



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

December 4, 2017

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

**Exempt from Review – Replacement Equipment**

**Record #:** 2436  
**Facility Name:** Duke University Hospital  
**FID #:** 943138  
**Business Name:** Duke University Health System  
**Business #:** 640  
**Project Description:** Replace existing CT (Brachytherapy Simulation) 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 letters of November 6, 2017 and November 21, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Brainlab Airo CT equipment to replace the existing Varian Acuity iX simulator. 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 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.

If you have any questions concerning this matter, please feel free to contact this office.

**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

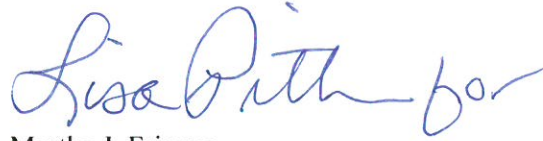
AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Sincerely,



Bernetta Thorne-Williams  
Project Analyst



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

cc: Acute and Home Care Licensure and Certification Section, DHSR  
Sharetta Blackwell, Program Assistant Healthcare Planning, DHSR  
Radiation Protection Section, DHSR



# Duke University Health System

**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning



November 6, 2017

Via Electronic Mail

Ms. Martha Frisone  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke University Hospital –  
Brachytherapy Simulation

Dear Ms. Frisone:

I am writing to provide you with prior written notice of the planned acquisition of Brainlab Airo CT equipment at Duke University Hospital as a replacement of an existing Varian Acuity simulator, to provide brachytherapy simulation procedures billed under CPT code 77290 and defined by ASTRO as follows:

### Simulation (CPT® codes 77280-77290)

After the physician has determined the appropriate treatment parameters within the clinical treatment plan, the next step is the physical targeting of the tumor or treatment volume to ensure accurate treatment delivery. Simulation is the process of defining relevant normal and abnormal target anatomy and acquiring the images and data necessary to develop the optimal radiation treatment process, without actually delivering a treatment. During simulation, the radiation oncologist, with the assistance of the radiation therapist, utilizes simulation equipment to define the exact treatment position for the patient. Simulation may be repeated during the treatment course as medically indicated depending on the type of cancer, radiation therapy utilized and the clinical response to the treatment. The simulation codes describe the work and complexity of establishing the proper patient positioning and obtaining adequate imaging with the patient in the treatment position.

The new equipment will be used exclusively for the same simulation procedures historically performed by the existing equipment. A completed equipment comparison form and capital cost form are enclosed. The vendor's quote is available for your review upon request. The existing equipment is currently in use at Duke, but upon placement of the replacement equipment into service the existing equipment will be returned to the vendor.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Simulator	CT
Manufacturer of Equipment	Varian	Brainlab
Tesla Rating for MRIs	n/a	n/a
Model Number	Acuity iX	Airo
Serial Number	518	
Provider's Method of Identifying Equipment		
Specify if Mobile or Fixed	Fixed	Mobile
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	12/19/2013	
Does Provider Hold Title to Equipment or Have a Capital Lease?		
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$975,000
Total Cost of Equipment	\$450,000	\$809,974
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Duke University Hospital Radiation Oncology	Duke University Hospital Radiation Oncology
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	Brachytherapy simulation (CPT Code 77290)	NA
Type of Procedures New Equipment is Capable of Performing	NA	Brachytherapy simulation (CPT Code 77290)



## Williams, Bernetta

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**From:** Catharine Cumber <catharine.cumber@duke.edu>  
**Sent:** Tuesday, November 21, 2017 12:01 PM  
**To:** Williams, Bernetta  
**Subject:** [External] RE: Additional information needed - DUH Equipment Replacement  
**Attachments:** Brachytherapy Imaging-Capital Cost Form.pdf

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

Bernetta,

Attached please find the capital cost form for this project (I apologize; I meant to include it with our original submission). Additional responses are as follows:

1) Varian, the vendor of the existing equipment, has represented to us that it intends to destroy the equipment upon replacement and sell the scrap metal, so it will not be put into service elsewhere in the state.  
2) The replacement equipment, like the existing equipment, will be owned, not leased.  
3) The new CT will be configured specifically for brachytherapy procedures to replace the functionality of the existing equipment. Our physicist provided the following additional input regarding the comparability of the equipment to the existing equipment, which are both used for the brachytherapy simulation procedures identified in our original request:

1. Both generate 2D radiograph (AIRO-digital reconstructed radiograph, Acuity-flat panel radiograph)
2. Both generate 3D tomographic images (ARIO - CT, Acuity-CBCT)
3. Those two features are the major functionalities for clinical application
4. Those are essential for precision brachytherapy, especially 3D images

I will call you about the quote. Please let me know if you have any further questions. Thanks!

