COMMENTS

To the State Health Planning Section
Related to Petitions for Mobile PET Services for
The 2015 State Medical Facilities Plan

Submitted by:
Catawba Valley Medical Center
810 Fairgrove Church Road, SE
Hickory, NC 28602
828-326-3800
J. Anthony Rose, FACHE
President and CEO
Contact: lhamby@catawbavalleymc.org

Background

On March 5, 2014, the SHCC Technology Committee received a number of petitions to revise the need determination for PET scanners in North Carolina to eliminate the East/West service areas for mobile scanners and to identify the need for additional mobile scanners in the 2015 SMFP. In one petition, submitted by MedQuest Associates, Inc., and Novant Health, Inc., the petitioners further requested that hospitals with more than two PET/CT scanners be allowed to replace one with a mobile PET/CT unit. In a second, Alliance, Inc. requested that in addition to expanding the need for mobile scanners identified in the 2015 SMFP, that potential host sites be expanded to include treatment centers with linear accelerators and Independent Diagnostic Treatment Facilities. As outlined below, both these proposals will result in a duplication of existing resources at a time when utilization rates are falling and industry concerns regarding over-utilization of complex imaging services, unnecessary radiation exposure, and improved cost management are likely to continue to place downward pressure on PET volumes.

SMFP Basic Principle: Safety and Quality

The most basic principle of the SMFP is to assure safety and quality of the health services provided in North Carolina. The Petitioners failed to address this most basic principle in requesting that mobile PET services be expanded. Image quality has been significantly improved in the more recent models and those combined with CT allow them to "... more accurately perform the range of studies now performed on hybrid machines." [1] Older PET scanners are unable to distinguish lesions as small as newer models or those combined with CT scanners. Reduced scan times also improve image quality by

[1] "Positron Emission Scanner," 2014 State Medical Facilities Plan. Date accessed March 18, 2014, http://www.ncdhhs.gov/dhsr/ncsmfp/2014/2014smfp.pdf.

reducing the risk of patient movement that can lead to the increased likelihood of motion-based image artifacts. [2] Later model scanners are thus able to reduce scan time, improve image detection, and reduce user error which can lead to costly re-scans.

Improved image scan time has become increasingly important as providers seek to reduce patients' exposure to radiation. Patient risks associated with exposure to radiation through complex imaging services is now a concern for regulators, accreditation bodies, and patients. Recently, The Joint Commission issued pre-publication standards effective July 1, 2014 to improve the safety of complex imaging services provided by accredited organizations.[3] While most of these standards relate to safety monitoring, new requirements have also been issued for provider qualifications for radiologists interpreting CT scans which will likely be expanded to include other complex imaging modalities in future, including PET and/or PET/CT.[4]

Patient safety can best be assured by ensuring all mobile PET sites meet these expanding safety requirements. Expanding mobile PET sites to include providers that are not required to meet these standards will undermine efforts to reduce radiation exposure, improve safety and quality, and duplicate costly technologies already available throughout the state.

Expanding the number of sites at which PET scans are offered is likely to further dilute the volume of scans performed at existing providers without significantly improving access. A study published in 2012 by IMV Medical Information Division, found that 1.85 million PET and PET/CT procedures were performed in the U.S. in 2011, a 6% increase from 2010. On the other hand, utilization per site rose only 0.6%.[5] This suggests that increases in PET utilization are slowing. This trend is likely to continue into the foreseeable future as providers seek ways to reduce unnecessary utilization and overall health system costs.

The number of PET scans performed in North Carolina is clearly declining according to volumes contained in the 2014 State Medical Facilities Plan, Tables 9M (1) and (2).

---

[2] "The end of stop and go," Biograph mCT Flow Brochure, http://www.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@global/@imaging/@molecular/documents/download/mdax/njgy/~edisp/biograph_mct_flow_brochure_final_june-00852312.pdf

[3] The Joint Commission Perspectives, January 2014, Volume 34, No. 1, pages 5 and 19. See Attachment 1.

[4] Standards Field Review, Diagnostic Imaging Standards Changes for Radiologists' Qualifications and Competency, Publish Date: Feb 27, 2014. See Attachment 1.

[5] Brice, James, "New PET/CT facilities power utilization growth, excerpted from Aunt Minnie.com, Last Updated 8/20/2012 4:08:04 PM. See Attachment 2.

North Carolina PET Scanning Volume

	Fixed PET Scans	Mobile PET Scans	Total PET Scans	Percent Ann. Chng
2007-08	32,831	5,815	38,646	
2008-09	36,879	5,258	42,137	9.0%
2009-10	36,622	5,138	41,760	-0.9%
2010-11	34,900	5,716	40,616	-2.7%
2011-12	32,729	5,571	38,300	-5.7%

Not only is the total volume of PET scans declining, so is the rate of scans per 1,000 population.

North Carolina PET Use Rates: 2008 - 2012

	Fixed PET Scans	Mobile PET Scans	Total PET Scans	NC Population	Use Rate/ 1,000 Pop
2007-08	32,831	5,815	38,646	9,278,794	4.16
2008-09	36,879	5,258	42,137	9,435,396	4.47
2009-10	36,622	5,138	41,760	9,574,477	4.36
2010-11	34,900	5,716	40,616	9,666,068	4.20
2011-12	32,729	5,571	38,300	9,765,229	3.92

Source: Volumes excerpted from State Medical Facilities Plan, Population from Office of State Management and Budget.

