

**Technology and Equipment
Committee Meeting**

**Positron Emission Tomography
(PET) Scanner
Material**

April 29, 2009

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-1980’s 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 use of PET scanning is increasing rapidly, and new applications involve the diagnosis of cancer. At North Carolina’s most active PET facilities, the diagnosis of cancer accounts for well over 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 a 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 cms., while the better dedicated scanners can disclose lesions as small as 0.5 to 1 cm. Because they can provide definitive studies for many patients and because they cost less, hybrid devices have quickly found a market. In fact, there are now over 85 dedicated scanners and more than 200 hybrid devices in the country.

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 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 are scanners used exclusively for PET imaging. 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 27 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 Hospitals, Carolinas Medical Center and University of North Carolina Hospitals also acquired a cyclotron generated fixed dedicated PET scanner each. Pitt County Memorial Hospital, Rex Hospital, Mission Hospitals, New Hanover Regional Medical Center, Catawba Valley / Frye Regional, Cape Fear Valley Medical Center, First Health Moore, Forsyth Medical Center, Moses Cone Health System, Gaston Memorial Hospital, NorthEast Medical Center, Craven Regional Medical Center, The Presbyterian Hospital, High Point Regional and Wake PET Services were approved for each entity to acquire one fixed dedicated PET scanner. Duke University Hospital, Carolinas Medical Center 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. The reported number of procedures performed on these fixed dedicated PET scanners for the years ending 9/30/2005, 9/30/2006, 9/30/2007 and 9/30/2008 are reflected in Table 9I.

Table 9I is followed by Tables 9J(1) and 9J(2), which reflect the reported number of procedures performed on mobile dedicated PET scanners for the years ending 9/30/2005, 9/30/2006, 9/30/2007 and 9/30/2008.

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.

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 as described in Appendix A) and the east region (HSAs IV, V, and VI as described in Appendix A).

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 twelve month period reflected in the owner's 2009 Hospital Licensure Renewal Application on file with the North Carolina Division of Health Service Regulation.¹ 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. 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. ~~;~~ and

The standard methodologies used to determine need for fixed PET scanners are calculated as follows:

Methodology 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 CON was issued but is pending development, and fixed PET scanners for which no CON has been issued because the decision on a need determination in a previous SMFP 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.

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.

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

Methodology 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 not own or operate a fixed dedicated PET scanner, except as provided in Step 8 for both methodologies combined.

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 by each methodology individually.

~~One fixed dedicated PET scanner is needed for each major cancer treatment facility that is hospital based and does not own or operate a fixed dedicated PET scanner.² For the purposes of this determination, a major cancer treatment facility, program, or provider is one that performed over 12,500 procedures/ESTVs in 2008 and has two operational linear accelerators, as reflected on the 2009 Hospital Licensure Renewal Application on file with the North Carolina Division of Health Service Regulation. The maximum need determination for an HSA in any one year will be two additional fixed dedicated PET scanners.~~

Need Determinations

The first part of the methodology indicates that there is no need for additional fixed dedicated PET scanners anywhere in the State. The second part of the methodology indicates that there is no need for any additional fixed dedicated PET scanners anywhere in the state. There is no need for any additional mobile dedicated PET scanners anywhere in the state.

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.

