also, “Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners” provides an exemption for these scanners in specific hospital settings. Alternatively, the Petitioner could use the Spring petition process to request the exclusion of SS-SRS LINACs from requiring a need determination prior to the filing of a CON application. The *SMFP* contains several services, equipment and other assets that do not require a need determination to be placed in the *Plan* prior to the filing of a CON application (e.g., mobile MRI scanners, mobile PET scanners, heart-lung bypass machines, and residential hospice beds).

The Agency recognizes the value of a discussion of how SS-SRS LINACs may need to be considered separately from traditional LINACs in the *SMFP*. The State Health Coordinating Council Chair plans to convene a workgroup this Fall to address various issues surrounding LINACs. The workgroup may opt to consider policy or methodology changes that address the issues raised in the petition.

Agency Recommendation:

The Agency supports the standard LINAC methodology. Given available information submitted by the August 6, 2025 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition.