

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 11, 2020

Lisa Griffin

llgriffin@novanthealth.org

Exempt from Review - Replacement Equipment

Record #: 3344

Facility Name: Novant Health Presbyterian Medical Center

FID #: 943501

Business Name: Novant Health, Inc.

Business #: 1341

Project Description: Replace existing linear accelerator and relocate it to the Novant Health

Presbyterian Heart & Vascular Institute and Cancer Center on the main campus

County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 4, 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 Varian TrueBeam linear accelerator to replace the Elektra MRT10771 linear accelerator and relocate it from the first floor of Novant Health Presbyterian Medical Center to the Novant Health Presbyterian Heart & Vascular Institute and Cancer Center located on the main campus. 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,

Julie M. Faenza, Project Analyst

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

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

September 4, 2020



Via Email

Julie Faenza, Project Analyst, Certificate of Need N.C. Department of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27603 2085 Frontis Plaza Boulevard Winston-Salem, NC 27103

Re:

Novant Health Presbyterian Medical Center (FID 943501)

Replacement of Existing Linear Accelerator #2

Charlotte, NC (Mecklenburg County)

Dear Ms. Faenza:

Pursuant to N.C. Gen. Stat. § 131E-184(f), this letter serves as prior written notice that Novant Health Presbyterian Medical Center ("NHPMC") intends to replace an existing fixed linear accelerator currently located in the Radiation-Oncology Department on the first floor of the hospital and relocate it to the Novant Health Presbyterian Heart & Vascular Institute and Cancer Center building ("HVI-CC") on the main campus of NHPMC.

NHPMC's project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for "replacement equipment" that exceeds two million (\$2,000,000) threshold in the following ways:

Main Campus

The HVI-CC is located at the corner of East Fourth Street and Queens Road directly across the street from NHPMC and is between 125.7 and 127 feet of the main hospital building. The main hospital building is the location at which NHPMC exercises financial and administrative control over the entire facility and the administrative suite is located on the first floor of NHPMC.

The HVI-CC is set to open in October 2020. See **Attachment A** for the Agency response dated July 17, 2018 deeming the HVI-CC project exempt from CON review and confirming the "main campus" location.

Previous Certificate of Need

The existing linear accelerator is a replacement of a unit that dated back to 2007; however, we are unable to find the documentation regarding its original certificate of need. NHPMC has reported two linear accelerators for many years on the Annual License Renewal Application ("LRA") as support that this linear accelerator has been in use and is still in use. **See Attachment B** for an excerpt of NHPMC's 2020 LRA.

Replacement Equipment

The proposed project meets the definition of "replacement equipment" found in N.C.G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

Ms. Julie Faenza September 4, 2020 Page 2

- (1) NHPMC will replace the existing equipment with the proposed equipment that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The replacement involves the existing linear accelerator which was acquired in 2007 and is well past its useful life and is outdated to current equipment capabilities. **Attachment E** contains the Equipment Comparison Form.

See **Attachment C** for the Equipment Quote for the new linear accelerator. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. Also, the existing equipment will be traded in and removed from North Carolina by Varian. The total capital cost for the proposed replacement equipment project is estimated to be \$5,330,472. See **Attachment D** – Project Capital Cost Form.

In support of our request, please find attached:

Attachment A - NHPMC HVI-CC Exemption Notice 2018

Attachment B - NHPMC 2020 LRA Excerpt

Attachment C - Equipment Quote

Attachment D - Project Capital Cost Form

Attachment E – NC CON Equipment Comparison chart

NHPMC's acquisition of the replacement fixed linear accelerator does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$5,330,472. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHPMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review as indicated above.

If you need additional information, please do not hesitate to contact me.

Sincerely,

Lisa Griffin

Manager, Operational Planning

Novant Health, Inc.

ATTACHMENT A



ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director

July 17, 2018

Denise M. Gunter 380 Knollwood Street, Suite 530 Winston-Salem, NC 27103

Exempt from Review

Record #:

2652

Facility Name:

Novant Health Presbyterian Medical Center

FID#:

943501

Business Name:

Novant Health, Inc.

