

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 #:

2988

Facility Name:

Duke University Hospital

FID #:

943138

Business Name:

Duke University Health System, Inc.

Business #:

640

Project Description:

Replace existing linear accelerator located in the Morris Clinic

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 27, 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 Varian TrueBeam Edge linear accelerator to replace the Varian 21IX linear accelerator. 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

Project Analyst

Martha J. Frisone

1. 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

Record# 2988



Duke University Health System

Catharine W. Cummer Regulatory Counsel, Strategic Planning

June 27, 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: Exempt Linear Accelerator Replacement Project at Duke University Hospital

Dear Ms. Frisone and Ms. Thorne-Williams:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement linear accelerator equipment 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 an existing linear accelerator currently in service in the Morris Clinic, which is part of the main building of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[t]he site of the

Ms. Martha Frisone Ms. Bernetta Thorne-Williams June 27, 2019 Page 2

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 and campus map have been previously provided to the CON Section. The construction plans showing the location of the project within the Morris Clinic are enclosed.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2004. As set forth in Project J-6294-00 (CON attached), as of 2000, Duke operated three linear accelerators (originally grandfathered), and was approved to acquire two additional linacs and to replace two existing linacs. The replacement of the third grandfathered linac was approved pursuant to an exemption granted in 2000 (letter attached). The equipment to be replaced now was one of the five linear accelerators approved in 2000 for acquisition or replacement.

(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 radiation oncology procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotations are available upon request. The total operating costs per procedure will increase by less than 1%, as the result of the cost of the services agreement for the replacement equipment. 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

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor,	Linear Accelerator	Linear Accelerator
MRI, PET, Simulator, C.I. Scanner, Other Major Medical Equipment	Varian	Varian
Model number	21IX	TrueBeam Edge
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Rm 005121	Rm 005121
1c the equipment mobile or fixed?	Fixed	Fixed
Date of actualities	2004	2019
Date of acquisition.	New	New
was the existing equipment from 50 coordinates and the project Attach a signed Projected Capital Cost form>	NA	5,895,000
	1,343,044	3,686,815
Total cost of the equipment https://www.nearsteader.com/ notes equipment if necessary>	Morris Bldg Rm	Morris Bldg Rm 005121
	Yes	AN AN
Document that the existing equipment is currently in use	3	
Will the replacement equipment result in any increase in the average charge per procedure?	NA	oN
If so, provide the increase as a percent of the current average charge per procedure	NA	
Will the replacement equipment result in any increase in the average operating expense per procedure?	AN	Yes
if con provide the increase as a percent of the current average operating expense per procedure	AN	0.40%
Two of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	See attached	NA
Type of proceedings the rapid period period will perform https://www.nc.tho.tanlacement.com.	NA	See attached

Type of procedures performed on the existing equipment

Description

IMRT Treatment, Simple 77385

IMRT Treatment, Complex 77386

Radiation Treatment Delivery, Simple 77402

Radiation Treatment Delivery, Intermediate 77407

Radiation Treatment Delivery, Complex 77412 Type of procedures the replacement equipment will perform

Description CPT

Stereotactic Radiosurgery, complete course 1 session 77372

Stereotactic Body, not to exceed 5 fractions 77373

IMRT Treatment, Simple 77385

IMRT Treatment, Complex

Radiation Treatment Delivery, Simple 77386

Radiation Treatment Delivery, Intermediate 77407

Radiation Treatment Delivery, Complex 77412

STATE OF NORTH CAROLINA

Department of Health and Human Services Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number J-6294-00

FID #943138

ISSUED TO: Duke University Health System 3100 Tower Bouleyard, Box 80 University Tower, Suite 13007

Durham, NE 27707

Pursuant to N.C. Gent-Stat. § 131E-175, et., seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. \$ 121E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. 8,13 TE-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE:

Duke University Health System shall acquire two additional linear accelerators, for a total of five linear accelerators, replace two linear accelerators; upgrade the ssimulator, acquire a second simulator and acquire additional hardware and software/Durham County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION:

Duke University Hospital 3000 Erwin Road Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE:

\$15,479,810

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE: September 1, 2001

This certificate is effective as of the 21st day of May, 2001.

