



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

July 18, 2019

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

Exempt from Review – Replacement Equipment

Record #: 2989
Facility Name: Duke Regional Hospital
FID #: 923142
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing computed tomography (CT) scanner
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 July 15, 2019, 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 the Siemens Somatom Force CT scanner to replace the Siemens Somatom Definition AS CT scanner. 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, Radiation Protection 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,

Bernetta Thorne-Williams
Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873



Catharine W. Cummer
Regulatory Counsel, Strategic Planning



July 15, 2019

Via Electronic Mail

Ms. Martha Frisone
Ms. Bernetta Thorne-Williams
Healthcare Planning and 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 and Ms. Thorne-Williams:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project for a CT scanner at Duke Regional Hospital and to request the Section's written confirmation that the project is exempt from certificate of need review.

This 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 CT scanner (currently designated as CT 1) 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

Ms. Martha Frisone
Ms. Bernetta Thorne-Williams
July 15, 2019

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, and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all hospital is located at 3643 North Roxboro Road in Durham. Floor plans for the replacement project and the hospital’s license are enclosed.

Previous Certificate of Need

The existing CT scanner was acquired pursuant to a replacement exemption issued in September 2009. I would note that at the time, there were two CT replacements approved and it is impossible to determine which exemption notice applied to the specific equipment that is being replaced now, and therefore we are enclosing both exemptions for purposes of this request.

Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment are CT scanners used for diagnostic imaging procedures. 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. A copy of the equipment quotation for the proposed new scanner 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).

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,

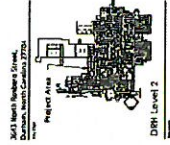


Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	Siemens	Siemens
Model number	Somatom Definition AS	Somatom Force
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	DRH CT 1	DRH CT 1
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	March 2010	October 2019
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$3.4M
Total cost of the equipment	\$867K	\$1.8M
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Duke Regional Hospital	Duke Regional Hospital
Document that the existing equipment is currently in use	In use	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	CT procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	CT procedures



3041 North Wake Street
 Durham, North Carolina 27610
 PROJECT AREA
 DRH - Level 2
 PROJECT NUMBER: 2013-013
 SHEET: 2013-013-013
 DATE: 05/20/13
 DRAWN BY: [Name]
 CHECKED BY: [Name]
 APPROVED BY: [Name]
RENOVATION PLAN

A201

LEGEND

	CURVED PARTITION
	VERTICAL GLASS PARTITION
	CURVED MOVABLE PARTITION
	NOTE KEY TO PLAN
	SECTION MARK
	INTERIOR ELEVATION
	ROOM TAG
	WALL TAG - SEE WALL TYPE ON SCHEDULE
	WINDOW TAG - SEE WINDOW SCHEDULE

GENERAL NOTES

- ALL WORK SHALL BE COMPLETED IN COMPLIANCE WITH ALL applicable local, state and federal codes and regulations. ALL WORK SHALL BE DONE IN ACCORDANCE WITH THE REQUIREMENTS OF THE CONTRACT AND ALL NECESSARY PERMITS SHALL BE OBTAINED PRIOR TO COMMENCEMENT OF WORK.
- CONTRACTOR SHALL VERIFY ALL DIMENSIONS, NOTIFY ARCHITECT IMMEDIATELY IN WRITING AT THE TIME OF DISCOVERY. DIMENSIONS AT FLOOR SHALL BE TO FACE UNLESS OTHERWISE NOTED OTHERWISE.
- ALL THE EXISTING WALLS AND PARTITIONS SHALL BE DEMOLISHED TO THE FINISH SURFACE UNLESS OTHERWISE NOTED. DEMOLITION SHALL BE TO THE FINISH SURFACE UNLESS OTHERWISE NOTED. DEMOLITION SHALL BE TO THE FINISH SURFACE UNLESS OTHERWISE NOTED. DEMOLITION SHALL BE TO THE FINISH SURFACE UNLESS OTHERWISE NOTED.