Business #:

1341

Project Description:

Develop a medical office building on the main hospital campus with a cost

greater than \$2 million and develop an adjacent parking deck

County:

Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 11, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g) and §131E-184(a)(4). Therefore, you may proceed to offer, develop, or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and the 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 this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

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: 2704 Mail Service Center, Raleigh, NC 27699-2704 www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Denise M. Gunter July 17, 2018 Page 2

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

Sincerely,

Julie M. Faenza Project Analyst Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

cc:

Construction Section, DHSR

Juli M. Jaerrya

Acute and Home Care Licensure and Certification Section, DHSR Amy Craddock, Assistant Chief, Healthcare Planning, DHSR



Denise M. Gunter T 336.774.3322 F 336.774.3372 denise.gunter@nelsonmullins.com NELSON MULLINS RILEY & SCARBOROUGH ATTORNEYS AND COUNSELORS AT LAW

380 Knollwood Street | Suite 530 Winston-Salem, NC 27103 T 336.774.3300 F 336.774.3299 nelsonmullins.com

July 11, 2018

Hand Delivered

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

Notice of Exemption for Two Projects Pursuant to N.C. Gen. Stat. § 131E-

Facility Name:

Novant Health Presbyterian Medical Center (NHPMC)

FID #:

943501

Business Name:

Novant Health, Inc.

Business #:

1341

Project Description: Construct Heart and Vascular Institute and Cancer Center on the Main Campus of NHPMC, as well as a

parking deck

County:

Mecklenburg

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-184(a)(4) and (g), this letter serves as prior written notice of two CON-exempt projects at NHPMC: (1) NHPMC's intent to construct a Heart and Vascular Institute and Cancer Center on its main campus (the "HVI/CC Facility"); and (2) NHPMC's intent to build a parking deck adjacent to the HVI/CC Project. Each project is discussed below.

Construct the HVI/CC Facility

The HVI/CC Facility will be a 7-story, approximately 257,000 square foot facility. Five of the floors will be built out and two of the floors will be shell space. The HVI/CC Facility will be located at the corner of East Fourth Street and Queens Road in Charlotte, Martha J. Frisone July 11, 2018 Page 2

directly across the street from NHPMC. A diagram showing the site is attached as **Exhibit A**. A rendering of the proposed HVI/CC Facility is attached as **Exhibit B**. A second rendering showing the building and the parking deck is attached as **Exhibit C**. The total capital cost of the HVI/CC Facility, including the parking deck discussed below, is estimated to be \$165.6 million. NHPMC presently estimates that the HVI/CC Facility will be completed in 2020.

The HVI/CC Facility will house comprehensive heart and vascular and cancer outpatient services, including cardiovascular and cancer rehabilitation, radiation oncology, a chemotherapy infusion center and physician offices. A stacking diagram showing the services that will go on each floor of the HVI/CC Facility is attached as **Exhibit D**. In addition, because Presbyterian Medical Tower ("PMT") is adjacent to the proposed HVI/CC Facility, a connector will be built between the two buildings. The Breast Center in PMT will be renovated, and physician and administrative offices needed to support the HVI/CC Facility will be constructed in PMT. The costs for these portions of the project are included in the \$165.6 million estimate.

- N.C. Gen. Stat. § 131E-184(g) provides that the Department shall exempt from CON review any capital expenditure that exceeds the \$2 million threshold in N.C. Gen. Stat. § 131E-176(16)b., if all of the following conditions are met:
 - (1) The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.
 - (2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.
 - (3) The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.
- N.C. Gen. Stat. § 131E-176(14n) defines "main campus" as:
 - 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

Martha J. Frisone July 11, 2018 Page 3

entire facility, including the buildings and grounds adjacent to that main building.

 Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The HVI/CC Facility meets the requirements of N.C. Gen. Stat. § 131E-184(g) and N.C. Gen. Stat. § 131E-176(14n) because:

- (1) NHPMC is an existing health service facility (Hospital License # H0010) located at 200 Hawthorne Lane in Charlotte. See Exhibit E, the NHPMC 2018 License. The sole purpose of the HVI/CC Facility is to expand an existing health service facility that is located on the main campus. As shown in Exhibit A, the location of the HVI/CC Facility is between 125.7 and 127 feet of NHPMC, which is the main building. The distance was measured by civil engineers. PMT is also approximately the same distance from NHPMC. The main building is the location at which NHPMC provides clinical patient services and from which NHPMC exercises financial and administrative control over the entire facility. administrative suite is on the first floor of NHPMC. Exhibit F, a letter from Barbara L. Freedy, Director, Certificate of Need, Novant Health, Inc., documenting this. Ms. Freedy's letter was submitted to the Agency in March 2018 in connection with another NHPMC project, and the facts stated in that March 2018 letter remain true today.
- (2) This renovation project will not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.
- (3) This letter constitutes the required prior written notice.

We would appreciate the Agency's written confirmation that the construction of the HVI/CC Facility is exempt from CON review.

Martha J. Frisone July 11, 2018 Page 4

Construct a Parking Deck

NHPMC proposes to construct a 1,000 space parking deck that will be adjacent to the HVI/CC Facility. N.C. Gen. Stat. § 131E-184(a)(4) provides that upon prior written notice, the Department shall exempt from CON review projects that:

... provide parking, heating or cooling systems, elevators, or other basic plant or mechanical improvements, unless these activities are integral portions of a project that involves the construction of a new health service facility or portion thereof and that is subject to certificate of need review.

The parking deck does not involve the construction of a new health service facility or portion thereof and that is subject to CON review. The parking deck is necessary to accommodate patients receiving treatment at the HVI/CC Facility as well the staff who will work in the HVI/CC Facility

We would appreciate the Agency's written confirmation that the foregoing parking deck construction is exempt from CON review.

If you need any further information, please let me know.

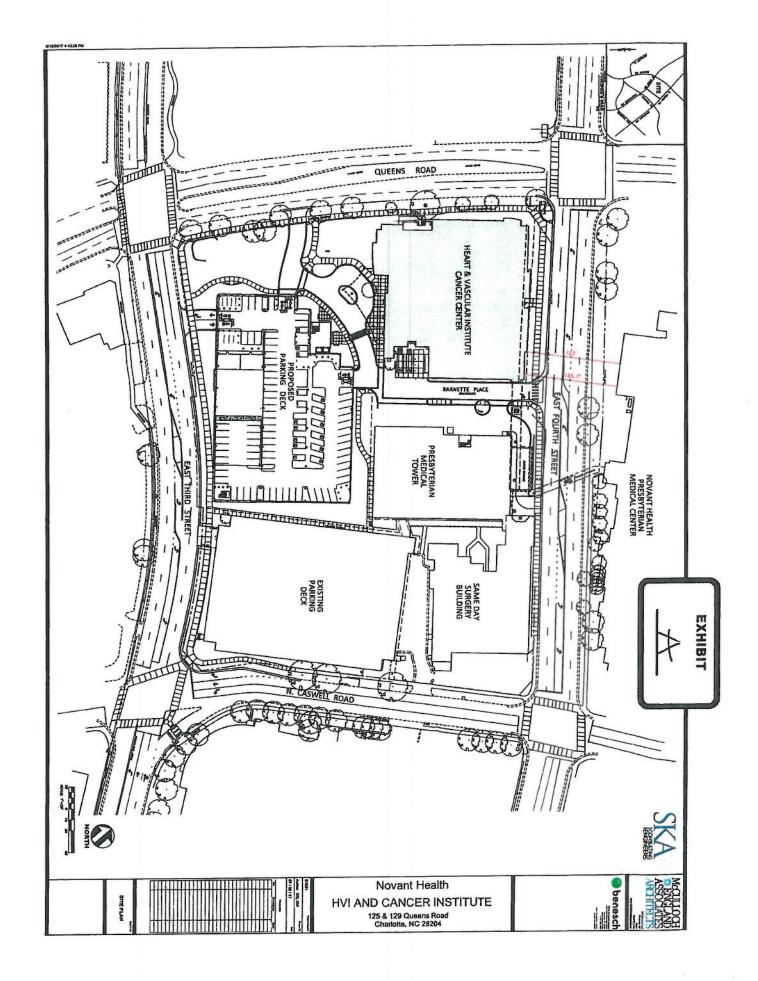
Thank you for your time and attention.