Division of Facility Services



Lee Hoffman, Section Chief Phone: 919-733-6360

Fax: 919-733-8139

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

Courier Number 56-20-05

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

October 6, 2000

Duncan Yaggy, Chief Planning Officer Duke University Health System 3100 Tower Boulevard, Suite 1500 Durham, North Carolina 27707

Exempt from Review/Duke University Medical Center/Replace a linear accelerator/Durham RE: County

FID # 943138

Dear Dr. Yaggy:

In response to your letter of September 15, 2000, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, the Varian Clinac 21EX Linear Accelerator may be acquired to replace the existing Varian Clinac 4, Serial Number 304, without a certificate of need. At no time shall Duke University Medical Center have more three linear accelerators until a certificate of need is obtained to acquire additional linear accelerators. 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,

Certificate of Need Section

Medical Facilities Planning Section, DFS Section Chief, Construction Section, DFS



Location: 701 Barbour Drive w Dorothea Dix Hospital Campus w Raleigh, N.C. 27603 An Equal Opportunity / Affirmative Action Employer



Green Vault Linac Renovation Duke Cancer Center, Sub-Basement Duke Health FPDC #3991

Cover Sheet



Duke Health #3997 - Green Vault Linac Renovation Morris Building, Sub-Basement. Part of the Duke Cancer Center 30 Duke Medicine Circle, Durham North Carolina 27710

Isley Hawkins

Architects: Isley Hawkins Architecture Durham, NC

Isley Hawkins

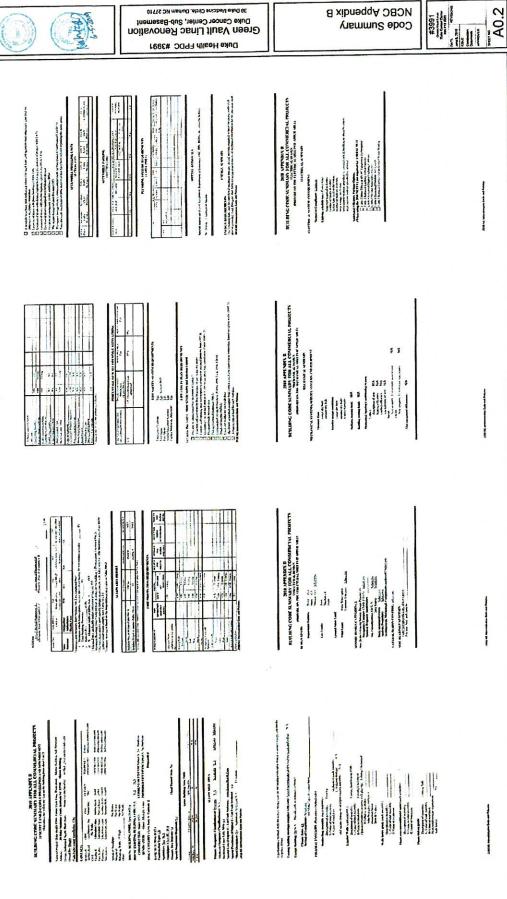
Mechanical, Electrical Edmondson Engineers & Plumbing Engineers: Durham, NC

