



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

July 28, 2017

Catharine W. Cumber
3100 Tower Boulevard, Suite 1300
Durham, NC 27707

Exempt from Review – Replacement Equipment

Record #: 2341
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace two cardiac catheterization labs located at Duke North
County: Durham

Dear Ms. Cumber:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 17, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need two units of the GE Biplane catheterization lab to replace two units of the Philips Biplane catheterization lab. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Handwritten signature of Bernetta Thorne-Williams in blue ink.

Bernetta Thorne-Williams
Project Analyst

Handwritten signature of Martha J. Frisone in black ink.

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

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



Record # 2341
FID # 943138
Business # 640

Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 17, 2017

Via Electronic Mail



Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of two cardiac catheterization labs currently used primarily for pediatric procedures at Duke University Hospital 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.

As set forth below, we believe that Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace existing cardiac catheterization located on the 7th floor of Duke North, which is part of the main building of Duke University Hospital. The

Ms. Martha Frisone
July 17, 2017
Page 2

"main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[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."

In this case, Duke University Hospital is a licensed health service facility, and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children's Hospital, the Duke Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. The hospital's license, a campus map and a floor plan showing the site of these replacements on the 7th floor of Duke North are enclosed.

(2) Previous Certificate of Need

Duke University Hospital currently operates seven cardiac catheterization labs including the two labs that will be replaced (excluding hybrid OR equipment). The enclosed CON for Project J-5327-86 documents that Duke was previously approved to operate eight cardiac catheterization labs. In 2004, DUH was approved to replace a cardiac lab with a bi-plane vascular system, leaving the number of cath labs at seven (see August 2, 2004 correspondence). We also enclose a 2003 notice of exempt replacement regarding the acquisition of one of the existing pieces of equipment.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide cardiac catheterization procedures. The total project cost exceeds \$2,000,000 reflecting equipment and installation expenses. Copies of the equipment quotations are 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).

Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON – DUKE UNIVERSITY HOSPITAL CATH LAB REPLACEMENTS

Type of Equipment (List Each Component)	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Manufacturer of Equipment	Peds Cath Lab 1: Philips Peds Cath Lab 2: Philips	GE
Tesla Rating for MRIs		
Model Number	Peds Cath Lab 1: Integris H5000 Peds Cath Lab 2: FD1010	IGS 620 Biplane (2 units)
Serial Number	Peds Cath Lab 1: 751 Peds Cath Lab 2: 116	NA
Provider's Method of Identifying Equipment	Peds Cath Lab 1 Peds Cath Lab 2	Peds Cath Lab 1 Peds Cath Lab 2
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	Peds Cath Lab 1: November 2003 Peds Cath Lab 2: January 2005	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	
Total Capital Cost of Project (Including Construction, etc.)		\$5,957,000
Total Cost of Equipment		\$2,945,320
Fair Market Value of Equipment		
Net Purchase Price of Equipment		\$2,920,320 (after trade-in)
Locations Where Operated		
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 catheterization	NA
Type of Procedures New Equipment is Capable of Performing	NA	Cardiac catheterization

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

*Effective January 01, 2017, this license is issued to
Duke University Health System, Inc.*

*to operate a hospital known as
Duke University Hospital
located in Durham, North Carolina, Durham County.*

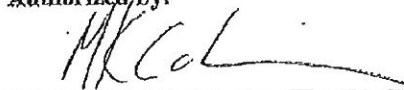
*This license is issued subject to the statutes of the
State of North Carolina, is not transferable and shall remain
in effect until amended by the issuing agency.*

*Facility ID: 943138
License Number: H0015*

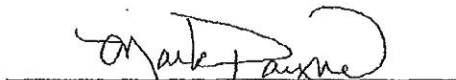
Bed Capacity: 957
General Acute 938, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6
Dedicated Ambulatory Surgical Operating Rooms: 9
Shared Surgical Operating Rooms: 50
Dedicated Endoscopy Rooms: 10