Catharine

Catharine Cumber  
Regulatory Counsel, Strategic Planning  
Duke University Health System  
3100 Tower Blvd, Suite 1300  
Durham NC 27707  
(919) 668-0857 (office)  
(919) 423-6928 (cell)

-----Original Message-----

From: Williams, Bernetta [mailto:bernetta.williams@dhhs.nc.gov]  
Sent: Tuesday, November 14, 2017 9:10 AM  
To: Catharine Cumber  
Subject: Additional information needed - DUH Equipment Replacement

Catharine,

Additional information is needed to determine if the equipment to be acquired is consistent with the definition of replacement equipment in N.C. Gen. Stat. §131E-176(22a) and 10A NCAC 14C .0303. Provide the following information:

- \*Documentation that the proposed equipment is comparable to the existing equipment pursuant to 10A NCAC 14C .0303(d).
- \*If the replacement equipment will be leased, a copy of the proposed capital lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).
- \*If the replacement equipment will be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.
- \*Documentation 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.
- \*Total capital cost associated with the replacement equipment.

Thank you,

Bernetta Thorne-Williams  
Project Analyst  
Division Health Service Regulation, Healthcare Planning and Certificate of Need Section North Carolina Department of Health and Human Services

919 855 3873 office  
bernetta.williams@dhhs.nc.gov

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

-----Original Message-----

From: Catharine Cumber [mailto:catharine.cumber@duke.edu]  
Sent: Monday, November 06, 2017 12:38 PM  
To: Frisone, Martha; Williams, Bernetta; Moore, Veronica M  
Subject: [External] DUH Equipment Replacement

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

Ladies,  
Attached please find a replacement notice for brachytherapy simulation equipment at Duke University Hospital. Please let me know if you have any questions. Thank you!

Catharine

Catharine Cumber  
Regulatory Counsel, Strategic Planning  
Duke University Health System

3100 Tower Blvd, Suite 1300  
Durham NC 27707  
(919) 668-0857 (office)  
(919) 423-6928 (cell)

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**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project Name:**

**Provider/Company:**

**A. Site Costs**

(1) Full purchase price of land		\$ _____	
Acres _____ Price per Acre \$ _____			
(2) Closing costs	\$ _____		
(3) Site Inspection and Survey		\$ _____	
(4) Legal fees and subsoil investigation		\$ _____	
(5) Site Preparation Costs			
Soil Borings.....	\$ _____		
Clearing-Earthwork...	\$ _____		
Fine Grade For Slab...	\$ _____		
Roads-Paving.....	\$ _____		
Concrete Sidewalks....	\$ _____		
Water and Sewer.....	\$ _____		
Footing Excavation....	\$ _____		
Footing Backfill.....	\$ _____		
Termite Treatment....	\$ _____		
Other (Specify).....	\$ _____		
Sub-Total Site Preparation Costs		\$ _____	
(6) Other (Specify)		\$ _____	
(7) <b>Sub-Total Site Costs</b>			\$ <u>  N/A  </u>

**B. Construction Contract**

(8) Cost of Materials			
General Requirements	\$ <u>11,000</u>		
Concrete/Masonry	\$ _____		
Woods/Doors & Windows/Finishes	\$ <u>7,500</u>		
Thermal & Moisture Protection	\$ _____		
Equipment/Specialty Items	\$ <u>5,000</u>		
Mechanical/Electrical	\$ <u>19,500</u>		
Other (Technology)	\$ <u>5,000</u>		
Sub-Total Cost of Materials.....		\$ _____	
(9) Cost of Labor.....		\$ <u>14,000</u>	
(10) Other (Equip Removal).....		\$ <u>10,000</u>	
(11) <b>Sub-Total Construction Contract</b>			\$ <u>72,000</u>

**C. Miscellaneous Project Costs**

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$ <u>810,000</u>	
(14) Movable Equipment Purchase/Lease		\$ <u>7,000</u>	
(15) Furniture		\$ <u>1,000</u>	
(16) Landscaping		\$ _____	
(17) Consultant Fees			
Architect and Engineering Fees	\$ <u>51,500</u>		
Legal Fees.....	\$ _____		
Market Analysis.....	\$ _____		
Other (Permit, Test & Balance).....	\$ <u>5,700</u>		
Other (Workers Comp)....	\$ <u>3,300</u>		
Sub-Total Consultant Fees.....		\$ _____	
(18) Financing Costs (e.g. Bond, Loan, etc.).		\$ _____	
(19) Interest During Construction.		\$ _____	
(20) Other (Contingency)		\$ <u>24,500</u>	
(21) <b>Sub-Total Miscellaneous..</b>			\$ <u>903,000</u>
(22) <b>Total Capital Cost of Project (Sum A-C above)</b>			\$ <u>975,000</u>

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

Nathan Isley - Isley Hawkins Architecture Date Certified: 11-3-2017  
 (Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

\_\_\_\_\_ Date Signed: \_\_\_\_\_  
 (Signature and Title of Officer Authorized to Represent Provider/Company)



*Effective May 30, 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: 11**