This decline has occurred in even in the face of increasing cancer incidence rates. According to the NC Cancer Registry, the total age-adjusted cancer incidence rate for the period 1997-2001 was 445.3 per 100,000. For the period 2007 – 2011, cancer incidence rose to 496.7 per 100,000. Despite this fact, the volume of PET scans has declined in North Carolina. This suggests that the need for PET scanners is not simply a function of the incidence of cancer or of an aging population.

As a result, the projected number of PET scans needed by North Carolina residents is unlikely to exceed existing supply for the foreseeable future. Assuming that the 2011-12 use rate remains unchanged at 3.92 per 1,000 population, the total number of projected PET scans in 2019 would equal 41,199 ((10,509,938 Projected July 2019 Population X 3.92)/1000 = 41,199 PET Scans). Thus, the projected number of PET scans remains well even today's existing capacity of 70,000 PET scans annually. (27 fixed scanners X 2,400 annual capacity = 64,800 + 2 mobile scanners X 2,600 annual capacity = 5,200 for total annual capacity of 70,000 PET scans.) Expanding the number of sites at which PET is available will only serve to dilute the volume at existing providers.

Expanding the number of mobile PET scanners is also likely to unnecessarily duplicate existing resources due to the increasing capacity of the newest scanners. Today's units are capable of significantly reducing scan times and, therefore, increasing capacity. With the latest scanners, whole body scans can be completed in as little as five to fifteen minutes compared to 45 to 60 minutes with older units.[6] As a result, many scan times are reduced by half without compromising image quality. This is accomplished by replacing the conventional "stop and go" technology with a single continuous motion of the patient table and with Time of Flight (TOF) which improves signal to noise by a factor of two.[7] In addition, the newer models provide organ-focused protocols in a single scan.[8] Conventional PET scanners require a two-scan protocol, thereby reducing scan times up to 25 percent.[9] This technology is not currently available through mobile providers due to its extensive cooling and space requirements. Continuing to expand the number of mobile scanners will not improve residents' access to these technological advancements that improve quality and safety as well as capacity.

While newer PET/CT scanners may increase per scanner capacity, they could also serve to reduce the number of scans required to make a definitive diagnosis. Greater image quality can reduce the need for repeat scans which result in unnecessary costs and increased patient anxiety. Such advances could serve to further dampen increases in PET volumes in future.

The potential for inappropriate use is also a concern. Studies increasingly suggest that imaging modalities are over-utilized. Multiple studies have shown that 20 percent to 40 percent of high-tech diagnostic imaging modalities fail to provide information that improves patient diagnosis and treatment and may be considered redundant or unnecessary.[10] More recently, the Choosing Wisely® initiative of the ABIM Foundation has identified specific exams that should be avoided because they may not be necessary and may cause harm, including several PET scans.[11] Avoiding unnecessary testing, particularly complex imaging modalities, is crucial to controlling health care costs. As the

---

[6] Brian Clement, "What's Driving PET/CT Growth?, The Advisory Board Company March 31, 2012, http://www.advisory.com/research/oncology-roundtable/oncology-rounds/2012/05/what-is-driving-pet-ct-growth. See Attachment 2.

[7] http://www.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@global/@imaging/@molecular/documents/download/mdax/njgy/~edisp/biograph_mct_flow_brochure_final_june-00852312.pdf.

[8] Ibid.

[9] Ibid.

[10] Ensuring Quality through Appropriate Use of Diagnostic Imaging, July 2008, America's Health Insurance Plans, pg.2.

[11] http://www.choosingwisely.org/wp-content/uploads/2013/02/Choosing-Wisely-Master-List.pdf accessed 3/19/14, pages 8, 75 and 119, An Initiative of the ABIM Foundation.

health care industry moves from a fee-for-service payment model to a value based one, providers will be incentivized to ensure that high-cost modalities such as PET are used judiciously.
Expanding mobile PET sites to include existing oncology treatment centers with one or more linear accelerators and existing or proposed Independent Diagnostic Testing Facilities (IDTFs) could further contribute to over-utilization of this complex imaging modality. IDTF services have historically been vulnerable to fraud, waste, and abuse.[12] In addition, the General Accounting Office has identified that physician self-referral creates financial incentives that can lead to overutilization of health care services, unnecessary spending and inappropriate, sometimes unnecessary, care for patients. [13] In a study published in 2012 addressing use of MRI and CT, the GAO found utilization twice as high for self-referring providers as for those that were not.[14] Expanding host sites to include IDTFs and free-standing treatment centers could increase the potential for over-utilization. As health care providers and payers seek ways to better manage patient costs, controlling the over-utilization or complex imaging modalities will be a primary area of focus.

SMFP Basic Principle: Access

The number of sites offering PET scanning has increased significantly in recent years. As a result, services are well distributed throughout the state at 23 fixed site locations and 29 mobile sites. However, improved geographic distribution does not improve access for all residents.[15] Because of the size of the bore in many of the older PET scanners, obese patients may not be appropriate candidates for scanning in the mobile units. According to the Centers for Disease Control, more than one-third of Americans are obese.[16] The same study placed North Carolina's prevalence of obesity at 29.6%. Obesity is a particular problem for the African-American community. Non-Hispanic blacks have the highest age-adjusted rates of obesity (49.5%) compared with Mexican Americans (40.4%), all Hispanics (39.1%) and non-Hispanic whites (34.3%).[17] For this reason, mobile PET scanners may do little to improve access to communities with significant non-white populations. Even though the mobile PET scanners may be capable of handling a patient weighing up to 450 pounds, the space available within the mobile unit may not accommodate a bariatric wheelchair or provide the space necessary to transfer a non-ambulatory patient to the table for scanning.