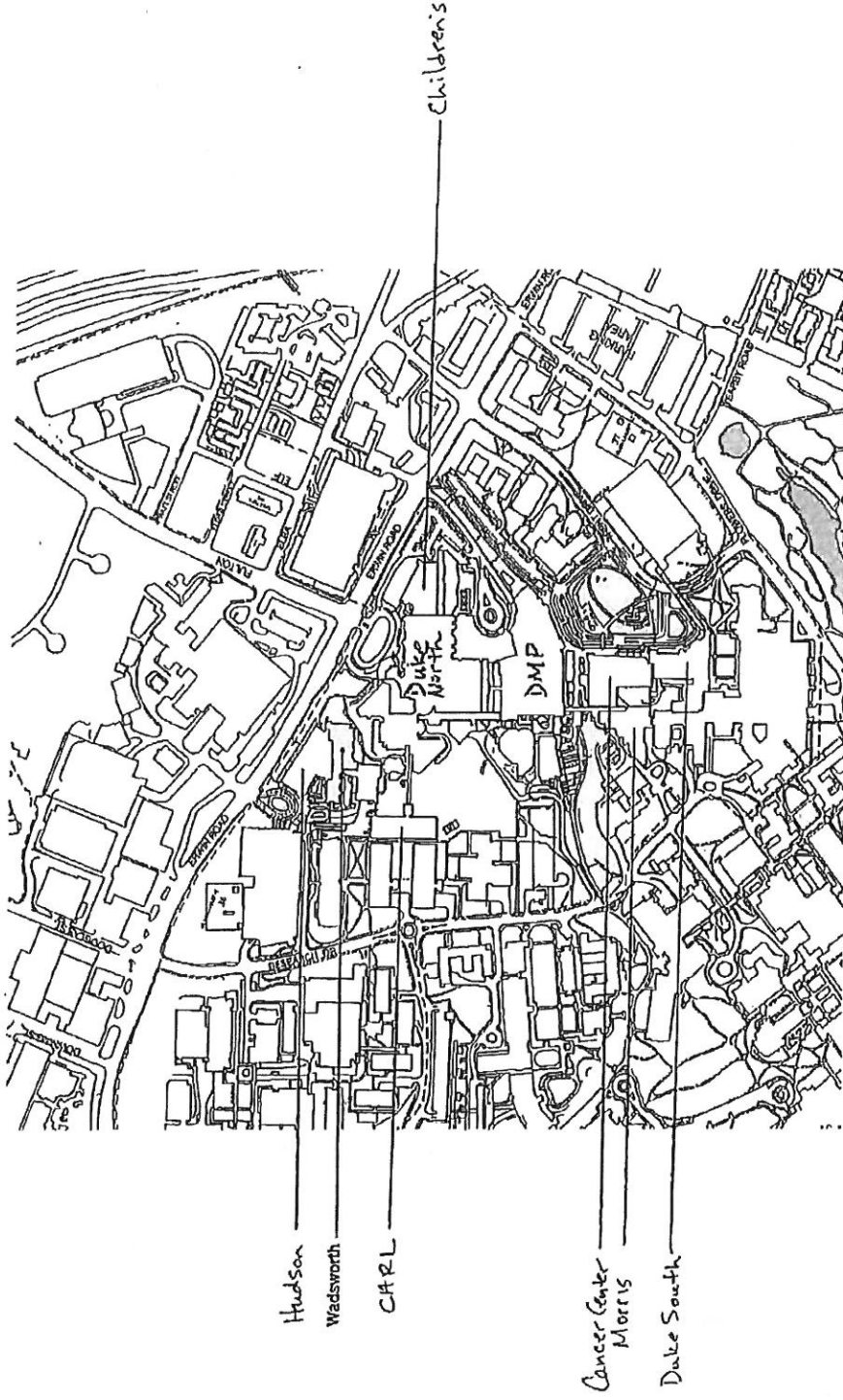
Authorized by:



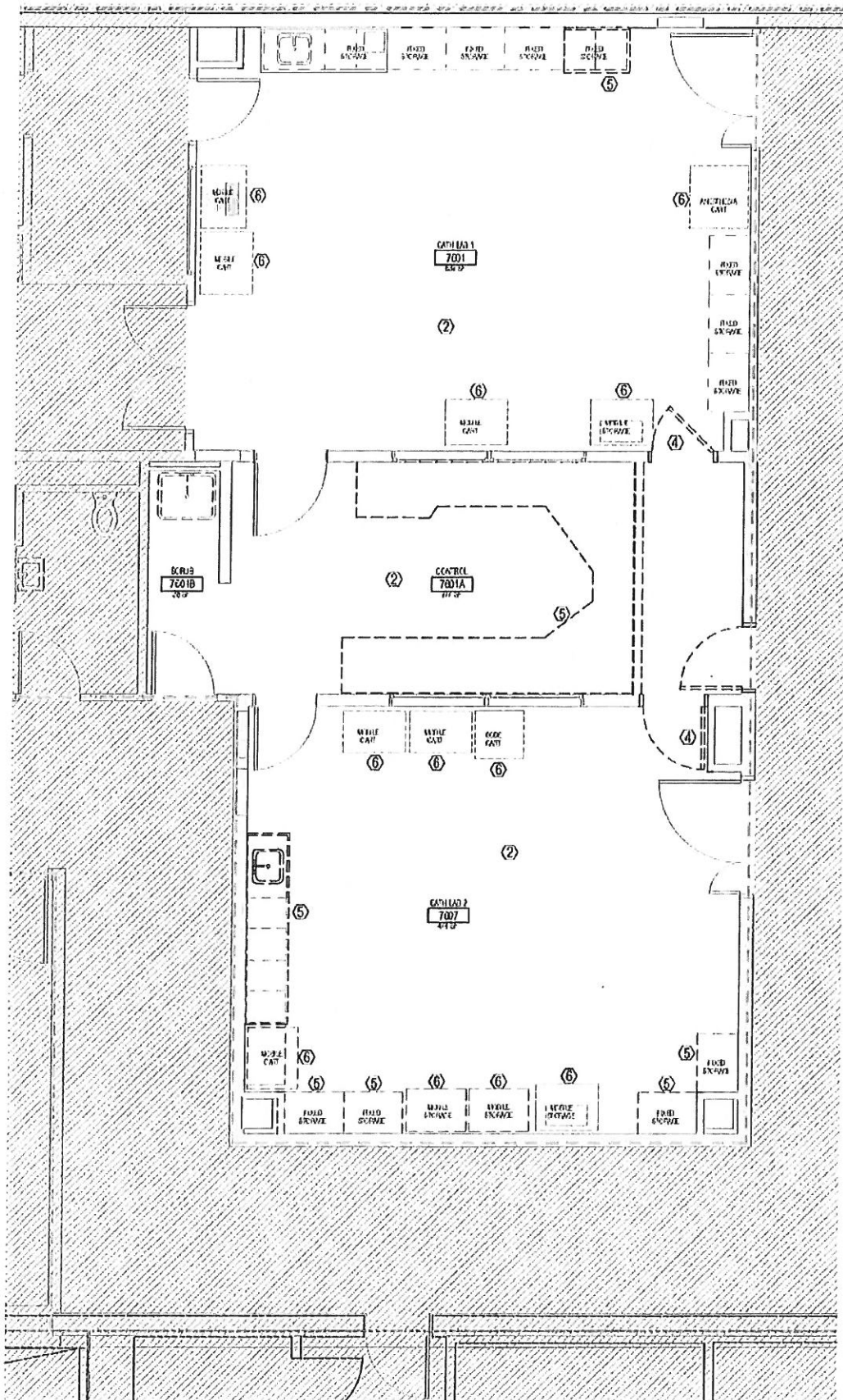
Secretary, N.C. Department of Health and
Human Services


