

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

February 24, 2020

Gary S. Qualls, Partner K&L Gates, LLP 430 Davis Drive, Suite 400 Morrisville NC 27560

Exempt from Review - Replacement Equipment

Record #:

3228

Facility Name:

University of North Carolina Hospitals at Chapel Hill

FID #:

923517

Business Name:

University of North Carolina Hospitals at Chapel Hill

Business #:

1900

Project Description:

Replace bacteriology laboratory equipment

County:

Orange

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 14, 2020, 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 bacteriology laboratory system to replace the existing bacteriology laboratory system. This determination is based on your representations that the existing equipment 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,

Project Analyst

Martha J. Frisone

Chief

cc:

Construction 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

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873





February 14, 2020

Gary S. Qualls Partner gary.qualls@klgates.com

T +1 919 466 1182 F +1 919 516 2072

By E-mail

Martha Frisone, Chief Department of Health and Human Services Division of Health Service Regulation Healthcare Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603

Re University of North Carolina Hospitals at Chapel Hill 923517

Letter Regarding Bacteriology Lab Replacement Equipment Exemption

Dear Martha:

On behalf of our client, University of North Carolina Hospitals at Chapel Hill ("UNCH"), we are writing to apprise you of a situation where, if prior notice existed, we would request your Agency's written confirmation of an exemption for replacement equipment to automate UNCH's bacteriology laboratory system, which otherwise satisfies the requirements under N.C. Gen. Stat. § 131E-184(f) for replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in N.C. Gen. Stat. § 131E-176(22a).

N.C. Gen. Stat. § 131E-184(f) contains the following conditions:

- (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.

Martha Frisone February 14, 2020 Page 2

As set forth below, UNCH's project meets the foregoing exemption standards with the exception of the prior notice condition. Unfortunately, through an oversight UNCH inadvertently acquired the replacement equipment in 2017, without giving your Agency prior notice.

(1) Main Campus

The purpose of this project is to replace a bacteriology laboratory system with a new automated system located in the East Wing of UNCH's main campus hospital tower. The "main campus" of the facility, as defined in N.C. Gen. Stat. §131E-176(14n), includes all of the following for the purposes of N.C. Gen. Stat. §131E-184(f):

- a. The 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.
- b. Other 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, UNCH is a licensed health service facility, and the main hospital building from which UNCH provides its clinical services and exercises financial and administrative control is the same building that houses the replacement equipment to automate UNCH's bacteriology laboratory system.

(2) Previous Certificate of Need (or Lack of Need Therefor)

The system being replaced included components acquired and put into service independently, each at a cost well under \$750,000, and later consolidated into that old system. Due to the price of the old equipment at the time of acquisition and initial operation, this system did not require a certificate of need upon acquisition. See Exhibit 1 (Equipment Comparison Form).

(3) Replacement Equipment

The replacement automated bacteriology laboratory system qualifies as replacement equipment pursuant to the statutory and regulatory definitions. A completed Equipment Comparison form is enclosed as Exhibit 1. Both the old and replacement systems are for the preparation and incubation of lab specimens. The old system required that samples be manually plated and set in incubators. Periodically, laboratory technicians would manually view samples that are in the incubators and pull those with growth for further testing.

The replacement process provides efficiencies by operating 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

Martha Frisone February 14, 2020 Page 3

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. The replacement system combines some incubators from the old manual system with the new automation components and Smart Incubators, but one or more existing incubators are replaced by this system or taken out of service.

Since this system automates the bacteriology data collection and transfer, it may also be considered data processing equipment, the acquisition of which is exempt pursuant to N.C. Gen. Stat. § 131E-184(a)(3).

The total project cost exceeds \$2,000,000, including equipment and related construction costs necessary for the installation of the automated system. See Exhibit 1 (Equipment Comparison Form). A copy of the equipment quotation is available upon request. UNCH 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).

This type of lab replacement equipment project is extremely similar to the project described in the Duke University Health System lab replacement equipment exemption request. That request and its approval are attached as Exhibit 2.

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

Sincerely,

Jary Qualls/Sup Gary S. Qualls

304343322 1

EXHIBITS

- 1. Equipment Comparison Form
 - a. Supplemental Form with Serial and ID Numbers
 - b. Supplemental Form with Serial and ID Numbers
- 2. Duke University Health System Lab Exemption Request and Approval