Sincerely,

Denise M. Gunter

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Enclosures



ATTACHMENT B

Custom System Proposal

Quotation Number - 2020-245646

3,711,472



*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***



Novant Presbyterian Hospital ("Customer")

Karen Johnson 200 HAWTHORNE LN

CHARLOTTE, North Carolina 28204 United States

Tel: 704-384-4188 Fax: 704-384-5299

Email: kaajohnson@novanthealth.org

Varian Medical Systems, Inc.

Jeffrey Boone

US District Sales Manager

3290 Northside Pkwy NW Suite 400

Atlanta, GA 30327 US Tel: (704) 737-9395

Email: jeffrey.boone@varian.com

*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***

Quote Information

Quotation Number: 2020-245646

Quotation Valid Until: October 21, 2020 Sales PO Required: Yes
Customer Requested Delivery Date: October 08, 2021 Customer Procurement Contact Needed

Quotation Date : February 19, 2020 Name :

Sales

Incoterms:

Payment Terms:

Shipment:

Acceptance:

Stror orders equal or less than \$75K, 100% upon shipment, net 30.

Finance support available: For lease and finance plans, call Toby Wann, Director Varian Customer Finance - 408.221.4294 / Toby.Wann@varian.com

Terms and Conditions

Products and Services: Customer's access to and use of the Products, Support Services and Services (except Software-as-a-Service or Subscription Services) as indicated in this Quotation are subject to and governed by: (a) the Varian Terms and Conditions of Sale (Form RAD 1652) at: https://www.varian.com/1652V_OCT_2018 and (b) any Schedules, Exhibits and/or additional terms (including third party terms) contained, attached, referenced or otherwise indicated in this Quotation. All terms and conditions provided in the website link listed in item (a) above are incorporated by reference and form part of the contract between Varian and Customer.

If there is a separate written agreement (e.g. master agreement) in effect between the parties that expressly provides for and governs the purchase and sale of the specific Products, Support Services, Software-as-a-Service and/or SubscriptionSubscription Service set forth in this Quotation, such written agreement shall govern. Hard copies of the referenced terms and conditions and any additional terms indicated will be provided to Customer upon request.

For and on behalf of Customer

Authorized Representative : Karen Johnson Authorized Representative : Jeffrey Boone

Title:

Date : February 19, 2020

Title: US District Sales Manager Date: February 19, 2020

Varian Medical Systems, Inc.

2020-245646 - February 19, 2020 - Page 2 of 18

Quotation Summary

varian

Offered Products (Sales)

Scalable TrueBeam, Mobius S/N: null
Machine Removal and Trade-In
Reserve and Travel and Lodging
Advantage Credits
Extended Warranty for Scalable TrueBeam
(1 Year)