Director, Division of Health Service Regulation

EX B

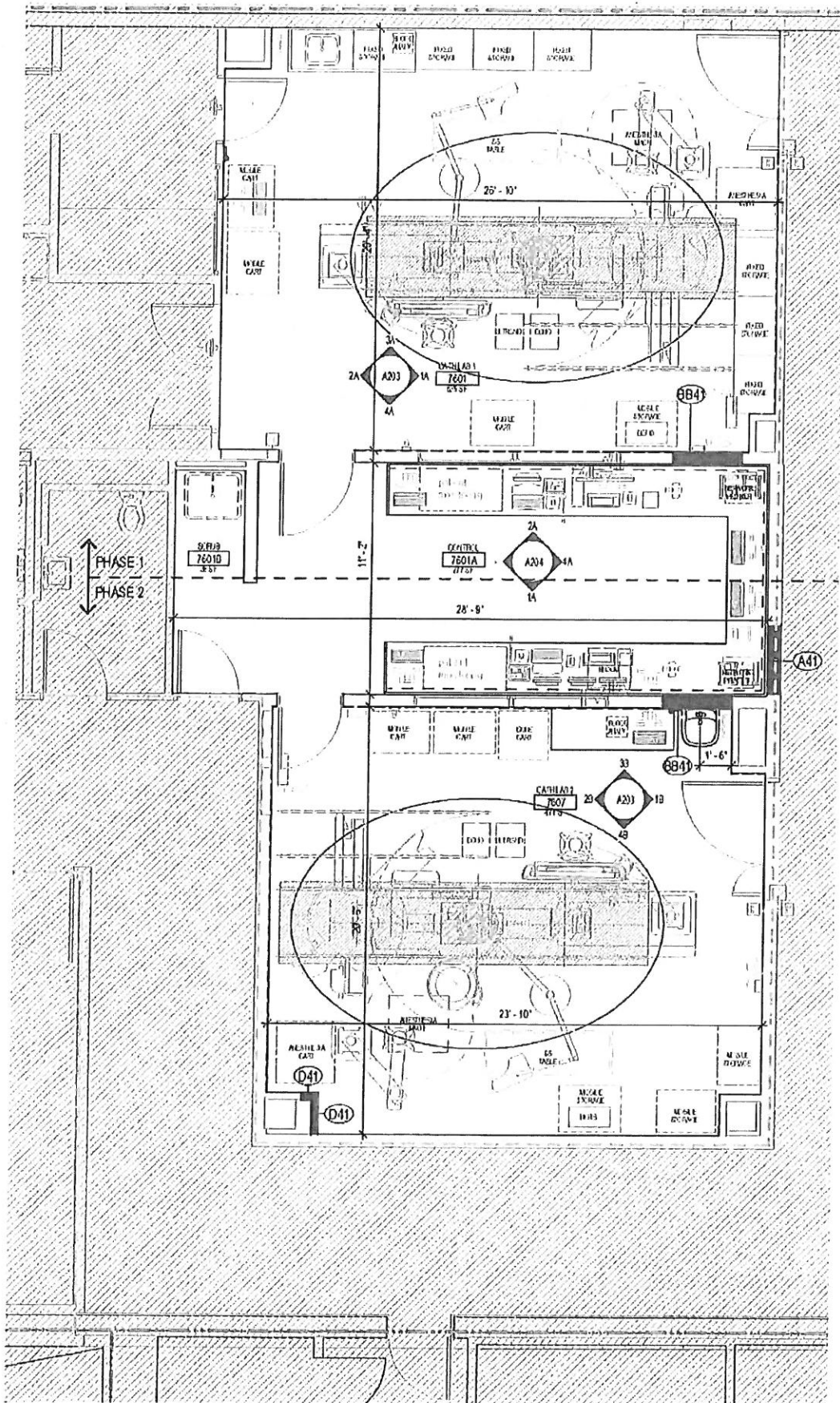


Campus Plan



① LEVEL 07 - DEMOLITION

1/4" = 1'-0"



① LEVEL 07 - FLOOR PLAN
 1/4" = 1'-0"

State Of North Carolina

Department Of Human Resources Division Of Facility Services Certificate Of Need

Project Identification Number J-5327-96 Effective Date July 16, 1996

Issued to: Duke University
3000 Erwin Road
Durham, NC 27710

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: See Reverse Side

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 3000 Erwin Road
Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$9,434,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 6, 1997

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

W. M. ...

Duke University will consolidate eight existing cardiac catheterization laboratories and two existing electrophysiology laboratories at Duke Hospital into a single suite with eight cardiac catheterization rooms on the seventh floor of Duke North Hospital. The suite will accommodate four interventional cardiology laboratories, three adult cardiac catheterization (diagnostic) laboratories; one pediatric cardiac catheterization laboratory providing diagnostic, therapeutic and electrophysiology services; and, essential support facilities, including a 16 bed holding area for patients and a family waiting area. Duke will also purchase two (2) bi-plane and two (2) single-plane cardiac imaging systems to replace existing equipment used in the interventional labs.