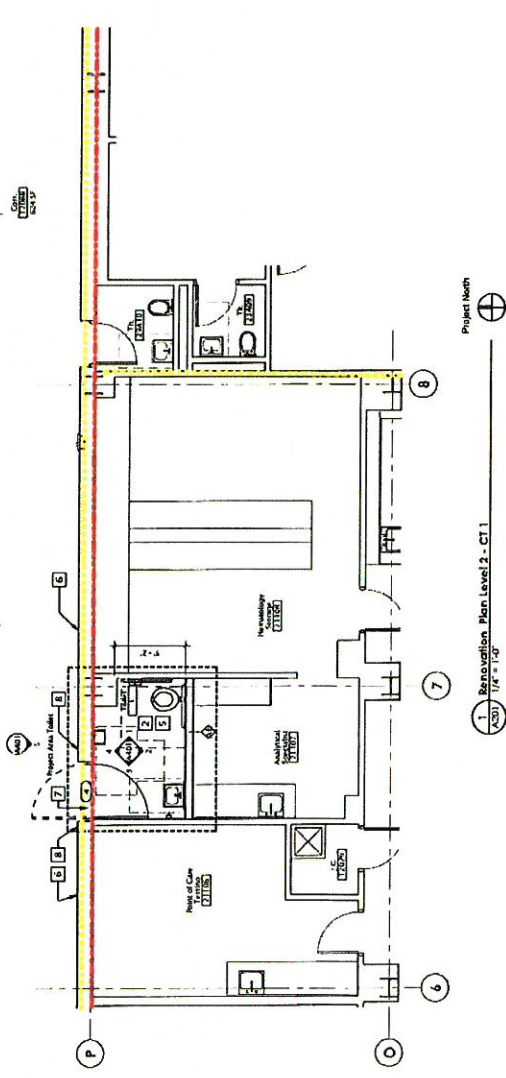
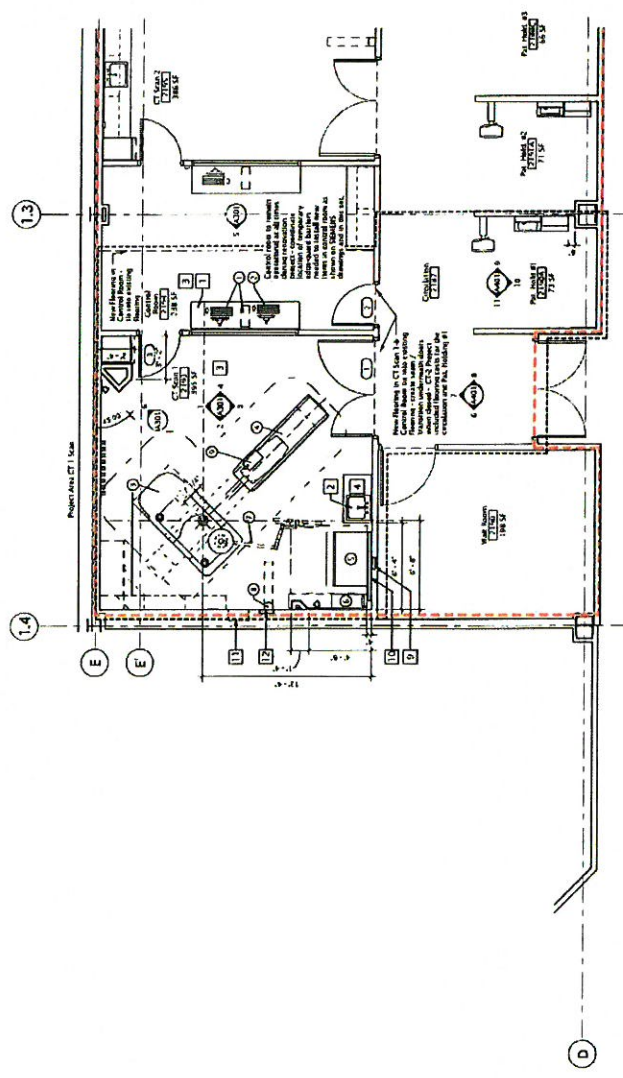
ABBREVIATIONS:
 GENERAL CONTRACTOR GC
 NOT IN CONTRACT N/C