Item	Description	Qty
Section	1. Scalable TrueBeam, Mobius S/N: null	
1,1	TrueBeam Version 2.7	1
1.2	New Universal Baseframe 52" Fixed Floor	1
1,3	15/16 MV (BJR 11/17)	1
	40 cm x 40 cm maximum field size, dose rate rarige 0-600 MU/Min.	
1.4	10/10 MV (BJR 11/17)	1
	40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	·
1,5	6/6 MV (BJR 11/17)	1
	40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	
1,6	16.MeV, 0-1000 MU/Min	
	.25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.7	12 MeV, 0-1000 MU/Min	1
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min	
1.8	9 MeV, 0-1000 MU/Min	1
	.25.cm x 25.cm maximum field size, dose rate range 0-1000 MU/Min.	
1.9	6 MeV, 0-1000 MU/MIn	1
	25 cm x 25 cm maximum field size, dose rate range 0 1000 MU/Min:	
1.10	PerfectPfich 6DoF Couch	ት
	Fully integrated & Degrees of Freedom (6DoF) couch system.	
	Features: Manual and automated positioning of the patient	
	Image-based 6DoF patient positioning with remote couch motion Prerequisites:	
	• ARIA® Oncology Information System for Radiation Oncology v.11 or later	4
1.11	Pivotal™ Prone Breast Solution	1
	The Pivotal™ treatment solution supports prone breast technique with the Qfix™ kVue™ Access 360™ prone breast insert. A Pivotal treatment solution online marketing program is included to help build awareness of your facility and promote the Pivotal treatment solution to patients, physicians, and your community. Includes a broad range of marketing materials including public relations, advertising, and educational content.	į.
	Features:	
	 Right and left prone breast couch top inserts with foam cushions Prone head cushion & contour pillow cushion Dual hand grip and ipsilateral hand grip 	
	 Dual hand grip and ipsilateral hand grip Adjustable CT Risers (superior & inferior) for CT simulation Storage Cart 	
	Prerequisites: Qfix™ kVue™ Couch top	

em	Description	Qty
	Notes:	
	Available for small and large bore CT scanners	
12	Low-X Imaging Energy	1
I.Z:	Low-X imaging Energy	
	Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam.	
13	HyperArc Treatment Delivery Capability	1
	Frameless, MLC-based technique for multiple intracranial SRS targets. Automated non-coplanar treatment delivery with integral intrafraction imaging at specified couch angles. Features:	
	HyperArc™ Delivery License Prerequisites:	
	• TrueBeam™ or Edge® system v2.7 or higher	
	RapīdArc® delivery license	
	PerfectPitch™ 6-Degrees of Freedom (6DoF) couch	
	 Varian IGRT couch top or QFix.KVue™ or KVue Calypso® couch top Encompass™ SRS Immobilization System by Qfix® 	
	Eclipse™ treatment planning system v15.5 or higher	
	HyperArc treatment planning license.	
	Eclipse RapidAro® planning license	
	ARIA® oncology information system for radiation oncology v15.1 or higher	
	Notes:	
	Use of external devices connected to Motion Management or ADI interfaces with HyperAtic are net validated or	
	supported by Varian. It is recommended that the patient CT scan used for treatment planning be acquired at a slice thickness of 125	
	mm or better.	W.
14	kV Imaging System	1
	A LOS AS OF THE	
	kV Imaging system, providing 2D radiographic and Riveroscopic and 3D CBCT imaging capability.	
	Features:	
	kV CBCT image acquisition, review and match to 3D reference image	
	 Radiographic image acquisition, with 20/20 and 20/30 image matching to reference image 	
	Fluoroscopic image acquisition with structure overlay on fluoroscopic images.	
	. kV CBCT image acquisition with a long field of view, provided by merging multiple indexed CBCT images. Online	
	data acquisition and viewing only	
	Prereguisites:	
	% ** ** ** ** ** ** ** ** ** ** ** ** **	
15	Triggered Imaging (1
	Automated intraffaction 20 kV radiographic imaging, with images triggered by respiration phase or amplitude, gantry	
	angle, time period/or MU. Automated image-based beam hold on fiducial markers, based on user-defined marker	
	motion thresholds	
	Features:	
	Respiration Triggered Imaging	
	MU Triggered Imaging	
	Gantry Triggered Imaging.	
	Time Triggered Imaging	
	Autobeam Hold	
	Prerequisites:	
	Respiratory Motion Management System	
16	Advanced Resp Motion Management System	.1
	Stereoscopic optical system for managing patient respiration motion during treatment delivery and imaging.	
	Features:	
	Features: Stereoscopic optical imager, including marker block for tracking patient respiration motion	