Construction Documents June 5, 2019

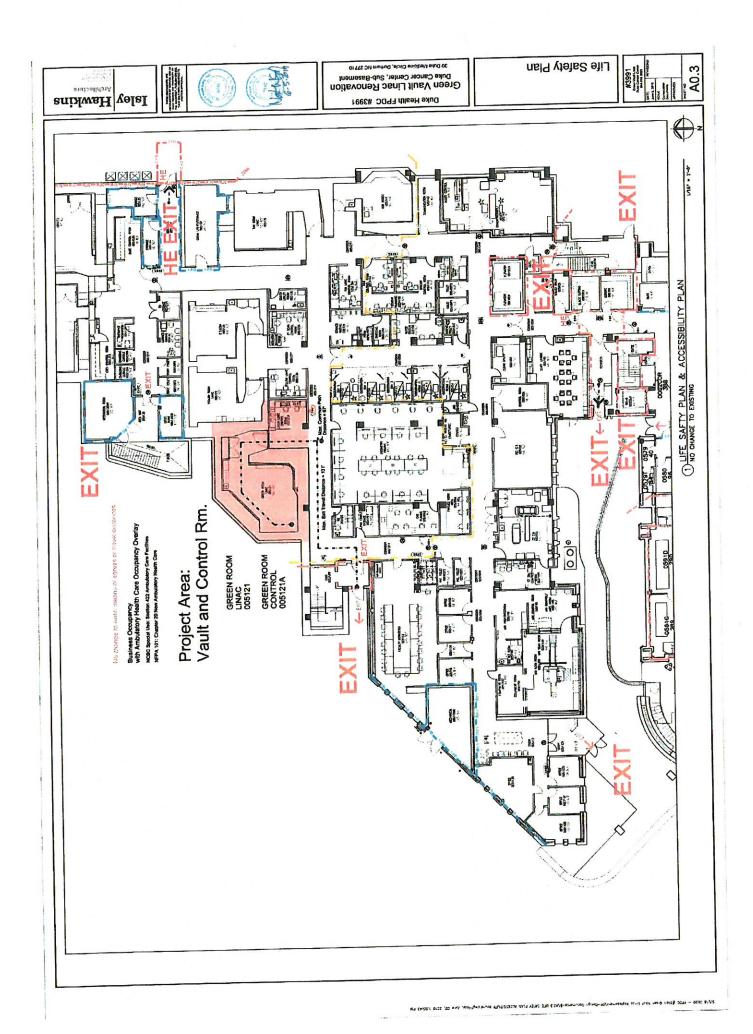
	Budding Code Summary - NCBC Appendix B	Indeptor Central Plan	OLIGINATION IN CO. LANCOUR.	Port Daniel Beneather Shieffer Concrete Sab Work	Reflected Colling Pisms - Demoliton, Renovation.	ENGINEERING DRAWINGS	Fire Protection Schedules, Legends and Details	Fire Protection Demotition Plan	Fire Protection Ranovetion Plan	Plumbing Leganda, Notes, Abbroviotoms and Detalls	Plumbing Demotition Plan	Plumbing Renovation Plan	Plumbing Waste and Vent Rizer Diagram and Details	Mechanical Legands, Notes, Abbreviators, and Specifications	Mechanical Demotition and Renavation Plans	Mechanical Piping and Roof Plans	Mechanical Controls and Schedules	Mechanical Details	Electrical Demolition Plan	Electrical Plans	Varian Connection Plan	Brain Lab Connection Plan	Electrical Details	Section Seculostant
The state of the s			9	Concrete Stab Work	. Finishes Floor Plan, Detade					Actulie			Details	d Specifications			The second secon					-		

