



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

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Division Director

July 8, 2015

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

Exempt from Review – Replacement Equipment

Record #: 1634
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System
Business #: 639
Project Description: Replace automated bacteriology laboratory 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 June 23, 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 Becton Dickinson automated bacteriology 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 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: Construction Section, DHSR
Assistant Chief, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR



Healthcare Planning and Certificate of Need Section

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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

June 23, 2015

Via Electronic Mail and Federal Express

Martha Frisone
Certificate of Need Section
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 Section's written confirmation that the acquisition of an automated bacteriology line satisfies the requirements under N.C.G.S. Section 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 is now exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace an existing manual bacteriology system with a new automated system that will be located in Duke University Hospital's Wadsworth Building, which is located on the "main campus" of the hospital. The "main campus" of the facility is



Martha Frisone
June 23, 2015

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 (see License attached as Exhibit A), 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 Medical Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the new Hudson building. The Wadsworth Building is adjacent to Duke North, Duke University Hospital’s primary acute care bed tower. A map of the hospital is attached as Exhibit B. The existing system is located in the CARL building, which is also on the main campus and identified on the map.

(2) Previous Certificate of Need

The proposed automated line is designed to replace an incubator system. The existing system includes components acquired and put into service independently each at a cost well under \$750,000, and later consolidated into the existing system. Due to the price of the incubators at the time of their acquisition and initial operation, this system did not require a certificate of need upon acquisition.

(3) 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 and replacement systems are for the preparation and incubation of lab specimens. The current system requires that samples be manually plated and set in incubators. Periodically, laboratory technicians manually view samples that are in the incubators and pull those with growth for further testing. The new process provides efficiencies by automating the front-end of barcoding, processing, and plating of liquid samples that are then sent down the conveyor belt to the Smart Incubators. Non-liquid samples are processed manually/semi-automatically and then entered into the conveyor belt system for holding in the incubators. The Smart Incubators detect growth on the plate and flag the sample for an operator. The operator then sends an electronic message to the Smart Incubators to have the sample pulled and put back on the conveyor belt to send to the operator’s workbench. We would note that the replacement system will combine some incubators from the existing manual system with the new automation components and Smart Incubators, but one or more existing incubators will be replaced by this system and taken out of service.

We would note that this system, which automates the bacteriology data collection and transfer, may also be considered data processing equipment, the acquisition of which is exempt pursuant to N.C.G.S. Section 131E-184(a)(3).

Martha Frisone
June 23, 2015

The total project cost exceeds \$2,000,000, including equipment and related construction costs necessary for the installation of the automated system. 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).

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

Very truly yours,

A handwritten signature in black ink, appearing to read "Catharine W. Cummer". The signature is fluid and cursive, with the first name being the most prominent.

Catharine W. Cummer

Enclosures

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

Effective January 01, 2015, 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: 4

Dedicated Ambulatory Surgical Operating Rooms: 9

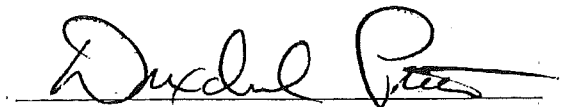
Shared Surgical Operating Rooms: 36

Dedicated Endoscopy Rooms: 10

Authorized by:



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



Director, Division of Health Service Regulation

EX A

2 X 17

EQUIPMENT COMPARISON
DUH MICROBIOLOGY

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Incubator	Bacteriology Automation Line
Manufacturer of Equipment	Forma Scientific	Becton, Dickinson and Company
Tesla Rating for MRIs	N/A	N/A
Model Number	3956	TBD
Serial Number	34402-1671	TBD
Provider's Method of Identifying Equipment	INC3, CE10179	TBD
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	5/15/1991	2016
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	TBD
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$7,711	\$2,465,000
Total Cost of Equipment	\$7,711	\$2,465,000
Fair Market Value of Equipment	\$1,055	\$2,465,000
Net Purchase Price of Equipment	\$7,711	\$2,218,500
Locations Where Operated	CARL Building	Wadsworth Building
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	Bacteriology	NA
Type of Procedures New Equipment is Capable of Performing	NA	Bacteriology