POSITRON EMISSION TOMOGRAPHY SCANNER

Definition
Positron Emission Tomography (PET) Scanner as defined in General Statute § 131E-176(19a), means "Equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures."

From its introduction in the mid-1980s, until the last few years, PET scanning was used more in research than clinical practice. Early clinical applications focused on the heart and the brain.

Now, the clinical uses of PET scanning include applications that involve the diagnosis of cancer. At North Carolina's most active PET facilities, the diagnosis of cancer accounts for more than 80 percent of clinical studies.

A PET scanner is a device with multiple radiation detectors designed to detect the two simultaneous photons emitted from the body after positron annihilation. Positron annihilation occurs after a positron (a sub-atomic particle) is emitted from certain radioactive substances. Such events are recorded over the course of a scan and subsequently reconstructed via computerized techniques into images. These images represent the cross-sectional distribution of the radioactive (positron-emitting) tracer in the body. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used both to diagnose physical abnormalities and to study body functions in normal subjects.

PET differs from other nuclear medicine both in the type of radiation emitted and in the type of scanner required to detect it. The radioactive tracers used in PET imaging may be produced on-site with a cyclotron (or generator, for some tracers) and appropriate chemistry labs, or may be ordered from commercial distributors, even though all PET tracers are relatively short-lived (110 minutes is the longest half-life). Therefore, the capital costs associated with developing the equipment capable of PET scanning can range from a few hundred thousand dollars (for the gamma camera being upgraded with coincident circuitry to perform PET scans) to less than one million dollars (for a low-end scanner) to several million dollars for a high-end scanner, a cyclotron, and associated chemistry capabilities.

Coincidence cameras are "built" by adding electronic circuitry to gamma cameras. The coincident circuitry makes it a PET system. The coincidence camera is nuclear medicine equipment that is designed, built or modified to detect only the single photon emitted from nuclear events other than positron annihilation. This hybrid machine is used as a gamma camera 90-95 percent of the time to perform non-PET imaging; thus, coincidence cameras are non-dedicated PET scanners.

The first PET scanners were dedicated machines performing only that service, supported by cyclotrons on-site. However, PET scanners also include hybrid machines, performing a variety of nuclear medicine studies and supported by new tracer production facilities housing cyclotrons in stand-alone facilities.

All these machines are PET scanners as defined in G.S. § 131E-176(19a), but they vary widely in their capabilities. The less expensive hybrid devices are capable of disclosing the presence of lesions as small as 1.5 to 2 centimeters, while the better dedicated scanners can disclose lesions as small as 0.5 to 1 centimeter. Because they can provide definitive studies for many patients and because they cost less, hybrid devices have quickly found a market.

The leading impetus to hybridization is the fact that the technology is rapidly improving. As a result, less expensive devices are now better than their predecessors and higher-end dedicated scanners are being

adapted to include computed tomography (CT) scanners, which will give them the capacity to perform, more accurately, the range of studies now performed on hybrid machines. Additionally, mobile PET scanners are available, and the number in operation in the United States is growing.

Dedicated PET scanners can be fixed or mobile. Mobile PET scanner means a dedicated PET scanner and its transporting equipment that is moved to provide services at two or more host facilities.

The rapid improvements in the equipment are being driven both by the rate of technological advances and by the steady growth in the number of clinical studies for which the Centers for Medicare & Medicaid Services (CMS) authorizes reimbursement. Among oncologists, oncologic surgeons, and radiation oncologists, PET is already recognized as essential to the diagnosis and treatment of patients with melanoma, colorectal cancer, lung cancer and lymphoma. CMS has approved reimbursement for studies for patients with solitary pulmonary nodules, carcinoma of the lung (non-small cell), melanoma, colorectal cancer, lymphoma, head and neck tumors, esophageal cancer, breast cancer, refractory seizures, perfusion of the heart, and questions concerning myocardial viability.