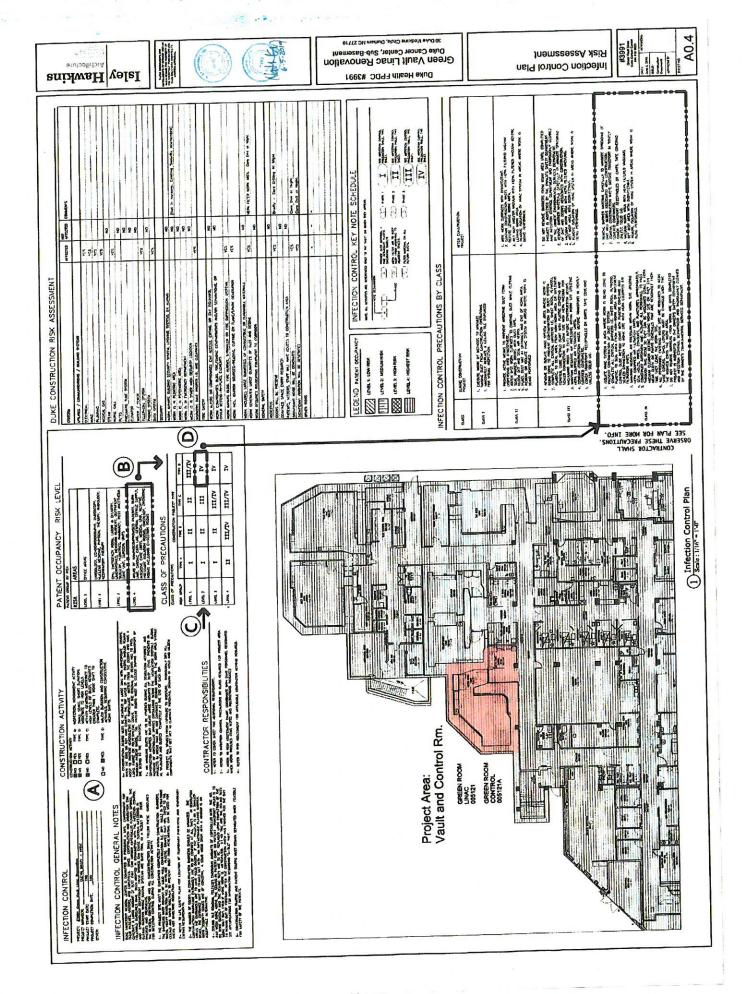
Project Site Keyplan: Sub-Basement Duke Clinic, Morris Building