---

[12] "Questionable Billing for Medicare Independent Diagnostic Testing Facility Services," DHHS Office of the Inspector General, page 1, March 2012 OEI-09-09-00380.

[13] Higher Use of Advanced Imaging Services by Providers Who Self-refer Costing Medicare Millions, Government Accounting Office, September 2012.

[14] Ibid.

[15] Map indicating location of fixed and mobile PET scanner sites, Attachment 3.

[16] Cynthia L. Ogden, Ph.D.; Margaret D. Carroll, M.S.P.H.; Brian K. Kit, M.D., M.P.H.; and Katherine M. Flegal, Ph.D NCHS Data Brief, Volume 82, January 2012, Prevalence of Obesity in the United States, 2009-2010.

[17] http://www.cdc.gov/obesity/data/adult.html.

Patient safety and quality of care will best be assured by continuing to require that sites at which PET services are offered provide a comprehensive array of cancer diagnosis and treatment services. Lack of care coordination often leads to overtreatment, costing the United States between $158 and $226 billion annually.[18] Cancer patients account for 95% of PET scanning volume.[19] Of that, 38% of PET scans were associated with cancer staging, another 13% for treatment planning, and 30% pertained to suspected recurrence and therapy follow-up.[20] The complexity of cancer care management requires careful coordination between providers. This can best be achieved by continuing to require that PET providers, including host sites, provide access to range of cancer diagnosis, treatment, and management services.

SMFP Basic Principle: Value

The State Medical Facilities defines health care value as the maximum health care benefit per dollar expended. Significant capital outlays have been made by fixed PET scanner providers throughout the state. In addition, the volume of PET scans performed in North Carolina has declined in recent years. Whether this is a function of a sluggish economy, changes to benefit plans, providers' increasing use of evidence-based protocols, more engaged patients or some combination of these factors, downward pressure on PET volumes are unlikely to be reversed in the near term. Given these trends, increasing the number of mobile PET scanners is unlikely to significantly improve patient safety, quality of care, access, or value.

Conclusion

The purpose of the health planning function is to balance access, quality, and the cost of health care services provided in North Carolina. Ignoring trends that suggest a slowdown in PET scanner volume would lead to a duplication of costly technological resources. Capacity of PET scanners is improving as older models are replaced with scanners that improve scan times and image quality. Finally, approaches to cancer treatment are rapidly changing and may actually results in a reduction in the number of cancers treated aggressively in future. In total, these trends suggest the current number of PET scanners is sufficient to meet the population's projected need for the foreseeable future.

---

[18] Berwick, D., and A. Hackbarth. "Eliminating Waste in U.S. Health Care." *Journal of the American Medical Association*. 2012;307(14).

[19] Brice, James, "New PET/CT facilities power utilization growth," excerpted from Aunt Minnie.com, Last Updated 8/20/2012 4:08:04 PM. See Attachment 2.

[20] Ibid.

ATTACHMENT 1

Pre-publication Requirements for Diagnostic Imaging Services
And
Radiologists' Qualifications and Competency, Proposed Imaging Requirements

The Joint Commission

The Joint Commission

• Issued December 20, 2013 •

Prepublication Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives®*. To begin your subscription, call 877-223-6866 or visit http://www.jcrinc.com.

Joint Commission Requirement

Revised Requirements for Diagnostic Imaging Services

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective July 1, 2014

Environment of Care (EC)

Standard EC.02.01.01
The [critical access] hospital manages safety and security risks.

Elements of Performance for EC.02.01.01

A 14. For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital manages safety risks in the MRI environment associated with the following:

- Patients who may experience claustrophobia, anxiety, or emotional distress
- Patients who may require urgent or emergent medical care
- Patients with medical implants, devices, or imbedded foreign objects (such as shrapnel)
- Ferromagnetic objects entering the MRI environment
- Acoustic noise

A 16. © For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital manages safety risks by doing the following:

- Restricting access of everyone not trained in MRI safety or screened by MRI-trained staff from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
- Making sure that these restricted areas are controlled by and under the direct supervision of MRI-trained staff.
- Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI unit, by its design, can have its magnetic field routinely turned on and off by the operator.

Standard EC.02.02.01
The [critical access] hospital manages risks related to hazardous materials and waste.

Element of Performance for EC.02.02.01

A 17. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: Staff dosimetry results are reviewed at least quarterly by the radiation safety officer or diagnostic medical physicist to assess whether staff radiation exposure levels are "As Low As Reasonably Achievable" (ALARA) and below regulatory limits.

Note 1: *For the definition of ALARA, please refer to U.S. Nuclear Regulatory Commission federal regulation 10 CFR 20.1003.*

Key: A indicates scoring category A; C indicates scoring category C; © indicates that documentation is required; Ⓜ indicates Measure of Success is needed; ⚠ indicates an Immediate Threat to Health or Safety; ⚠ indicates situational decision rules apply; ⚠ indicates direct impact requirements apply; R indicates an identified risk area

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard EC.02.04.01
The [critical access] hospital manages medical equipment risks.

