# Technology and Equipment Committee
# Recommendations to the NC State Health Coordinating Council
# June 5, 2024

The Technology and Equipment Committee has convened twice since the last full SHCC meeting, on April 3rd and May 15th.

The topics reviewed and discussed included:

- policies and methodologies related to technology and equipment, which were reviewed at the Committee's April meeting;
- an Agency proposal regarding linear accelerators (LINAC);
- petitions regarding intraoperative magnetic resonance imaging scanners (iMRIs) and positron electronic tomography (PET) scanners; and
- preliminary drafts of need projections for technology and equipment, based on the currently available data.

The following is an overview of the Committee's recommendations for the Technology and Equipment chapter for the *Proposed 2025 SMFP*.

## Cardiac Catheterization Equipment

The Committee received no petitions or comments regarding cardiac catheterization equipment. The Committee reviewed the policies and methodology for this equipment in April. Draft data tables were posted to the webpage and discussed during the May meeting. Based on data available at the time of the meeting, application of the methodology resulted in need determinations for four units of fixed cardiac catheterization equipment, one each in the Haywood, Johnston, New Hanover, and Wayne County service areas. There is no need determination for shared fixed cardiac catheterization equipment.

## Gamma Knives

The Committee received no petitions or comments regarding gamma knife equipment. The SMFP has no need determination methodology for Gamma Knives.

## Linear Accelerators

The Committee received no petitions from the public regarding linear accelerators (LINACs).

***Agency Proposal to Add a Policy Exemption for LINACs.*** However, at the March SHCC meeting, the Agency presented a proposal to add a policy that would

allow cancer treatment centers/oncology programs that do not have a LINAC to obtain one without regard to a need determination in the SMFP. The rationale for the proposal is based on the stance that LINAC is standard of care for the treatment of many types of cancers. The Agency staff's perspective was that this policy would be consistent with Policy TE-3, which allows acute care hospitals with 24-hour emergency care that do not have a magnetic resonance imaging scanner (MRI) to obtain one without regard to a need determination in the SMFP because MRIs are also considered standard of care. The Agency received six comments in opposition to this proposal. Authors of these comments expressed the adequacy of the current methodology and summer petition process; a concern for quality of care and patient safety if LINACs are allowed to proliferate in smaller centers; and the fact conditions that precipitate the use of MRIs and LINACs are dissimilar, and thus the proposed policy is not analogous to Policy TE-3 for MRIs. The Agency recommended the Committee further deliberate on this matter at its April meeting. The Committee decided to revisit the topic in the Spring of 2025.

The Committee reviewed the policies and methodology for this LINACs in April. Draft data tables were posted to the webpage and discussed during the May meeting. Based on data available at the time of the meeting, application of the methodology resulted in a need determination for one LINAC in Service Area 7, which consists of Anson, Mecklenburg, and Union counties.

## Lithotriptors

The Committee received no petitions or comments regarding lithotriptors.

The Committee reviewed the policies and methodology for this equipment in April. Draft data tables were posted to the webpage and discussed during the Committee's second meeting. Based on data available at the time of the May meeting, application of the methodology resulted in no need determinations for additional lithotriptors.

## Magnetic Resonance Imaging Scanners

The Committee received one petition regarding Intraoperative Magnetic Resonance Imaging, or iMRI, scanners. This was reviewed at the Committee's April meeting.

***Atrium Health*** petitioned to revise the language in *Policy TE-2: Intraoperative Magnetic Resonance Imaging Scanners* so that these scanners can be used for selected outpatient procedures. There was one letter of opposition submitted to the Agency. Among other conditions, the current Policy TE-2 requires that the applicant is an acute care hospital that is in a metropolitan statistical area with at least 350,000 residents, performs a certain number of neurosurgical cases, and has at least two neurosurgeons performing intracranial surgeries. The current policy also stipulates that iMRI cannot be used for outpatients. However, due to advancements in health care, it is now also used in other procedures that may or

may not be surgical, including outpatient procedures. The Agency recommended approving the petition to modify the policy's language so that iMRIs can be used for selected outpatient procedures. According to Agency staff review, iMRIs can be better utilized to meet patient needs by removing the policy limitations on the types of procedures for which iMRIs can be used, and by eliminating the requirement that the procedures are inpatient only. Further, the policy revision is unlikely to lead to the proliferation of iMRIs because a substantial neurosurgery program is necessary to support an iMRI. The Agency also recommended additional policy language revisions that would remove the neurosurgery-related restrictions in the policy but leave the population threshold and hospital-based requirements in place. The Committee agreed with the Agency's recommendations.