EQUIPMENT LEGEND

NO.	DESCRIPTION	INSTALLER
1	MECHANICAL EQUIPMENT	MECHANICAL CONTRACTOR
2	ELECTRICAL EQUIPMENT	ELECTRICAL CONTRACTOR
3	PLUMBING EQUIPMENT	PLUMBING CONTRACTOR
4	TELEPHONE EQUIPMENT	TELEPHONE CONTRACTOR
5	TELEVISION EQUIPMENT	TELEVISION CONTRACTOR
6	VIDEO EQUIPMENT	VIDEO CONTRACTOR
7	COMPUTER EQUIPMENT	COMPUTER CONTRACTOR
8	PERIPHERAL EQUIPMENT	PERIPHERAL CONTRACTOR
9	SERVER EQUIPMENT	SERVER CONTRACTOR
10	NETWORK EQUIPMENT	NETWORK CONTRACTOR
11	SECURITY EQUIPMENT	SECURITY CONTRACTOR
12	ACCESS CONTROL EQUIPMENT	ACCESS CONTROL CONTRACTOR
13	TIME AND ATTENDANCE EQUIPMENT	TIME AND ATTENDANCE CONTRACTOR
14	POSTAL EQUIPMENT	POSTAL CONTRACTOR
15	MAIL EQUIPMENT	MAIL CONTRACTOR
16	RECEPTION EQUIPMENT	RECEPTION CONTRACTOR
17	TRAINING EQUIPMENT	TRAINING CONTRACTOR
18	CONFERENCE EQUIPMENT	CONFERENCE CONTRACTOR
19	RECEPTION EQUIPMENT	RECEPTION CONTRACTOR
20	TRAINING EQUIPMENT	TRAINING CONTRACTOR
21	CONFERENCE EQUIPMENT	CONFERENCE CONTRACTOR

KEYED RENOVATION NOTES

No.	NOTES
1	REMOVE EXISTING WALLS AND PARTITIONS.
2	REMOVE EXISTING WALLS AND PARTITIONS.
3	REMOVE EXISTING WALLS AND PARTITIONS.
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21	REMOVE EXISTING WALLS AND PARTITIONS.
22	REMOVE EXISTING WALLS AND PARTITIONS.



Renovation - Plan Level 2 - CT 1
 1/4" = 1'-0"





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

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

September 16, 2009

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

RE: Exempt from Review - Replacement Equipment/Duke University Health System d/b/a Durham Regional Hospital/Replacement of GE QX/1 Lightspeed computed tomography (CT) scanner with a GE Definition AS64 CT scanner/Durham County

Dear Dr. Yaggy:

In response to your correspondence of July 28, 2009 and August 21, 2009, 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 GE Definition AS64 CT scanner to replace the existing GE QX/1 Lightspeed CT scanner [Serial # 257739CN3]. 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. Feel free to contact this office if you have any questions concerning this matter.

Sincerely,

Michael J. McKillip, Project Analyst

Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR





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

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Sincerely,


Michael J. McKillip, Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Effective January 01, 2019, this license is issued to
Duke University Health System, Inc.

to operate a hospital known as
Duke Regional 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: 923142

License Number: H0233

Bed Capacity: 369

General Acute 316, Rehabilitation 30 , Psych 23,

Dedicated Inpatient Surgical Operating Rooms: 2

Dedicated Ambulatory Surgical Operating Rooms: 0

Shared Surgical Operating Rooms: 13

Dedicated Endoscopy Rooms: 4