Item	Description	Qty
	 Respiratory gated MV image acquisition and online review, respiration synchronized cine image acquisition and 	
	 online review Respiratory gated kV image acquisition and online review, respiration synchronized fluoroscopic image acquisition and online review 	
1.17	VCD Option, couch mounted	1
	Couch-mounted display system provides visual feedback to the patient for respiration stabilization or breath hold position during respiratory gated image acquisition or treatment delivery.	
	Features:	
	 2 rechargeable batteries and charging system Video interface for optional use of customer-provided video goggles Wireless display system with adjustable count mount 	
	Prerequisites:	
	TrueBeam® v2.7 or higher One of the following: Advanced Respiratory Motion Management System Basic Respiratory Motion Management System Respiratory Motion Management System Optical Imager	
1.18	VCD w/Couch Mount - kVue	
1.19	Gated CBCT	1
	Provides the ability to acquire CBCT images synchronized with patient respiration (free-proathing or breath hold).	
	Features: Gated CBCT Imaging License: CBCT image acquisition, image review, and image match to respiratory gated reference image.	
	 Short Arc CBCT Imaging License: CBOT image acquisition using a 120/150 degree arc, image review, and image match to respiratory gated reference image. Short arc CBCT is an option for single breath hold CBCT data acquisition. 	
	Prerequisites: One of the following: Advanced Respiratory Motion Management System Basic Respiratory Motion Management System Respiratory Motion Management System Optical Imager kV Imaging System	
1.20	4D CBCT Imaging Package	:1
	Provides the ability to acquire 4D CBCT images for patient positioning at the time of treatment delivery or for 4D target motion analysis post treatment delivery.	
	Features: 4D kV CBCT Image Match Review License: 4D CBCT image acquisition, image review, and image match to	
	structure or Maximum Intensity Projection (MIP) at the time of treatment delivery	
	 4D CBCT Image Acquisition License: 4D kV CBCT image acquisition in Advanced Reconstructor Mode for post- treatment image reconstruction, viewing, and offline analysis 	
	Prefequisites: One of the following:	
	Advanced Respiratory Motion Management System	
	Basic Respiratory Motion Management System Respiratory Motion Management System	
	 Respiratory Motion Management System Optical Imager 	
	kV Imaging System	
	Customer Responsibilities: Customer must verify compatibility with 3rd party systems & devices	
	Notes:	

Notes: TrueBeam v2.7 or higher is required to utilize 4D CBCT Match Review license

Item	Description	Qty
1,21	Itérative CBCT	1
	Iterative CBCT provides improved detectability of stationary or gating-immobilized soft tissue anatomy. Features: Iterative CBCT license Reconstruction computer with GPU hardware	
1,22	LAP Apollo Green Room Laser Kit	1
	Features: One Apollo Green Remote Controlled Ceiling Crosshair Laser Two Apollo Green Remote controlled Lateral Crosshair Lasers One Apollo Green Remote Vertical or Horizontal Controlled Sagittal Line Laser (selected prior to system production)	
1.23	Filtrine Water Chiller for 2 Systems	1
	A closed loop water cooling system, providing clean water at a constant flow, pressure, and temperature for cooling two high energy medical linear accelerators. Ideal for sites where a dependable source of clean water for cooling is not available.	
1,24	Additional MotionView CCTV Camera System	
	Additional set of two Motion View CCTV cameras and displays. Camera placement is at customer discretion. Features: Two pan, filt, zoom CCTV cameras Two desktopt.CD displays with built in camera controls Adjustable viewing angle for patient privacy Push button pan, filt, zoom, and home position control Prerequisites: Motion View camera system, provided with light system.	
1.25	Main Circuit Breaker Panel Main circuit breaker panel, interfacing to a single power input feed from the facility Mains. Circuit breakers provide independent over-current projection for equipment at the console and in the treatment room. UL and IEC/CE certified.	1
1,26	Power Cond., 3phase 50KVA Transfector 50KVA, 3-phase power conditioning unit, providing transient protection, line power regulation, and Input and Output circuit breakers for over-current protection. UL and IEC/CE certified. Notes: Supports voltage configurations from 208 to 600 VAC and in 50 or 60 Hz for US and ROW applications.	1
1.27	RPC Liting Phantom Service	1
	A service provided through the MD Anderson Dosimetry Lab (MDADE) to supply a Radiological Physics Center (RPC) lung phantom for QA and commissioning of advanced technologies. Features: Roundtrip shipment of anthropomorphic lung phantom with imageable targets, avoidance structures, and heterogeneities that contain thermoluminescent dosimeter (TLD) and radiochromic film dosimeters. Remote analysis by MDADL of the planning and dose delivery of the treatment on the phantom Report of analysis from MDADL Prerequisites: Acceptance of TrueBeam® or Edge™ system with which the lung phantom will be used Customer Responsibilities: Login to www.myvarian.com to access the Customer Technical Bulletin CTB-GE-930 for instructions on redeeming the lung phantom service	
1,28	SRS Encompas IMB Qfix Couchtop	1