CONDITIONS

1. Duke University shall materially comply with all representations made in the certificate of need application.
2. Duke University shall dispose of the existing cardiac catheterization equipment that is being replaced as part of this project.
3. Duke University shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

Applicant acknowledged acceptance of and compliance with all applicable conditions with correspondence received by the Certificate of Need Section on June 19, 1996.

TIMETABLE

Completion of preliminary drawings	March 8, 1996 - June 7, 1996
Completion of final drawings and specifications	June 14, 1996 - October 11, 1996
Approval of final drawings and specifications by Construction Section, DFS	July 26, 1996 - November 22, 1996
Contract Award	August 9, 1996 - December 9, 1996
25% completion of construction	September 6, 1996 - June 26, 1998
50% completion of construction	October 4, 1996 - July 17, 1998
75% completion of construction	November 1, 1996 - August 7, 1998
Completion of construction	November 29, 1996 - August 28, 1998
Occupancy/offering of service	December 9, 1996 - October 26, 1998
Ordering equipment	December, 1997
Arrival of equipment	June, 1998 - August, 1998
Operation of equipment	July, 1998 - September, 1998



DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

*fix
Duff Eight
Cath Lab*

August 2, 2004

Mr. James W. Keene, Planner
N. C. Department of Health & Human Services
Division of Facility Services
State Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Cardiac Catheterization Laboratory in Room 1548K at Duke University
Hospital

Dear Mr. Keene:

The purpose of this letter is to confirm that a cardiac catheterization lab now located in Room 1548K in Duke Hospital will be removed permanently from service to make way for the development of a bi-plane vascular system. The acquisition and installation of the new vascular lab, which will replace a lab now located in Room 1548K5, was authorized by the Certificate of Need Section on June 14, 2004.

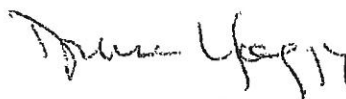
The cardiac cath lab to be removed from service was purchased from Philips Medical System in 1991 and installed in 1992. It has been in continuous service ever since. The model number of the cath lab is 9896-000-17341, and its serial number is 130121605965.

Removal of the lab from Duke Hospital will reduce the number of cardiac catheterization labs at Duke from eight to seven. Please adjust your inventory accordingly.

Page Two

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Duncan Yaggy", with a date "4/29/17" written below it.

Duncan Yaggy

cc: Lee Hoffman, Chief, CON Section
Marti Taylor
Jon Gardner



North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

June 14, 2004

Duncan Yaggy, Chief Planning Officer
Duke University Health System
3100 Tower Boulevard
Suite 600, Box 80
Durham, NC 27707

RE: Exempt from Review/Duke University Health System/Replace existing Phillips Integris V3000 bi-plane vascular system with a Phillips Integris Allura bi-plane vascular system/Durham County FID # 943138

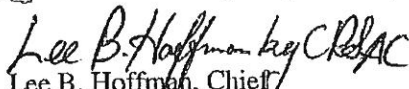
Dear Mr. Yaggy:

In response to your letter of June 7, 2004, 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 Phillips Integris Allura bi-plane vascular system to replace the existing Phillips Integris V3000 bi-plane vascular system [Serial # 2955280]. 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. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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,


Michael J. McKillip, Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
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North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

October 1, 2003

Duncan Yaggy, Chief Planning Officer
Duke University Health System
3100 Tower Boulevard
Suite 600, Box 80
Durham, NC 27707

RE: Exempt from Review/Duke Hospital/Replace existing Toshiba Medical Systems pediatric cardiac catheterization unit with a Philips Medical Systems unit/Durham County
FID # 943138

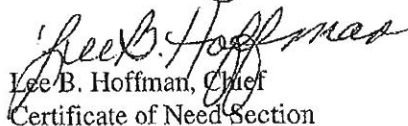
Dear Mr. Yaggy:

In response to your letter of August 27, 2003 and October 1, 2003, 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 Philips Medical Systems Integris Allura 9 Biplane pediatric cardiac catheterization unit to replace the existing Toshiba Medical Systems pediatric cardiac catheterization unit [Model # KXO-2000A/B; Serial # A4512059]. 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. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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,


Michael J. McKilip Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



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