



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

November 19, 2015

Catharine W. Cummer
3100 Tower Blvd
Suite 1300
Durham, NC 27707

Exempt from Review – Replacement Equipment

Record #: 1791
Facility Name: Duke Regional Hospital
FID #: 923142
Business Name: Duke University Health System
Business #: 639
Project Description: Replace existing vascular equipment
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of November 12, 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, Allura Xper FD20 fixed vascular equipment. 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.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Section, 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.



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

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

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

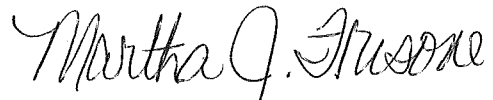
An Equal Opportunity/ Affirmative Action Employer



Sincerely,



Bernetta Thorne-Williams
Project Analyst



Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Kelli Fisk, Program Assistant, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR

 **Duke University Health System**

Catharine W. Cummer
Regulatory Counsel, Strategic Planning



November 12, 2015

Via Electronic Mail

Ms. Martha Frisone
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 Ms. Frisone:

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 Phillips V5000 vascular lab equipment originally installed in 1998 at Duke Regional Hospital. The equipment has reached end of life and 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 vascular lab 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.”

As set forth in previous submissions, Duke Regional Hospital is a licensed health service facility, 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.

Certificate of Need

The acquisition of the existing equipment was exempt from certificate of need requirements, as set forth in the correspondence attached as Exhibit A.

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 B. Both the existing equipment and the replacement equipment are vascular 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 more than \$2 million, 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).

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

Very truly yours,



Catharine W. Cummer

Enclosures

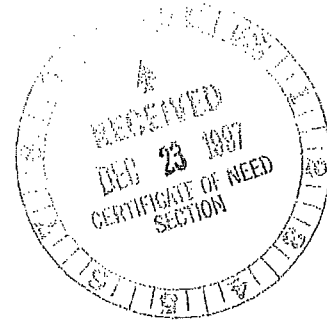


**DURHAM COUNTY
HOSPITAL CORPORATION**

Your Community Health System

December 22, 1997

Mrs. Lee Hoffman, Chief
Certificate of Need Section
Division of Facility Services
PO Box 29530
Raleigh NC 27626-0530



Dear Mrs Hoffman:

Durham County Hospital Corporation (DCHC) is hereby notifying you of its intent to replace its interventional vascular system. The existing equipment was originally purchased in 1985, with one upgrade installed in 1992. Parts are no longer available and frequent break-downs are disrupting operation of the lab.

919-270-4000
3643 N. Roxboro Road
Durham, North Carolina
27704-2763

Enclosed are:

- A comparison of the existing (Philips PolyDiagnost U/V) and replacement (Philips Integris V5000) equipment,
- A description of the technology and capabilities of the existing and replacement equipment,
- Product brochures for the replacement equipment. Unfortunately, we no longer have a product brochure for the existing equipment.
- A copy of the purchase orders and quote for the original equipment and the upgrade which was installed in 1992,
- A copy of the bill of sale (in lieu of the title) for the original equipment,
- A copy of the proposed purchase order and quote for the replacement equipment,
- A letter from Philips stating that the existing equipment will be used for parts,
- A capital cost spreadsheet for the project.

You will note that the quote and brochures are for a V3000 model. DCHC was recently informed by Philips that it is upgrading the V3000 model to the V5000 model and that we would receive the V5000 model at the same price. Updated brochures are not yet available; however, enclosed is a letter from the Philips sales representative explaining the newer features, etc.

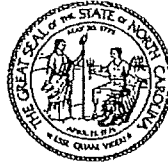
The existing equipment is still in operation and will not be shut down until approximately four weeks before the replacement equipment arrives. During that time, renovation will take place to combine the control rooms of DCHC's two vascular labs so that staff can be used more efficiently. We will also eliminate a darkroom and use that space to expand the procedure room. During the time the lab is closed (eight weeks total), a mobile C-arm machine will be placed in an operating room and used for simple interventional procedures such as placing shunts (see enclosed letter).

Per G.S. 131E-184(a)(7), DCHC requests that the CON Section send notification that there will be no review of this purchase. Should you have any questions, please call me at 470-6547.