Table 9I: PET Scanner Utilization of Existing Fixed Dedicated Scanners

Center	Procedures				HSA	Inventory	Utilization Rate 2008 Procedures/ 3000 as Capacity	Need Determination by Criteria - 80% of Present Capacity
	2004- 2005	2005- 2006	2006- 2007	2007- 2008				
Mission Hospitals (f)	875	1003	1607	1674	I	1	53.57%	
Catawba Valley/ Frye Reg. (j)	848	1258	1574	1597	I	1	52.47%	
N.C. Baptist Hospitals	1266	1477	1919	2011	II	1	67.03%	
Moses Cone Health System (o)	1352	1760	1955	NR	II	1	0.00%	
Forsyth Medical Center (p)	1579	2417	2983	3208	II	2	53.47%	
High Point Regional (r)	356	574	785	1101	II	1	36.70%	
Alamance Reg. Medical Ctr. (u)		374	480	37	II	1	1.23%	mobile procedures, too
Carolinas Med Center(a),(k)	3049	3635	3654	3510	III	2	58.50%	
CMC-Union				400	III	1	13.33%	
Gaston Memorial Hospital/CIS Summit (m)	700	846	984	870	III	1	29.00%	
CMC-NorthEast Medical Center (n)	481	615	818	868	III	1	28.93%	
The Presbyterian Hospital (q)	1544	1988	2173	2062	III	1	68.73%	
Iredell Memorial Hospital (t)			NA	306	III	1	10.20%	
Duke Univ. Hospital (d)	3091	3596	3858	3924	IV	2	65.40%	
UNC Hospitals (b)	1144	1386	1878	1553	IV	2	51.77%	
Rex Hospital (e)	1544	1913	2139	1704	IV	1	56.80%	
Wake PET Services, Wake Radiology Oncology, Wake Radiology (s)		NA	NA	NA	IV	1	0.00%	
New Hanover Reg. Med. (g)	582	755	895	1020	V	1	34.00%	
Cape Fear Valley Medical Ctr. (h)	1218	2069	2268	NA	V	1	0.00%	
First Imaging of the Carolinas (i)	529	550	865	1025	V	1	34.17%	
Pitt Co. Memorial (c)	393	832	981	1120	VI	1	37.33%	
Craven Regional Medical (1)	719	831	852	869	VI	1	28.97%	
Nash General Hospital (u)		336	421	0	VI	1	0.00%	mobile procedures only
TOTAL	21,270	28,215	33,089	28,859		27		0

NA Not Applicable for time period ending September 30, 2008.

NR No Report at this time.

(a) Approved for additional scanner in November 2001.

(b) Approved for scanner in June 2000 and additional scanner under Policy AC-3 in November 2005.

(c) Approved for scanner in August 2001.

(1) Approved for scanner in October 2003.

(m) Approved for scanner in December 2003.

(n) Approved for scanner in December 2003. Operational in October 2004.

Table 9J(1): PET Scanner Provider of Mobile Dedicated Scanners

PET Scanners Planning Region	Provider	Procedures	Inventory	Utilization Rate
				Year 2008 Procedures / 2600 as Capacity
1 (HSAs I, II, III)	Alliance Imaging	3196	1	
2 (HSAs IV, V, VI)	Alliance Imaging	2619	1	
TOTAL		5,815	2	

Table 9J(2): PET Scanner Sites Utilization of Existing Mobile Dedicated Scanners

Center					HSA	Sites	Utilization Rate	Need Determination by Criteria - 80% of Present Capacity
	2004-2005	2005-2006	2006-2007	2007-2008			Year 2008 Procedures/ 2600 as Capacity	
Caldwell Memorial Hospital			78	143	I	1	6%	
Cleveland Regional	38	67	190	278	I	1	11%	
Grace Hospital	77	101	78	93	I	1	4%	
Margaret Pardee		113	178	141	I	1	5%	
Park Ridge		91	216	205	I	1	8%	
Rutherford Hospital				6	I	1	0%	
Valdese Hospital	97	101	105	108	I	1	4%	
Watauga Medical Center	62	101	123	138	I	1	5%	
West Care Harris Regional		197	241	251	I	1	10%	
Alamance Regional	288	374	471	440	II	1	17%	
High Point Regional	356	16	0	0	II	1	0%	
Hugh Chatham	50	84	103	138	II	1	5%	
Northern Hospital Surry		90	129	189	II	1	7%	
CMC - Union		60	350	350	III	1	13%	
Gaston Memorial	0	0	0	0	III	1	0%	
Lake Norman Medical Center			121	199	III	1	8%	
Northeast Medical Center	0	0	0	0	III	1	0%	
Rowan Regional	478	290	443	517	III	1	20%	
Duke Raleigh Hospital	201	303	375	554	IV	1	21%	
FirstHealth Moore	529	0	0	0	V	1	0%	
Scotland Memorial	76	93	155	117	V	1	5%	
Southeastern Regional	211	268	274	290	V	1	11%	
Albemarle Hospital	458	261	268	250	VI	1	10%	
Lenoir Memorial Hospital				235	VI	1	9%	
Nash General Hospital	240	336	423	434	VI	1	17%	
Wayne Memorial	255	190	274	418	VI	1	16%	
Wilson Medical Center	205	292	267	321	VI	1	12%	
TOTAL	3,621	3,428	4,862	5,815		27		0