Element of Performance for EC.02.04.01

A 7. The [critical access] hospital identifies quality control and maintenance activities to maintain the quality of diagnostic images produced. The organization identifies how often these activities should be conducted. (*See also* EC.02.04.03, EP 15)

Standard EC.02.04.03
The [critical access] hospital inspects, tests, and maintains medical equipment.

Elements of Performance for EC.02.04.03

C 15. The [critical access] hospital maintains the quality of the diagnostic images produced. (*See also* EC.02.04.01, EP 7)

A 17. ◎ For [critical access] hospitals ~~in California~~ that provide diagnostic computed tomography (CT) services: ~~A qualified~~At least annually, a diagnostic medical physicist ~~measures~~does the following: ~~◎~~ ⚠

- Measures the ~~actual~~ radiation dose ~~*~~(in the form of volume computed tomography dose index [CTDIvol]) produced by each diagnostic CT imaging system ~~at least annually~~for the following four CT protocols: adult brain, adult abdomen, pediatric brain, and ~~verifies~~pediatric abdomen. If one or more of these protocols is not used by the [critical access] hospital, other commonly used CT protocols may be substituted.
- Verifies that the radiation dose (in the form of CTDIvol) displayed ~~on~~by the CT imaging system for ~~standard adult brain, adult abdomen, and pediatric brain protocols~~each tested protocol is within 20 percent of the ~~actual amount of radiation dose delivered.~~CTDIvol displayed on the CT console. The dates, results, and verifications of these ~~verifications~~measurements are documented.

Note 1: *This element of performance is ~~applicable~~ only applicable for systems capable of calculating and displaying radiation doses in the form of CTDIvol.*

~~* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.~~

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 19. ◎ For [critical access] hospitals that provide diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:

- Image uniformity
- Slice thickness accuracy
- Slice position accuracy (when prescribed from a scout image)
- Alignment light accuracy
- Table travel accuracy
- Radiation beam width
- High-contrast resolution
- Low-contrast resolution
- Geometric or distance accuracy
- CT number accuracy and uniformity
- Artifact evaluation

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 20. ◎ For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: At least annually, a diagnostic medical physicist or MRI scientist conducts a performance evaluation of all MRI imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:

- Image uniformity for all radiofrequency (RF) coils used clinically
- Signal-to-noise ratio (SNR) for all coils used clinically
- Slice thickness accuracy
- Slice position accuracy
- Alignment light accuracy

- High-contrast resolution
- Low-contrast resolution (or contrast-to-noise ratio)
- Geometric or distance accuracy
- Magnetic field homogeneity
- Artifact evaluation

A 21. ◎ For [critical access] hospitals that provide nuclear medicine (NM) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all NM imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluations are conducted for all of the image types produced clinically by each NM scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics:

- Image uniformity/system uniformity
- High-contrast resolution/system spatial resolution
- Low-contrast resolution or detectability (not applicable for planar acquisitions)
- Sensitivity
- Energy resolution
- Count-rate performance
- Artifact evaluation

A 22. ◎ For [critical access] hospitals that provide positron emission tomography (PET) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all PET imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluations are conducted for all of the image types produced clinically by each PET scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics:

- Image uniformity/system uniformity
- High-contrast resolution/system spatial resolution
- Low-contrast resolution or detectability (not applicable for planar acquisitions)
- Artifact evaluation

Note: *The following tests are recommended, but not required, for PET scanner testing: sensitivity, energy resolution, and count-rate performance.*

A 23. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), nuclear medicine (NM), or magnetic resonance imaging (MRI) services: The annual performance evaluation conducted by the diagnostic medical physicist includes testing of image acquisition display monitors for maximum and minimum luminance, luminance uniformity, resolution, and spatial accuracy.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard EC.02.06.05

The [critical access] hospital manages its environment during demolition, renovation, or new construction to reduce risk to those in the organization.

Elements of Performance for EC.02.06.05

A 4. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: Prior to installation of new imaging equipment, replacement of existing imaging equipment, or modification to rooms where ionizing radiation will be emitted or radioactive materials will be stored (such as scan rooms or hot labs), a medical physicist conducts a structural shielding design* to specify required radiation shielding.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

* For additional guidance on shielding designs and radiation protection surveys, see National Council on Radiation Protection and Measurements Report No. 147 (NCRP-147).

A 6. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: After installation of imaging equipment or construction in rooms where ionizing radiation will be emitted or radioactive materials will be stored, a medical physicist conducts a radiation protection survey to verify the adequacy of installed shielding.* This survey is conducted prior to clinical use of the room.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

* For additional guidance on shielding designs and

radiation protection surveys, see National Council on Radiation Protection and Measurements Report No. 147 (NCRP-147).

Human Resources (HR)

Standard HR.01.02.05
The [critical access] hospital verifies staff qualifications.