Sincerely,

Judith M. Orser
Corporate Planner

EXHIBIT A



North Carolina Department of Health and Human Services
Division of Facility Services

701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530
Courier Number 56-20-05

James B. Hunt, Jr., Governor
H. David Bruton, M.D., Secretary

Lynda D. McDaniel, Director

Certificate of Need Section
Phone: (919) 733-6360
Fax: (919) 733-8139

January 5, 1998

Judith M. Orser, Corporate Planner
Durham County Hospital Corporation
3643 N. Roxboro Road
Durham, NC 27704-2763

RE: Request for Information/Interventional Vascular System Replacement/Durham County

Dear Ms. Orser:

In response to your letter of December 22, 1997, regarding the above referenced proposal, the CON Section requests clarification regarding the following:

1. What is the status of acquisition of the replacement equipment? Has Durham County Hospital Corporation or another entity entered into an obligation for a capital expenditure for the proposed equipment?
2. Does the equipment being replaced have the capability of performing cardiac angioplasty or cardiac catheterization procedures as defined in NCGS 131E-176?
3. Will the new equipment have the capability of performing cardiac angioplasty or cardiac catheterization procedures?

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

A handwritten signature in black ink, appearing to read "Floyd Cogley, Jr.", written over a large, loopy flourish.

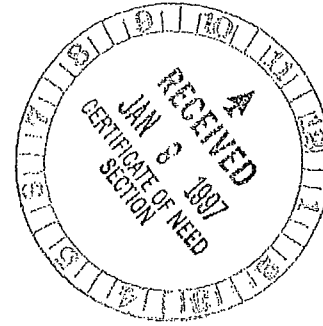
Floyd Cogley, Jr., Project Analyst



**DURHAM COUNTY
HOSPITAL CORPORATION**

Your Community Health System

2/10/98



January 7, 1998

Mr. Floyd Cogley, Jr., Project Analyst
Certificate of Need Section
Division of Facility Services
PO Box 29530
Raleigh NC 27626-0530

919-470-4000
3643 N. Roxboro Road
Durham, North Carolina
27704-2763

Dear Mr Cogley:

Listed below is the clarifying information you requested in your letter dated January 5, 1998:

1. *What is the status of acquisition of the replacement equipment? Has DCHC or another entity entered into an obligation for a capital expenditure for the proposed equipment?*

Attached is a copy of a more recent purchase order (P.O.) than what was included in the December 22, 1997 documentation and a letter from Philips recognizing that the P.O. is contingent on receiving CON approval for the replacement equipment.

2. *Does the equipment being replaced have the capability of performing cardiac angioplasty or cardiac catheterization procedures as defined in NCGS 131E-176?*

No.

3. *Will the new equipment have the capability of performing cardiac angioplasty or cardiac catheterization procedures?*

No.

Please feel free to contact me if you have additional questions (470-6547). Thanks.

Sincerely,

Judith M. Orser
Corporate Planner



North Carolina Department of Health and Human Services
Division of Facility Services

701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530
Courier Number 56-20-05

James B. Hunt, Jr., Governor
H. David Bruton, M.D., Secretary

Lynda D. McDaniel, Director

Certificate of Need Section
Phone: (919) 733-6360
Fax: (919) 733-8139

January 9, 1998

Judith M. Orser, Corporate Planner
Durham County Hospital Corporation
3643 N. Roxboro Road
Durham, NC 27704-2763

RE: Exempt from Review/Interventional Vascular System Replacement/Durham County

Dear Ms. Orser:

In response to your letters of December 22, 1997, and January 7, 1997, 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 offer, develop or establish the above referenced project without a certificate of need. However, you may need to contact the Construction Section of the Division of Facility Services to determine if they have any special requirements for 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,

Floyd Cogley, Jr., Project Analyst

Lee B. Hoffman, Chief
Certificate of Need Section

cc: Section Chief, Construction Section, DFS

EQUIPMENT COMPARISON
DRH Vascular Interventional Radiology

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Vascular	Vascular
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	n/a	n/a
Model Number	V5000	Allura Xper FD20
Serial Number	607361	To be determined
Provider's Method of Identifying Equipment	Asset # 114770	To be determined
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	n/a	n/a
Mobile Tractor Serial Number/VIN #	n/a	n/a
Date of Acquisition of Each Component	1998	2016
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>	n/a	\$3,584,000
Total Cost of Equipment	\$919,897	\$1,090,409
Fair Market Value of Equipment	n/a	\$1,090,409
Net Purchase Price of Equipment	\$919,897	\$1,090,409
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
Number Days In Use/To be Used in N.C. Per Year	250	250
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	Vascular Interventional Radiology Procedures	NA
Type of Procedures New Equipment is Capable of Performing	NA	Vascular Interventional Radiology Procedures