UNCH Replace Bacteriology Lab Project EQUIPMENT COMPARISON

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Incubators, Biological safety cabinet	Bacteriology Automation Equipment
Manufacturer of Equipment	Forma, Forma, Barnstead, Thermo, Nuaire	Becton Dickinson and Company
Tesla Rating for MRIs	N/A	N/A
Model Number	3956, 3956, N/A, N/A, N/A	See attachments
Serial Number	35843-2000, 35059-1905, 1455100250947, 306921-1535, 139955090810	See attachments
Provider's Method of Identifying Equipment	By model and serial #	By model and serial #
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	1/1/1993, 12/1/1996, 8/1/2010, 12/31/2006, 10/1/2010	May 23, 2017
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=""></use>	N/A	\$2,599,192
Total Cost of Equipment	\$41,016	\$2,599,192
Fair Market Value of Equipment	\$41,016	\$2,599,192
Net Purchase Price of Equipment	\$41,016	\$2,599,192
Locations Where Operated	UNCH Main Campus Building, East Wing	UNCH Main Campus Building, East Wing
Number Days in Use/To Be Used in N.C. per Year	365	365
Percent of Change in Patient Charges (by procedure)	N/A	No Change
Percent of Change in Per Procedure Operating Expenses (by procedure)	N/A	No Change
Type of Procedures Currently Performed on Existing Equipment	Bacteriology	Bacteriology
Type of Procedures New Equipment is Capable of Performing	Bacteriology	Bacteriology

Policy Procedure

Document ID: KLAIFMSER049B Page: 5 of 12

Change No. 5-108908, Ver. E, Rev. 05

2.2. Deliverables

The systems major components are listed below. Identification of the components and the included software is managed in BD Service Management Systems (ServiceMax). The ServiceMax system report is attached to this SAT. Include the identification numbers from this report in the table below.

Expected Results	Serial Number or confirmation of installation	Initials	Deviations Number (If applicable)
BarcodA I installed	16471ST001	AT/EA	
BarcodA II installed	na		
InoquiA I installed	IFA-000118 / ISA-000118	AT/EA	
InoquiA II installed	na		
Slide Preperation Module (SPM) I installed	SPM-0084	AT/EA	
Slide Preperation Module (SPM) Il installed	na		
Bio Safety Cabinet (BSC) #1 installed	122359	AT/EA	
Bio Safety Cabinet (BSC) #2installed	na		
ProceedA installed	17152ST001	AT/EA	
ReadA Compact 1 installed	16474ST002/RC1	AT/EA	
ReadA Compact 2 installed	16495ST002/RC2	AT/EA	
ReadA Compact 3 installed	16365ST001/RC3	AT/EA	
ReadA Compact 4 installed	na		
ReadA Compact 5 installed	na		
ReadA Compact 6 installed	na		
Amount Plate Carts installed	3	AT/EA	
Amount Reada Browsers	5	AT/EA	
System Controle Unit (SCU)	na		
Vision Toolbox	na		
Dashboard	1.	AT/EA	1
Urine Culture App	na		

Steps:	Executed by:	Date: 12/13/1	7
	(Signature)		

