



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

Pat McCrory  
Governor

Richard O. Brajer  
Secretary DHHS

Mark Payne  
Assistant Secretary for Audit and  
Health Service Regulation

July 21, 2016

David French  
PO Box 2154  
Reidsville, NC 27323

**Exempt from Review – Replacement Equipment**

**Record #:** 1990  
**Business Name:** Alliance Imaging, Inc.  
**Business #:** 2391  
**Project Description:** Temporarily replace mobile PET/CT scanner  
**County:** Health Service Areas IV, V and VI

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 18, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7) . Therefore, you may proceed to utilize, without a certificate of need, the Siemens Biograph 6 mobile PET CT 53 scanner (already owned). This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

It should be noted that the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

  
Jane Rhoe-Jones  
Project Analyst

  
Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Paige Bennett, Assistant Chief, Healthcare Planning, DHSR



**Healthcare Planning and Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

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ALLIANCE HEALTHCARE SERVICES  
1233 Front Street, Suite A  
Raleigh, NC 27612



July 18, 2016

Martha Frisone  
Assistant Chief,  
Health Planning and Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699-2704

RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for Temporary Replacement  
PET/ CT Equipment for the Eastern Mobile PET/ CT Scanner

Dear Ms. Frisone:

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 eastern North Carolina, Health Service Areas IV, V and VI.

In 2003, Alliance Imaging Inc. obtained approval for project application # H-6702-02 to implement a mobile PET scanner to serve Health Service Areas IV, V and VI. 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 44 Serial Number 1M9A6A8256H022243. This unit needs to have extensive maintenance, repairs and upgrades.

Please accept this notice of exemption to temporarily replace the above unit with PET/ CT unit 53, serial number 1S9FS482961182996. This unit is owned by Alliance Imaging is readily available to serve as the temporary replacement for the eastern PET/ CT 44. When this unit is no longer needed to serve as a temporary replacement for PET/CT 44 it will be removed from North Carolina.

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 44 requires extensive 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.

The temporary use of replacement PET/ CT unit 53 to serve CON approved host sites in North Carolina will be discontinued when the repair of PET CT 44 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,



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

Cc: Melissa VanOostrom  
Manager of Operations  
Alliance Healthcare Services  
Phone: 910-340-1494

Andre' D. Kellogg, Sr., MPA  
Director of Operations  
Alliance Healthcare Services  
Phone: 404-317-7800

**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 6
Serial Number	1M9A6A8256H0222243	1S9FS482961182996
Provider's Method of Identifying Equipment	PET CT 44	PET CT 53
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	
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	Already owned purchased on 2004
Fair Market Value of Equipment	NA	
Net Purchase Price of Equipment	NA	same
Locations Where Operated	See attached 2016 PET CT 44 inventory form	Same sites as 2016 PET CT 44 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

# AMERICAN

July 15, 2016

Cathy Weinhold  
Asset Manager  
Alliance Healthcare Radiology  
Newport Beach, CA 92660

Re: Value of Imaging Equipment

Cathy,

As requested, the following is the estimated "Fair Market Value" for imaging equipment described below:  
**2004 Siemens Biograph 6 Mobile PETCT Unit.**

**Fair Market Value: \$75,000 to \$100,000**

Market value is based on system and trailer to be in good to excellent condition and appearance.

Please contact me if I can be of further assistance.

Sincerely,

Matthew Pac  
Vice President