Elements of Performance for HR.01.02.05

C 19. ◎ For [critical access] hospitals that provide computed tomography (CT) services: Starting July 1, 2015, the [critical access] hospital verifies and documents that a radiologic technologist who performs CT exams has the following qualifications: Ⓓ

- Registered and certified by the American Registry of Radiologic Technologists (ARRT), or certified by the Nuclear Medicine Technology Certification Board (NMTCB)
- Trained and experienced in the operation of CT equipment

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

C 20. ◎ For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital verifies and documents that diagnostic medical physicists that support CT services have board certification in diagnostic radiologic physics or radiologic physics by the American Board of Radiology, or in Diagnostic Imaging Physics by the American Board of Medical Physics, or in Diagnostic Radiological Physics by the Canadian College of Physicists in Medicine, or meet all of the following requirements: Ⓓ

- A graduate degree in physics, medical physics, biophysics, radiologic physics, medical health physics, or a closely related science or engineering discipline from an accredited college or university
- Formal graduate-level coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or a similar topic related to the practice of medical physics
- Documented experience in a clinical CT environment conducting at least 10 CT performance evaluations under the direct supervision of a board-certified medical physicist

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard HR.01.05.03
Staff participate in ongoing education and training.

Elements of Performance for HR.01.05.03

A 14. ◎ For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital verifies and documents that radiologic technologists who perform CT examinations participate in ongoing education that includes annual training on radiation dose reduction techniques, Image Gently®, and Image Wisely®.

Note 1: *Information on the Image Gently® and Image Wisely® initiatives can be found online at http://www.imagegently.org and http://www.imagewisely.org, respectively.*

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 25. ◎ For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital verifies and documents that technologists who perform MRI examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following:

- Patient screening criteria that address ferromagnetic items, medical implants and devices, and risk for nephrogenic systemic fibrosis (NSF)
- Proper patient positioning activities to avoid burns
- Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional)*
- MRI safety response procedures for patients who require urgent or emergent medical care
- MRI equipment emergency shutdown procedures
- Patient hearing protection
- Management of patients with claustrophobia, anxiety, or emotional distress

** Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (http://www.astm.org).*

Medication Management (MM)

Standard MM.06.01.01
The [critical access] hospital safely administers medications.

Element of Performance for MM.06.01.01

A 13. Before administering a radioactive pharmaceutical for diagnostic purposes, staff verify that the dose to be administered is within 20% of the prescribed dose, or, if the dose is prescribed as a range, staff verify that the dose to be administered is within the prescribed range. ⚠3

Provision of Care, Treatment, and Services (PC)

Standard PC.01.02.15
The [critical access] hospital provides for diagnostic testing.

Elements of Performance for PC.01.02.15

C 5. ◎ For [critical access] hospitals ~~in California~~ that provide diagnostic computed tomography (CT) services: The [critical access] hospital documents in the patient's medical record the radiation dose ~~*~~(CTDIvol or DLP) on every study produced during a CT examination. ◍ ⚠3

Note 1: *This element of performance is ~~applicable~~ only applicable for systems capable of calculating and displaying radiation doses.*

Note 2: *This element of performance does not apply to systems used for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.*

~~* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.~~

Note 3: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

C 6. For [critical access] hospitals ~~in California~~ that provide diagnostic computed tomography (CT) services: The interpretive report of a diagnostic CT study includes the volume computed tomography dose index (CTDIvol) or dose-length product (DLP) radiation dose. ~~*~~ The dose is either recorded in the patient's interpretive report or included on the protocol page~~, which is then attached to the interpretive report~~. ◍

Note 1: *This element of performance is ~~applicable~~ only applicable for systems capable of calculating and displaying radiation doses.*

~~* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.~~

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

C 7. ~~For [critical access] hospitals in California that provide computed tomography (CT) services: The [critical access] hospital electronically sends each CT study and protocol page that lists the radiation dose * and related technical factors to the [critical access] hospital's electronic picture archiving and communications system.~~

Note: *~~This element of performance is applicable only for systems capable of calculating and displaying radiation doses.~~*

~~* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.~~

A 10. For [critical access] hospitals that provide diagnostic computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), or nuclear medicine (NM) services: Prior to conducting a diagnostic imaging study, the [critical access] hospital verifies the following: ⚠3

- Correct patient
- Correct imaging site
- Correct patient positioning
- For CT only: Correct imaging protocol
- For CT only: Correct scanner parameters

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 12. For [critical access] hospitals that provide diagnostic computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), or nuclear medicine (NM) services: The [critical access] hospital considers the patient's age and recent imaging exams when deciding on the most appropriate type of imaging exam. ⚠3

Note 1: *Knowledge of a patient's recent imaging exams can help to prevent unnecessary duplication of these examinations.*

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies*

performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Standard PC.01.03.01
The [critical access] hospital plans the patient's care.

Elements of Performance for PC.01.03.01

A 25. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital establishes imaging protocols based on current standards of practice, which address key criteria including clinical indication, contrast administration, age (to indicate whether the patient is pediatric or an adult), patient size and body habitus, and the expected radiation dose range. (*See also* PI.01.01.01, EP 46) ⚠

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 26. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: Imaging protocols are reviewed and kept current with input from an interpreting radiologist, medical physicist, and lead imaging technologist to make certain that they adhere to current standards of practice and account for changes in CT imaging equipment. These reviews are conducted at time frames identified by the organization. ⚠

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Performance Improvement (PI)

Standard PI.01.01.01
The [critical access] hospital collects data to monitor its performance.

