



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

January 29, 2015

Catharine Cummer, Regulatory Counsel, Strategic Planning  
Duke University Health System  
3100 Tower Blvd, Suite 1300  
Durham NC 27707

**Exempt from Review - Replacement Equipment**

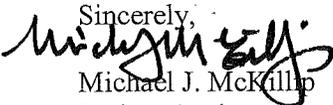
Facility: Duke Regional Hospital  
Project Description: Replace cardiac catheterization equipment  
County: Durham  
FID #: 923142

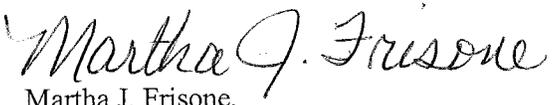
Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 13, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the Philips Flashpoint Allura Xper cardiac catheterization equipment to replace the existing Philips Integris cardiac catheterization equipment located in Cath Lab 2. Also, Duke University Health System may proceed to use its existing mobile cardiac catheterization lab at Duke Regional Hospital during interim between removal of the existing equipment and installation of the new equipment. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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,  
  
Michael J. McKillip  
Project Analyst

  
Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Assistant Chief, Healthcare Planning, DHSR  
Construction Section, DHSR  
Radiation Protection Section, DHSR



**Healthcare Planning and Certificate of Need Section**

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

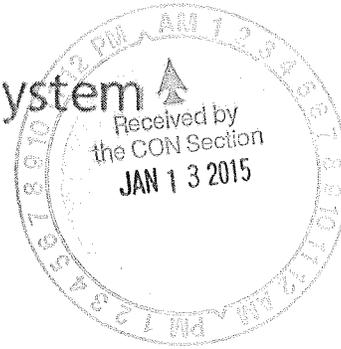
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# Duke University Health System

**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning



January 13, 2015

Via Electronic Mail

Mr. Michael J. McKillip, Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Regional Hospital

Dear Mr. McKillip:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project and to request the Section's written confirmation that the project is exempt from certificate of need review. The project involves the replacement of cardiac catheterization equipment originally installed in 2000 at Duke Regional Hospital.

The current equipment in the lab is an Integris 5000C that was introduced by Philips in 1999 as the first dedicated cardiac imaging system. Within the past year, as a result of its age, the equipment has become increasingly unreliable and logged a significant amount of downtime that has resulted in interruptions to patient care. Philips has confirmed that end-of-life for the Integris 5000C model was December 2013. At that time, Philips is no longer able to provide full service support for the equipment and the manufacturing of replacement parts has ceased. This limited availability of both parts and service will contribute to increased downtime in the event of an equipment failure and significantly limit the department's ability to provide catheterization services. Accordingly, Duke Regional Hospital now seeks to replace the equipment.

This equipment replacement project satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.

- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection."

#### Main campus

The existing and replacement catheterization equipment are/will be located in the main Duke Regional Hospital building. This is on the "main campus" of the facility, as defined in 131E-176(14n), as "[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building" and "[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building."

Duke Regional Hospital is a licensed health service facility (license available upon request), and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all Duke Regional Hospital services is located at 3643 North Roxboro Road in Durham. (As it happens, Duke Regional Hospital's chief executive office and chief financial officer also have their offices within this same building, in the Watts annex.) A map showing the hospital building and identifying the site of the proposed construction are attached as Exhibit A.

#### Certificate of Need

The existing catheterization equipment was acquired pursuant to a certificate of need issued for Project J-6148-99, attached as Exhibit B.

#### Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form is enclosed as Exhibit C. Both the existing equipment and the replacement equipment are cardiac catheterization laboratories. The existing machine is currently in service and will remain so until the replacement equipment is operational, at which time it will be removed from service within the state unless the Certificate of Need Section otherwise approves its continued use in the state.

The total project cost is approximately \$2,886,000, including equipment and related construction costs necessary for the installation of the new machine. A copy of the equipment quotation is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

Mr. Michael J. McKillip  
January 13, 2015  
Page 3

Temporary use of mobile cath lab

Duke further seeks confirmation that Duke Regional Hospital may proceed with the temporary use of a mobile cardiac catheterization lab during the renovation process without certificate of need review. Duke University Health System previously received an exemption to replace an existing mobile cardiac catheterization laboratory with equipment to be installed at Duke University Hospital in a hybrid operating room. Duke has not used the mobile laboratory since that replacement, but still holds title to the laboratory.