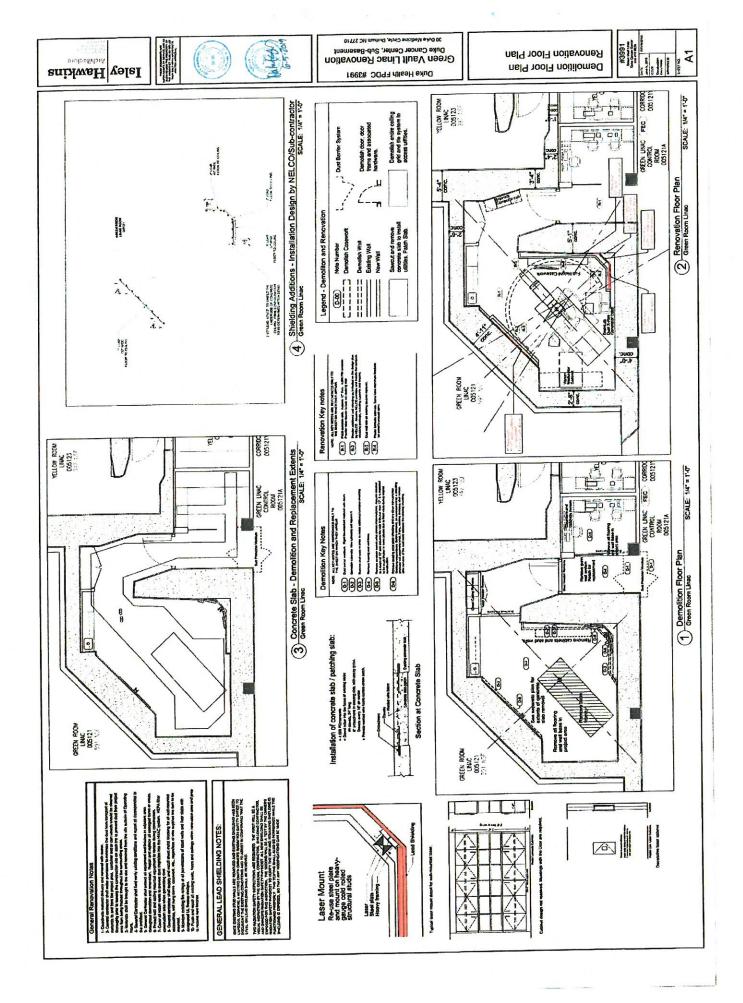
Duke Cancer Center "Front" Side

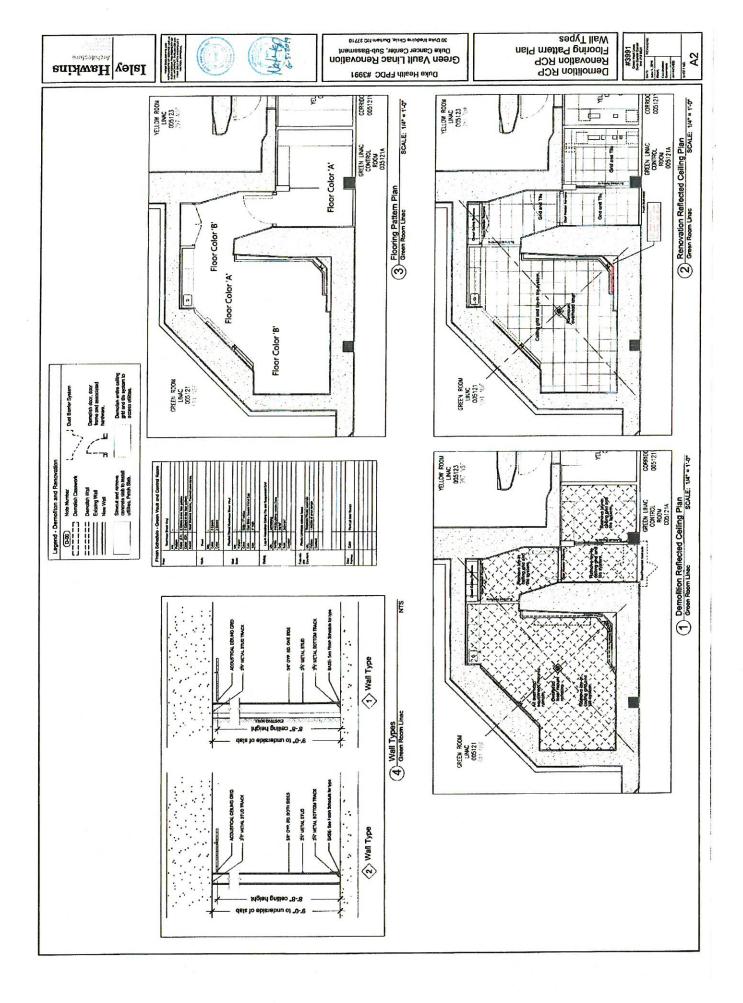


Isley Hawkins









Effective January 10, 2019, 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: 979 General Acute 960, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6

Dedicated Ambulatory Surgical Operating Rooms: 9

Shared Surgical Operating Rooms: 50

Dedicated Endoscopy Rooms: 1

Williams, Bernetta

From:

Catharine Cummer < catharine.cummer@duke.edu>

Sent:

Tuesday, July 16, 2019 5:44 PM

To:

Williams, Bernetta

Cc:

Lara Orgain

Subject:

[External] Re: statement

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

Bernetta,

Thank you for your message. This will confirm that the existing equipment will be removed by the vendor, and that therefore we understand it will not be put back into service in North Carolina without certificate of need approval. Thank you.

Catharine

Sent from my iPhone

On Jul 16, 2019, at 12:26 PM, Williams, Bernetta

bernetta.williams@dhhs.nc.gov wrote:

Catharine,

Hope you are well. Concerning your equipment replacement exemption letter request dated June 28, I need a statement which addresses the existing machine will be either 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.

Thanks,

Bernetta Thorne-Williams
Project Analyst
<u>Division of Health Service Regulation</u>, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services

Office: 919-855-3873 btwilliams@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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