



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 16, 2013

David French
PO Box 2154
Reidsville, NC 27323

Exempt from Review - Replacement Equipment

Facility: Alliance Imaging, Inc.
Project Description: Temporarily replace mobile PET/CT scanner
County: HSA I, II, III

Dear Mr. French:

In response to your letter of September 28, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the mobile Siemens PET/CT scanner unit 101 (Serial Number 1M9A6A82X5W022233) to temporarily replace the existing mobile Siemens PET/CT scanner unit 45 (Serial Number 1M9A6A8276H022244). This determination is based on your representations that the temporary PET/CT scanner will be removed from North Carolina upon completion of repairs to the approved mobile PET/CT scanner and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Construction and Radiation Protection Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie Halatek
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR



Certificate of Need Section

www.ncdhhs.gov

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ALLIANCE HEALTHCARE SERVICES

September 28, 2013

Mr. Craig Smith
Chief, Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704



RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for **Emergency Temporary Replacement PET/ CT Equipment for the Western Mobile PET/ CT Scanner (PET CT 45)**

Dear Mr. Smith:

I am writing on behalf of my client Alliance Imaging Inc. regarding the urgent need to temporarily replace the mobile PET/ CT scanner that is utilized in western North Carolina, Health Service Areas I, II and III.

In 2003, Alliance Imaging Inc. obtained approval for project application # F-6650-02 to implement a mobile PET scanner to serve Health Service Areas I, II and III. In 2006, Alliance obtained an equipment replacement exemption to replace the PET scanner equipment with a PET/CT. The unit that is currently in use is PET/ CT 45 Serial Number 1M9A6A8276H022244. This unit needs repairs that can be scheduled for early October, 2013

Please accept this notice of exemption to temporarily replace the above unit with PET/ CT unit 101, serial number 1M9A6A82X5W022233. This unit is owned by Alliance Imaging and is readily available to serve as the temporary replacement for the western PET/ CT.

This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. Alliance Imaging Inc. also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules:

G.S. 131E-176 (22a) Replacement equipment definition
G.S. 131E-184 (a) (7) Exemptions from review to provide replacement equipment
10A NCAC 14C.0303 Replacement Equipment Administrative Rules

Overview

The existing PET/CT requires temporary replacement for several reasons:

- 1) The existing PET/ CT 45 requires repairs and the completion date is not known at this time.
- 2) Service to the existing host sites will be disrupted if a temporary replacement mobile PET/ CT unit cannot be provided.
- 3) Patient diagnosis and treatment at the host sites will be seriously disrupted without access to PET/ CT.
- 4) Alliance does not have available capacity on other PET/ CT units in North Carolina to provide coverage for the unit that needs to be repaired.

Alliance Imaging recognizes the need to provide high quality, cost effective, and reliable mobile PET/ CT scanner service.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The fair market value for the PET/ CT scanner will be the same as the purchase price of the equipment as reflected in the attached quotes.

The replacement PET/ CT equipment will be used for the same diagnostic purposes as the existing equipment.

In addition, Alliance Imaging is providing prior written notice to the Department in accordance with G.S. 131E-184 (a) (7) Exemption from Review to provide replacement equipment.

Applicability and Conformance with Administrative Rule 10A NCAC 14C.0303 Replacement Equipment

Alliance Imaging Inc. plans to use an existing mobile PET/ CT as a temporary replacement. No equipment will be purchased. The temporary replacement equipment conforms to the rules as follows:

10A NCAC 14C.0303 Replacement Equipment

(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).

Alliance Imaging Inc. has reviewed this rule definition.

(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

Alliance Imaging Inc. has reviewed this rule definition.

(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

Alliance Imaging Inc. has reviewed this rule definition.

(d) Replacement equipment is comparable to the equipment being replaced if:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

The replacement PET/ CT scanner is comparable to the equipment being replaced because the temporary replacement equipment will also obtain PET/ CT images and data. The proposed replacement mobile PET/ CT scanner is used to acquire the same type of PET/ CT images and data.

(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment in use and is not used to provide a new health service; and

Alliance Imaging Inc. certifies that the replacement mobile PET/ CT equipment will be used for the same diagnostic purposes as the existing unit.

- (3) *The acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.*

The host sites will utilize the temporary replacement PET/ CT scanner and shall be notified by Alliance Imaging that no increases in costs or patient charges will result from the temporary replacement.

- (e) *Replacement equipment is not comparable to the equipment being replaced if:*
- (1) *the replacement equipment is new or reconditioned, the existing equipment was purchased second hand and the replacement equipment is purchased less than three years after the acquisition of the existing equipment.*

Not applicable. This notice involves a temporary replacement. The existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

- (2) *The replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or*

Not applicable. See the explanation above.

- (3) *The replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or*

Not applicable. The replacement equipment is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the existing equipment. The existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

- (4) *The replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease;*

Not applicable. The existing equipment is not leased.

- (5) *The replacement equipment is a dedicated PET scanner and the existing equipment is:*

- (A) *a gamma camera with coincidence capability; or*
(B) *nuclear medicine equipment that was designed, built, modified to detect only the single photon emitted from nuclear events other than positron annihilation.*

Not applicable. The existing equipment is not a gamma camera or nuclear medicine equipment.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT (To be temporarily removed from NC for repairs.)	TEMPORARY REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	PET CT	PET CT
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	Siemens Biograph	Siemens Biograph
Serial Number	1M9A6A8256H022243	1M9A6A82X5W022233
Provider's Method of Identifying Equipment	PET CT 45	PET CT 110
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #	NA - No changes	NA - No changes
Date of Acquisition of Each Component	2006	2008
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Holds Title
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New when acquired
Total Capital Cost of Project (no construction involved)	NA	Existing equipment
Total Cost of Equipment	NA	Purchased in 2008 at a cost of
Fair Market Value of Equipment	NA	\$1,047,312
Net Purchase Price of Equipment	NA	same
Locations Where Operated	Sites listed in 2014 SMFP in HAS I, II and III for PET CT 45	Same sites as PET CT 45 inventory form
Number Days In Use/To be Used in N.C. Per Year	365	Specified days for temporary replacement
Percent of Change in Patient Charges (by Procedure)	NA	No increase will result
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No increase will result
Type of Procedures Currently Performed on Existing Equipment	PET CT Procedures	PET CT Procedures
Type of Procedures New Equipment is Capable of Performing	NA	PET CT procedures

The temporary replacement PET/ CT unit 63 will be removed from North Carolina when the repair of PET CT 45 has been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,

A handwritten signature in cursive script, appearing to read "David French", written over a horizontal line.

David French
Consultant to Alliance Imaging Inc.
P.O. Box 2154
Reidsville, NC 27323
djfrench45@gmail.com

Cc: Kevin Smith
704-905-5131 cell

List of Mobile PET CT Sites Served by PET CT 45

Caldwell Memorial
Cleveland Regional
Grace Hospital
Margaret R. Pardee Hospital
Park Ridge Hospital
Rutherford Hospital
Valdese General
Watauga Medical Center
MedWest Harris
Randolph Hospital
Thomasville Medical Center
Northern Hospital of Surry
Lake Norman Regional
Rowan Regional
Stanly Regional
Presbyterian Hospital- Matthews
Presbyterian Hospital-Hunsterville