The renovation of the space for the new cath equipment at Duke Regional will take several months during which time the existing equipment must be taken out of operation. In order to ensure continuity of care for patients during the renovation, Duke now proposes to bring the mobile cath lab into service during the interim period. Duke Regional's existing scanner will be removed some time in the summer of 2015. Construction is estimated to last three months. During that time, Duke would put into service at Duke Regional the mobile lab, to be staffed by Duke Regional staff and operated on its existing mobile equipment pad. Duke will remove the mobile equipment upon installation of the permanent replacement equipment, and will not operate it again in North Carolina thereafter without approval of the Certificate of Need Section. Because Duke holds title to this equipment, it would add minimal costs to the capital cost of the replacement project. At no time will Duke operate more than two cardiac catheterization labs as authorized by its certificate of need (Duke has a second lab that will be unaffected by this project). Alternatively, this could be considered as a two-part replacement, first the replacement of the existing equipment by the mobile lab previously taken out of service, and then the subsequent replacement of that equipment by the permanent equipment described in the equipment comparison form.

It is our understanding that this replacement project would be exempt from review under N.C.G.S. 131E-184(a)(7) and/or 184(f), and we would appreciate your confirmation of this understanding. If you have questions or need any further information, please let me know. We would appreciate your confirmation that this project is exempt from CON review. Thank you for your attention to this request. If you have questions, please let me know.