The Committee reviewed the policies and methodology for MRIs in April. Draft data tables were posted to the webpage and discussed during the May meeting. Based on data available at the time of the meeting, application of the methodology resulted in need determinations for 12 fixed MRI scanners – one each in the following service areas:

- Alamance
- Catawba
- Durham/Caswell/Warren
- Guilford
- Mecklenburg
- Moore
- Nash
- New Hanover
- Onslow
- Union
- Wayne
- Wilkes

Application of the methodology also resulted in an additional need determination for 15 fixed MRIs in Pender County. Because this is the result of a data anomaly, the Agency recommended removal of this need determination and the Committee concurred.

## Positron Emission Tomography (PET) Scanners

The Committee received two petitions regarding PET scanners.

***Carteret Health*** submitted both petitions as alternative approaches to the Petitioner's request to lower the requirements for obtaining a fixed PET scanner so that cancer centers with lower volumes might be able to obtain machines that function both as PET scanners and LINAC simulators. One petition requested modifications to the fixed PET scanner methodology and the second petition

proposed the addition of a policy exemption for dual-functioning fixed PET scanners in “mid-sized” cancer centers in the 2025 SMFP. The Agency received 10 comments in support of these petitions and two in opposition. In its request to change the fixed PET scanner methodology, Carteret Health proposed lowering the number of ESTVs from 12,500 to 7,000. They also requested lowering the volume required on a fixed PET scanner by its third year of operation if it also functions as a linear accelerator. Under their proposal, the number of required PET scans would be 1,040 scans rather than 2,080. The Agency noted that any potential modifications to the methodology would need to be examined by Agency staff, SHCC members and field experts through workgroups or meetings of interested parties and that changes to performance standard thresholds must be addressed through the rulemaking process.

The policy proposed in Carteret Health’s alternative petition would provide an exemption, under certain conditions, for mid-size cancer centers that do not have existing or CON-approved fixed PET scanners to obtain one without regard to a need determination. The Agency found support for the following items of the policy: 1) limiting the exemption to acute care hospitals with two linear accelerators; 2) requiring that the acquired machine function as both a PET scanner and a linear accelerator simulator; and 3) stipulating that the applicant demonstrate that it would perform at least 1,040 PET procedures during the third full operating year. However, the Agency did not find support for the condition in the proposed policy that would require applicants to already offer mobile PET scanning services for exemption under the policy.

The Petitioner suggested delineating ‘mid-size’ cancer centers from major cancer centers by employing a system designed by the American College of Surgeons, whereby facilities are grouped based on their number of newly diagnosed cancer cases. Since the Agency does not collect data on the number of newly diagnosed cancer cases, it proposed using the number of ESTV procedures to define mid-sized centers. Based on their review of the data, staff recommended that the policy language define eligible hospitals as those that performed an average of between 3,126 and 6,249 ESTV procedures on a LINAC during the most recent data year.

The Agency recommended denial of the petition to modify the need determination methodology for fixed PET scanners, but approval of the petition to add a policy for fixed PET scanners that included Agency staff’s edits to the Petitioner’s proposed policy. The Committee concurred with the Agency’s recommendations.

The Committee reviewed the policies and methodology for PET scanners at its first meeting. Draft data tables were posted to the webpage and discussed during the May meeting. Based on data available at the time of the meeting, application of the methodology resulted in need determinations for four fixed PET scanners – one each in Health Service Areas I and II, and two in Health Service Area IV.

## Recommendation for Chapter 15: Technology & Equipment for the Proposed 2025 SMFP

The Committee recommends that the State Health Coordinating Council (SHCC) approve the policies, methodologies, and draft need determinations for all sections of Chapter 15 for the Proposed 2025 SMFP. Also, the Committee recommends that the SHCC authorize staff to update chapter narratives, tables, and need determinations as necessary.