Elements of Performance for PI.01.01.01

A 46. For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital collects data on patient burns that occur during MRI exams.

A 47. For [critical access] hospitals that provide magnetic resonance imaging (MRI) services: The [critical access] hospital collects data on the following:

- Incidents where ferromagnetic items entered the MRI scanner room
- Injuries resulting from the presence of ferromagnetic items in the MRI scanner room

Standard PI.02.01.01
The [critical access] hospital compiles and analyzes data.

Elements of Performance for PI.02.01.01

A 6. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital compiles and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Radiologists' Qualifications and Competency

Proposed Imaging Requirements

Applicable to Ambulatory Health Care:

HR.02.01.03, EP 39

For organizations that provide computed tomography (CT) services: At the time of granting initial privileges, the organization verifies and documents that a radiologist who interprets CT exams is board-certified in radiology or diagnostic radiology by the American Board of Radiology, American Osteopathic Board of Radiology, or an equivalent source. If the radiologist is not board-certified, then the organization verifies and documents that he or she has achieved the following qualifications and experience:

- Completed an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) diagnostic radiology residency
- Performance and interpretation of 500 CT examinations in the past 36 months

HR.02.01.03, EP 40

For organizations that provide computed tomography (CT) services: Upon renewal of privileges, the organization verifies and documents that a radiologist who interprets CT examinations has the following experience:

- The radiologist meets the Maintenance of Certification (MOC) requirements of the American Board of Radiology.
- For radiologists reading CT examinations across multiple organ systems, he or she has read 135 exams in the past 24 months.
- For radiologists reading organ system-specific CT examinations (for example, abdominal, musculoskeletal, head), he or she has read a minimum of 40 organ system-specific CT examinations in the past 24 months. In addition, he or she must have also read a total of 135 cross-sectional imaging studies for MRI, CT, PET/CT and ultrasound in the past 24 months.

HR.02.01.03, EP 41

For organizations that provide computed tomography (CT) services: Upon renewal of privileges, the organization verifies and documents the ongoing education of a radiologist who interprets CT examinations. Ongoing education must include As Low As Reasonably Achievable (ALARA), Image Gently, Image Wisely, and one of the following:

- Meets the Maintenance of Certification (MOC) requirements of the American Board of Radiology
- Completion of 100 hours of relevant continuing medical education (CME) in the past 24 months; this must include 50 hours of Category 1 CME
- Completion of 10 hours CME in the past 24 months specific to the imaging modality or organ system

Radiologists' Qualifications and Competency

Proposed Imaging Requirements

Applicable to Critical Access Hospitals:

MS.06.01.03, EP 10

For critical access hospitals that provide computed tomography (CT) services: At the time of granting initial privileges, the critical access hospital verifies and documents that a radiologist who interprets CT exams is board-certified in radiology or diagnostic radiology by the American Board of Radiology, American Osteopathic Board of Radiology, or an equivalent source. If the radiologist is not board-certified, then the critical access hospital verifies and documents that he or she has achieved the following qualifications and experience:

- Completed an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) diagnostic radiology residency
- Performance and interpretation of 500 CT examinations in the past 36 months

MS.06.01.05, EP 16

For critical access hospitals that provide computed tomography (CT) services: Upon renewal of privileges, the critical access hospital verifies and documents that a radiologist who interprets CT examinations has the following experience:

- The radiologist meets the Maintenance of Certification (MOC) requirements of their certifying body.
- A radiologist reading CT examinations across multiple organ systems has read 135 exams in the past 24 months.
- A radiologist reading organ system-specific CT examinations (for example, abdominal, musculoskeletal, head), has read a minimum of 40 organ system specific CT examinations in the past 24 months. In addition, he or she must have also read a total of 135 cross-sectional imaging studies for MRI, CT, PET/CT and ultrasound in the past 24 months

MS.06.01.05, EP 17

For critical access hospitals that provide computed tomography (CT) services: Upon renewal of privileges, the critical access hospital verifies and documents the ongoing education of a radiologist who interprets CT examinations. Ongoing education must include As Low As Reasonably Achievable (ALARA), Image Gently, Image Wisely, and one of the following:

- Meeting the Maintenance of Certification (MOC) requirements of their certifying body
- Completing 100 hours of relevant continuing medical education (CME) in the past 24 months; this must include 50 hours of Category 1 CME
- Completing 10 hours CME in the past 24 months specific to the imaging modality or organ system

Radiologists' Qualifications and Competency

Proposed Imaging Requirements

Applicable to Hospitals:

MS.06.01.03, EP 10

For hospitals that provide computed tomography (CT) services: At the time of granting initial privileges, the hospital verifies and documents that a radiologist who interprets CT exams is board-certified in radiology or diagnostic radiology by the American Board of Radiology, American Osteopathic Board of Radiology, or an equivalent source. If the radiologist is not board-certified, then the hospital verifies and documents that he or she has achieved the following qualifications and experience:

- Completed an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) diagnostic radiology residency
- Performance and interpretation of 500 CT examinations in the past 36 months

MS.06.01.05, EP 16

For hospitals that provide computed tomography (CT) services: Upon renewal of privileges, the hospital verifies and documents that a radiologist who interprets CT examinations has the following experience:

- The radiologist meets the Maintenance of Certification (MOC) requirements of their certifying body.
- A radiologist reading CT examinations across multiple organ systems has read 135 exams in the past 24 months.
- A radiologist reading organ system-specific CT examinations (for example, abdominal, musculoskeletal, head), has read a minimum of 40 organ system specific CT examinations in the past 24 months. In addition, he or she must have also read a total of 135 cross-sectional imaging studies for MRI, CT, PET/CT and ultrasound in the past 24 months.