EXHIBIT

solver

1 A

Product	Serial/Lot Number	Product Group	Attribute Name	Attribute Value	Additional information	Location	
loogula SA	ISA-000118	Inpaul	InoquiA software	9,4,181,90		UNIV NORTH CAROLINA HOSPITALS	
Inoquia SA	ISA-000118	InoquiA	SpreadA	8,1,1488,2		UNIV NORTH CAROLINA HOSPITALS	
Inoquia SA	ISA-000118	InoquiA	Align Wizard	3,1,2806,16		UNIV NORTH CAROLINA HOSPITALS	
inoquia SA	(SA-000118	InoquiA	Sample Creator	Other	1.0.6.1	UNIV NORTH CAROLINA HOSPITALS	
Inoquia SA	ISA-000118	InoquiA	ZeusTestTool	2.0.2386,4		UNIV NORTH CAROLINA HOSPITALS	
Inoquia SA	ISA-000118	InoquiA	InoquiA PLC	7.0.1.58		UNIV NORTH CAROLINA HOSPITALS	
447900 - Proceeda TLA 4	17152ST001	ProceedA	ProceedA software	5.1.0.2		UNIV NORTH CAROLINA HOSPITALS	
D44E 5132801	BDKBARCODA	InequilA	PC Type and MAC Address		98-80-95-C0-2B-CA	UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BDKBARCODA	InoquiA	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	PC	ProceedA	PC Type and MAC Address	Other	00-08-A8-A1-89-84	UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	PC	ProceedA	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BDKREADACOMP1	ReadA Compact	PC Type and MAC Address	Other	00-0B-AB-A1-89-84	UNIV NORTH CAROLINA HOSPITALS	
D44E 5132801	BDKREADACOMP1	ReadA Compact	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BOKREADACOMP3	ReadA Compact	PC Type and MAC Address	Other	00-08-AB-A9-EB-8B	UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BDKREADACOMP3	ReadA Compact	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BDKREADACOMP2	ReadA Compact	PC Type and MAC Address	Other	00-08-A8-BA-14-C1	UNIV NORTH CAROLINA HOSPITALS	
D44E 5132601	BDKREADACOMP2	ReadA Compact	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW1	ReadA Browser	PC Type and MAC Address		48-4D-7E-F9-8F-24	UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW1	ReadA Browser	0/5	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW2	ReadA Browser	PC Type and MAC Address	Other	48-4D-7E-F9-E7-84	UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW2	ReadA Browser	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BOKREADABRW3	ReadA Browser	PC Type and MAC Address	Other	48-4D-7E-F9-EB-A8	UNIV NORTH CAROLINA HOSPITALS	
5000-885-01-01	BOKREADABRW3	ReadA Browser	S/O	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BOKREADABRW4	ReadA Browser	PC Type and MAC Address	Other	48-4D-7E-F9-E7-FC	UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW4	ReadA Browser	0/8	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRW5	ReadA Browser	9/0	Windows 7 - 32 bit		UNIV NORTH CAROLINA HOSPITALS	
5000-985-01-01	BDKREADABRWS	ReadA Browser	PC Type and MAC Address	Other	48-4D-7E-F7-57-CC	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Interbase version	Other	12,1,0,147	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00118APP1	Server Applications	Database version	3.0,65	*	UNIV NORTH CARCLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Validate dish Import	Other	2.0.0.0	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	ASTM plugin	1.2.2.117		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Archiva viewer	1.0.0.8		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	F-17-00116APP1	Server Applications	DB Manager	3,0.1.0		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	ReadA overview	1.1.0.2		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Barcode login generator	2.0.2420.7		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00118APP1	Server Applications	KLA Maller	Other	1,0,5,0	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	KLA Service Manager	2.0.5.0		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Journalling App	Other	1.0.0.6	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	DB Backup	Other	1,0.0,6	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	KLA DB Manager	2,3.3.5		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Informa	1,0.0.7		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Performa	Other	1.0.5.0	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00118APP1	Server Applications	MisExtractor	4.0.1.18		UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00116APP1	Server Applications	Archiva	Other	1.0.0.8	UNIV NORTH CAROLINA HOSPITALS	
Server Applications	P-17-00118APP1	Server Applications	KLA Service helper	1.0.0.16		UNIV NORTH CAROLINA HOSPITALS	



447212 - BarcodA TLA 447212 - BarcodA TLA 447307 - Workflow Dashboard License	P-17-00118APP1 16471ST001 16471ST001 BDKDASHBOARD	Server Applications KLA Service BercodA BercodA Both BercodA BercodA PLC Dashboard Dashboard so	KLA Service BarcodA software BarcodA PLC Dashboard service	2,0,6,0 7,0,1,14 6,17,1,17 2,2,0,1		UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS
	16474ST002 16474ST002 16474ST002	ReadA Compact ReadA Compact ReadA Compact	Incubation type ReadA Compact Daemon ReadA Compact PLC	CO2 2.5 Other	2.0.3.462	UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS
	16495ST002 16495ST002 16495ST002 16495ST002	ReadA Compact ReadA Compact ReadA Compact ReadA Compact	ReadA Compact software incubation type ReadA Compact Daemon ReadA Compact PLC	1.2.5.9 CO2 2.5 Other	2.0.3.462	UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS
acc at	164955T002 16365ST001 16365ST001	ReadA Compact ReadA Compact ReadA Compact	ReadA Compact software Incubation type ReadA Compact Daemon	1,2,5,9 02 2,5		UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS
-0 000	16365ST001 18365ST001	ReadA Compact ReadA Compact	ReadA Compact PLC ReadA Compact software	Other 1,2.5.9	2.0.3.462	UNIV NORTH CAROLINA HOSPITALS UNIV NORTH CAROLINA HOSPITALS



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

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

dhhs

Healthcare Planning and Certificate of Need Section

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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

POD



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

3100 Tower Blvd Suite 1300 * Durham, NC 27707 * tel (919) 668-0857 * catharine.cummer@duke.edu



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,

Catharine W. Cummer

Ham Wann

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:

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

Campus Plan

EQUIPMENT COMPARISON DUH MICROBIOLOGY

	EXISTING	REPLACEMENT
	EQUIPMENT	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=""></use>	\$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

Waller, Martha K

From:

Hall, Carolyn < Carolyn. Hall@klgates.com>

Sent:

Friday, February 14, 2020 1:51 PM

To:

Waller, Martha K

Cc:

Qualls, Gary

Subject:

[External] Replacement Equipment Exemption for UNC Hospitals

Attachments:

UNC Hospitals Replacement Equipment Exemption.PDF

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report spam@nc.gov

Ms. Waller,

Attached please find a letter on behalf of UNC Hospitals for a replacement equipment exemption.

Thank you, Carolyn Hall



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