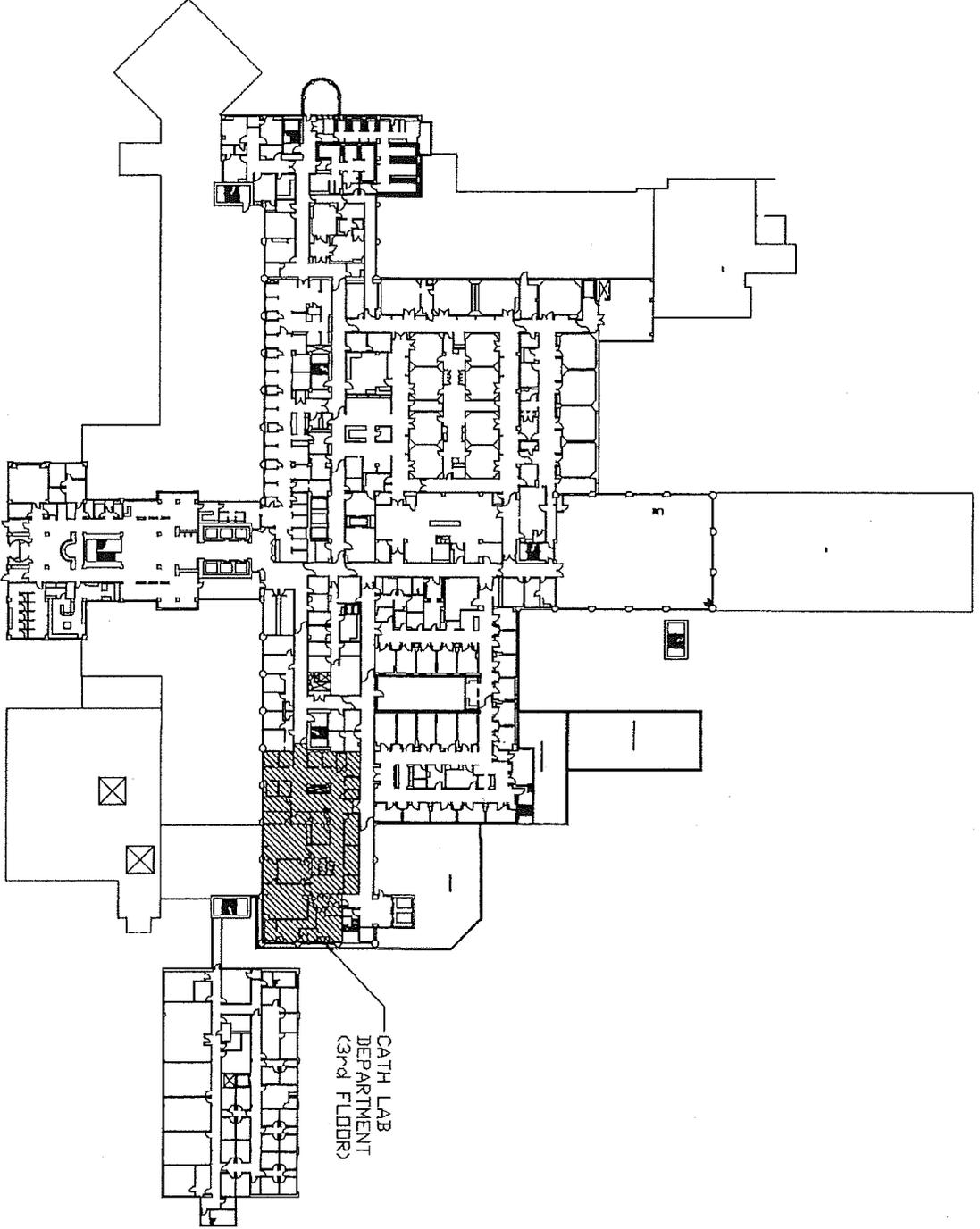
Very truly yours,



Catharine W. Cummer

Enclosures

DUKE REGIONAL HOSPITAL



CATH LAB  
DEPARTMENT  
(3rd FLOOR)

# STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

## CERTIFICATE OF NEED

for

Project Identification Number J-6148-99

FID #943138

ISSUED TO: Duke University Health System  
3000 Erwin Road  
Durham, NC 27710

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Duke University Health System shall acquire one unit of cardiac catheterization equipment to be located at Durham Regional Hospital for a total of two units of cardiac catheterization equipment at Durham Regional Hospital/Durham County

CONDITIONS: See Reverse Side

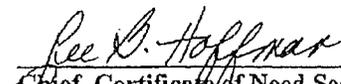
PHYSICAL LOCATION: Durham Regional Hospital  
3643 North Roxboro Road  
Durham, NC 27704

MAXIMUM CAPITAL EXPENDITURE: \$4,362,226

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: October 1, 2000

This certificate is effective as of the 21<sup>st</sup> day of April, 2000.

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Facility Services

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## CONDITIONS

1. Duke University Health System shall materially comply with all representations made in the certificate of need application.
2. Duke University Health System shall not acquire, as part of this project, equipment that is not included in the capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.
3. Duke University Health System shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.
4. Prior to issuance of the certificate of need, Duke University Health System shall submit to the Certificate of Need Section a written description of patient selection criteria, including referral arrangements for high risk patients.

A letter acknowledging acceptance and compliance with a conditions stated herein to the Certificate of Need Section was received by the Certificate of Need Section on April 12, 2000.

## TIMETABLE

### Design

Completion of preliminary drawings	October 1, 1999
Completion of final drawings and specifications	February 25, 2000
Approval of final drawings and specifications by the Construction Section, DFS	February 1, 2000

### Construction

Contract Award	April 10, 2000
25% completion of construction	July 1, 2000
50% completion of construction	November 1, 2000
75% completion of construction	February 1, 2001
Completion of construction	May 1, 2001
Occupancy/offering of service(s)	July 1, 2001

### Acquisition of Medical Equipment

Ordering equipment	November 1, 2000
Arrival of equipment	May 7, 2001
Operation of equipment	July 1, 2001

EQUIPMENT COMPARISON  
Duke Regional Hospital Cath Lab

Type of Equipment (List Each Component)	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Manufacturer of Equipment	Cardiac Cath Lab Philips	Cardiac Cath Lab Philips
Tesla Rating for MRIs	NA	NA
Model Number	Integris 5000C	Flashpoint Allura Xper FD20
Serial Number	49818114	NA
Provider's Method of Identifying Equipment	Cath Lab 2	Cath Lab 2
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	12/2000	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$4,362,226	\$2,886,000
Total Cost of Equipment		\$1,807,369
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	Cardiac cath	NA
Type of Procedures New Equipment is Capable of Performing	NA	Cardiac cath

C