MS.06.01.05, EP 17

For hospitals that provide computed tomography (CT) services: Upon renewal of privileges, the hospital verifies and documents the ongoing education of a radiologist who interprets CT examinations. Ongoing education must include As Low As Reasonably Achievable (ALARA), Image Gently, Image Wisely, and one of the following:

- Meeting the Maintenance of Certification (MOC) requirements of their certifying body
- Completing 100 hours of relevant continuing medical education (CME) in the past 24 months; this must include 50 hours of Category 1 CME
- Completing 10 hours CME in the past 24 months specific to the imaging modality or organ system

ATTACHMENT 2

Select Articles Regarding PET Utilization Trends

New PET/CT facilities power utilization growth

By James Brice, AuntMinnie.com contributing writer

August 21, 2012 -- The growing acceptance of PET/CT as an essential part of oncology services has helped increase its use in step with the hybrid modality's expanding installed base, according to a new report on PET/CT and PET market conditions.

The analysis by IMV Medical Information Division found that 1.85 million PET and PET/CT procedures were performed in the U.S. in 2011, a 6% increase from 2010. On the other hand, utilization per site rose only 0.6% last year, according to Lorna Young, senior director of market research at IMV. The findings were based on telephone surveys with managers at one-third of the 2,210 PET imaging services in U.S.

"We observed flat use at sites, but growth in the number of sites that are performing PET," Young told *AuntMinnie.com*.

The 6% increase indicates that demand for PET is still growing, but the finding also reflects slower growth more recently. Surveys conducted by IMV in 2005 and 2008 found average annual growth rates of about 10%, she noted.

Hospitals continue to open new cancer treatment centers in anticipation of increased demand and the generally lucrative nature of the services. PET/CT is still fairly well reimbursed and has become a standard component of comprehensive oncology services, Young said.

The report identified 1,130 PET/CT sites equipped with at least one fixed PET/CT scanner. A total of 100 fixed dedicated PET sites with at least one PET system were operational last year, along with 980 mobile PET/CT and PET services.

Mobile services were most popular with 200-bed or smaller hospitals. A majority of hospitals with fewer than 400 beds provided mobile PET/CT if they offered the image modality at all.

Mobile PET can be viewed as an incubator for future fixed-site sales, according to Young. "Therein lays the promise for future markets," she said.

Fourteen percent of PET and PET/CT users plan to purchase a new system in the next three years, according to the report.

Oncology dominates

PET/CT utilization trends illustrate how thoroughly oncology dominates the field. Approximately 94% of PET procedures in 2011 were related to cancer assessment. The other 6% were evenly divided between cardiology and neurology.

Oncology's market share has actually grown, from 86% of total PET and PET/CT procedures in 2001 to 95% in 2010. In 2011, 38% of the oncology volume was associated with cancer staging, another 13% was used for treatment planning, and 30% pertained to suspected recurrence and therapy follow-up.

F-18 FDG remains the mainstay of PET/CT, as about 95% of all clinical PET procedures are performed with the radiopharmaceutical, according to the report. In cardiology, rubidium-82 and nitrogen-13 ammonia are both employed for PET myocardial perfusion imaging. In neurology, the U.S. Food and Drug Administration's (FDA) approval of F-18 florbetapir (Amyvid, Eli Lilly) for beta-amyloid plaque brain imaging in April 2012 may lead to greater demand for PET for diagnosing and monitoring Alzheimer's disease and other forms of cognitive degeneration, the report noted.

Data for IMV Medical Information Division's "2012 PET Imaging Market Summary Report" was drawn from telephone surveys of 738 facilities selected from a universe of 2,210 known fixed-site and mobile PET and PET/CT services in the U.S. The surveys were conducted from April 1, 2011, to May 31, 2012.

Responses were projected to create a statistically valid of profile of PET and PET/CT service experiences as a whole.

Disclosure notice: AuntMinnie.com *is owned by IMV, Ltd.*

Last Updated 8/20/2012 4:08:04 PM

What's driving PET/CT growth?

May 31, 2012

Brian Clement, Oncology Roundtable

Our Technology Insights program has projected that PET/CT utilization will grow 22% over the next five years and 55% over the next ten years. Technological advances, demographic trends, decreasing price points, and reimbursement changes are driving this projected growth.

PET/CT technological capabilities still increasing

While PET/CT scanners are already the standard for oncology imaging, several developments in scanning technology have the potential to make PET/CT an even more powerful tool for treatment planning in the future.

- More precise measurement: increased granularity in tumor imaging will allow for better differentiation and measurement of tumors.
- Increased data storage: greater data storage capacity will allow providers to archive more information from patients' previous scans and help oncologists track tumor developments over time.
- Less patient movement: changes in the physical design of the newest PET/CT scanners provide better patient movement restriction to ensure consistent, precise imaging.

Aging baby boomers will increase cancer incidence

While this isn't news to most of the oncology community, it bears repeating: increasing cancer incidence as baby boomers age will drive up demand for oncology imaging services such as PET/CT scans.