Facility Inventory-Service Volume

There are 28 approved or operational fixed dedicated PET scanners in North Carolina. Duke University Hospital acquired a cyclotron generated fixed dedicated PET scanner in 1985. During the following years, North Carolina Baptist Hospital, Carolinas Medical Center (CMC) and University of North Carolina (UNC) Hospitals also acquired a cyclotron generated fixed dedicated PET scanner each. Vidant Medical Center, Rex Hospital, Mission Hospital, New Hanover Regional Medical Center, Catawba Valley Medical Center/Frye Regional Medical Center (joint ownership), Cape Fear Valley Medical Center, FirstHealth Moore Regional Hospital, Novant Health Forsyth Medical Center, Cone Health, CaroMont Regional Medical Center, Carolinas Medical Center - NorthEast, CarolinaEast Medical Center, Novant Health Presbyterian Medical Center, High Point Regional Health and Wake PET Services were approved for each entity to acquire one fixed dedicated PET scanner. Duke University Hospital, CMC and UNC Hospitals were also approved to acquire a second fixed dedicated PET scanner. There were three additional need determinations in the North Carolina 2006 State Medical Facilities Plan, one each in HSAs II, III, and VI. Alamance Regional Medical Center, Iredell Memorial Hospital, and Nash General Hospital were approved in 2007 to acquire fixed dedicated PET/CT scanners. In the 2008 State Medical Facilities Plan, there were two need determinations, one each in HSAs II and III. Novant Health Forsyth Medical Center was approved to acquire a second fixed PET/CT scanner and CMC-Union was approved to acquire a fixed PET scanner. The 2013 State Medical Facilities Plan identified the need for one additional fixed dedicated PET scanner in HSA II. North Carolina Baptist Hospital was approved in 2014 to acquire a second dedicated PET/CT scanner. The reported number of procedures performed on these fixed dedicated PET scanners for the years ending 9/30/2010, 9/30/2011, 9/30/2012, and 9/30/2013 are reflected in Table 9L. Table 9L is followed by Tables 9M(1) and 9M(2), which reflect the reported number of procedures performed on mobile dedicated PET scanners for the years ending 9/30/2010, 9/30/2011, 9/30/2012, and 9/30/2013.

Fixed Dedicated PET Scanner Need Methodology

A fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located. The HSAs are the six multi-county groupings as defined in Appendix A of the North Carolina Proposed 2015 State Medical Facilities Plan.

~~A mobile PET scanner's service area is the planning region in which the scanner is located. There are two mobile PET scanner planning regions, the west region (HSAs I, II, and III) and the east region (HSAs IV, V, and VI).~~

A mobile PET scanner has a statewide service area.

One additional fixed dedicated PET scanner is needed for each existing fixed dedicated PET scanner that was utilized at or above 80 percent of capacity during the 12-month period reflected in the owner's "2014 Hospital Licensure Renewal Application" or "2014 Registration and Inventory of Medical Equipment Form" for PET scanners on file with the North Carolina Division of Health Service Regulation.[1] In the 2009 State Medical Facilities Plan, the North Carolina State Health Coordinating Council approved a change in the annual capacity for fixed dedicated PET scanners from 2,600 to 3,000 procedures. For the purposes of this determination, the annual capacity of a fixed dedicated PET scanner is 3,000 (3,000 X .80 = 2,400) procedures.

The standard methodology used to determine need for fixed PET scanners is calculated as follows:

Methodology Part 1:

Step 1: Determine the planning inventory of all fixed PET scanners in the state, to include existing fixed PET scanners in operation, approved fixed PET scanners for which a certificate of need was issued but is pending development, and fixed PET scanners for which no certificate of need has been issued, because the decision on a need determination in a previous year is under review or appeal.

Step 2: For each facility at which a PET scanner is operated, determine the total number of procedures performed on all fixed PET scanners located at each facility as reported for the 12-month period reflected in the Hospital License Renewal Application or Registration and Inventory of Equipment on file with the North Carolina Division of Health Service Regulation.

Step 3: Multiply the number of fixed PET scanners at each facility by 3,000 procedures to determine the PET scanner capacity at each facility.

Step 4: Divide the total number of PET scanner procedures performed at each facility, as determined in Step 2, by the capacity calculated in Step 3. Multiply the results by 100 to convert the numbers to a utilization percentage.

Step 5: A need is determined for an additional fixed PET scanner if the utilization percentage is 80 percent or greater at a facility, except as provided in Step 8 for both parts of the methodology combined.

Methodology Part 2:

Step 6: Identify each major cancer treatment facility, program or provider in the state, i.e., providers that operate two linear accelerators and performed over 12,500 ESTV procedures in the 12-month period reflected on the Hospital License Renewal Application or Equipment Registration and Inventory Form.

Step 7: A need is determined for one additional fixed PET scanner if a major cancer treatment facility, program or provider identified in Step 6 is hospital-based and does

[1] The need generated by this part of the methodology may be met by any applicant, and not just the owner or operator of the scanner that has achieved the target utilization.

not own or operate a fixed dedicated PET scanner, except as provided in Step 8 for both parts of the methodology combined.[2]

Step 8: The maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology.

[2] The need generated by this part of the methodology may be met by any applicant, and not just a major cancer treatment facility, program, or provider that does not own or operate a fixed dedicated PET scanner.