For a better understanding of how these changes will impact oncology volumes at your hospital, access the Oncology Outpatient Market Estimator.

PET/CT machines becoming more affordable

The falling costs of investing in a PET/CT machine could substantially change ROI projections. While the price range of these scanners used to span from $1.8 million-$3 million, they're now sold for $1.2 million-$2.3 million.

Increased efficiency as scanning time decreases

As equipment costs have dropped, patient scan time has also decreased precipitously. A full body scan will take 5-15 minutes, compared to older equipment that required 45-60 minutes per scan.

Increased efficiency means that more patients can be scanned per day, which enhances the financial attractiveness of PET/CT scanners for oncology imaging.

Expanded payer coverage

Recent payment changes by CMS—which were also widely followed by private payers—are also likely to drive PET/CT growth. These changes have expanded coverage for FDG-PET, which accounts for 90–95% of all PET studies.

Scans are now covered for the following purposes:

- Staging: one FDG-PET scan is covered by Medicare for initial treatment strategy—local Medicare contractors have the ability to authorize additional FDG-PET scans on a case-by-case basis.
- Treatment monitoring: one FDG-PET scan for assessing subsequent treatment strategy will also be covered by Medicare.

Learn more

For more information about PET/CT growth prospects, view Technology Insights' article, "PET/CT: Strong growth ahead."

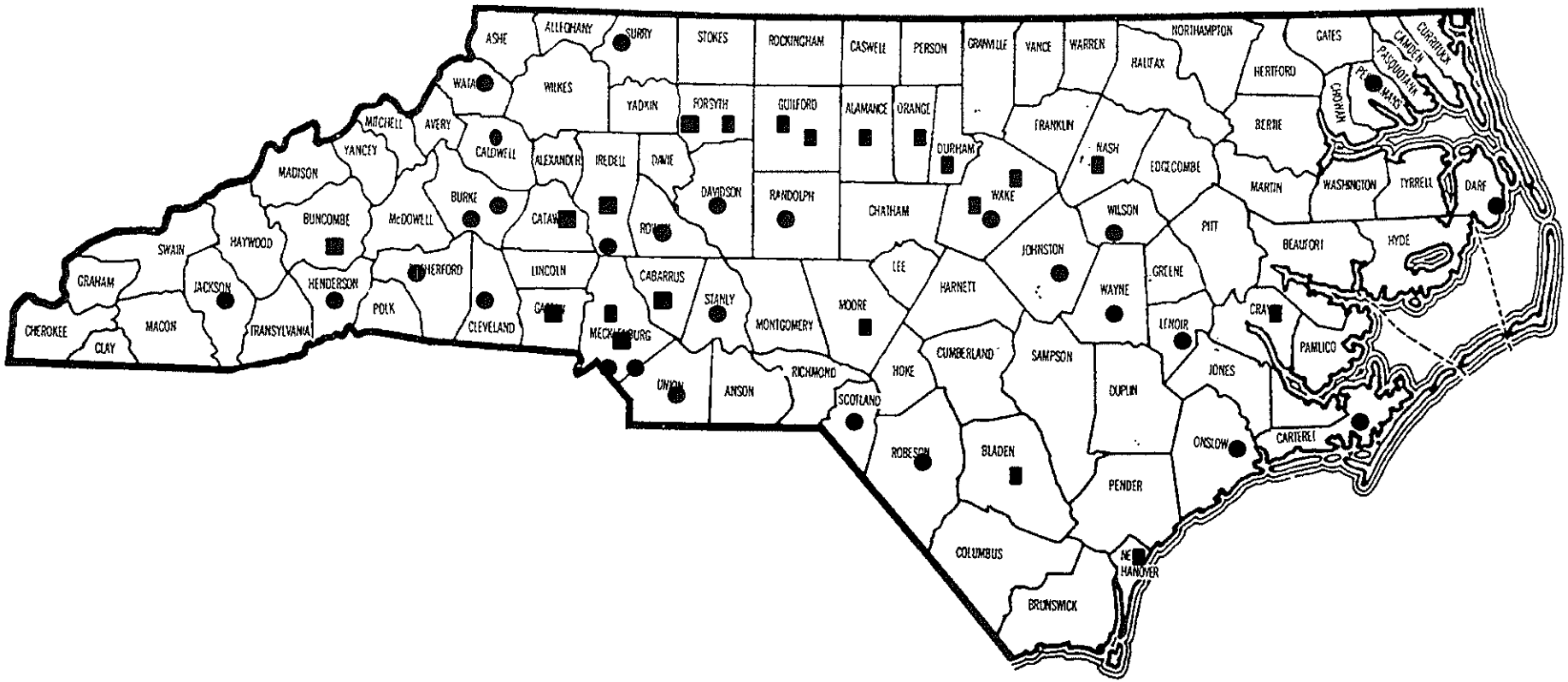
Members may also access "Oncology Technology Update 2011" to view a webconference that provides a general overview of oncology technology.

The advisory Board Company,

ATTACHMENT 3

North Carolina Map Indicating PET Scanning Locations

North Carolina PET Scanner Locations



■ Fixed PET

● Mobile PET

Note: Symbols indicate general locations and do not necessarily reflect the actual number of scanners per site.