Item Description

The SRS Encompass™ Immobilization package from Qfix™ is a dedicated SRS immobilization package specifically tailored for use with the Qfix kVue™ and Calypso® kVue couch tops.

- kVue Encompass Intracranial Insert (quantity: 1)
- Encompass Intracranial Standalone Device for CT (quantity: 1)
- Encompass mask system (quantity: 10)
- Locating bar (quantity: 1)

Prerequisites:

- Qfix kVue or Calypso kVue couch top
- TrueBeam® v2.0 and higher
- VitalBeam® v2.5 (China only) and higher

Notes:

Training will be provided by Qfix

1.29 Motion Management Interface

Motion management interface is an integrated interface for validated external devices that provide patient positioning, patient and target motion monitoring, and/or respiratory gating. The Motion management interface supports connection of up to four external devices, two of which may be used for respiratory motion management or high speed beam hold. Features:

- 4-DoF or 6-DoF patient positioning capability for compatible validated devices and couch configurations
- Integrated external device beam hold and image-based patient repositioning workflow
- Patient-specific external device activation and patient plan verification

1.30 STD TRNG: TB Platform On-Site

The on-site review of the TrueBeam/Edge/VitalBeam components includes imaging and use cases for support of patient treatment for therapists. This support is to ensure that personnel who attended the classroom training are able to operate the TrueBeam Platform machine in a safe and effective manner in the clinical environment.

Features:

- Includes support for TrueBeam/Edge VitalBeam
- Offer is valid for 18 months after installation of product

Prerequisites:

TrueBeam Platform classroom trainings

Notes:

Training is non-refundable and non-transferable

1.31 INCL ED: TB201 TB Platform Physicists

TrueBeam Physics and Administration: TrueBeam Physics and Administration course is designed for personnel (primarily Medical Physicists) responsible for the acceptance, commissioning, and QA program development of the TrueBeam in the clinical environment. It is recommended that the student attend the TrueBeam Physics and Administration course shortly before the installation of the TrueBeam. The course provides instruction of the basic delivery components, basic imaging components, and a general overview of the motion management system components. Machine commissioning, calibration, and QA of the machine are included. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall commissioning, calibration, and QA of the TrueBeam and its components. Extensive hands-on laboratory exercises are included.

Features:

- Includes support for TrueBeam/Edge/VitalBeam
- Includes Tuition and Materials for ONE person.
- Length: 4.5 days
- Offer is valid for 18 months after installation of product

Customer Responsibilities:

Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals)

Notes:

Training is non-refundable and non-transferable

1,32 INCL ED: TB101 TB Platform Operations

TrueBeam Operations is a course designed for personnel (primarily Radiation Therapists) responsible for the routine operation and clinical use of the TrueBeam. It is recommended that students attend the TrueBeam Operations course shortly before clinical use and the commencement of patient treatments. The course provides instruction of the basic

Qty

1

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Item Description Qty

delivery components, basic imaging components, and a general overview of the motion management system components. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall understanding of the TrueBeam function and operation to include imaging and respiratory gating. Extensive hands-on laboratory exercises are included. The attendees of this class will be provided tools to allow them to instruct other clinical staff upon their return.

Features:

- Includes support for TrueBeam/Edge/VitalBeam
- Includes Tuition and Materials for ONE person
- Length: 4 days
- Offer is valid for 18 months after installation of product

Customer Responsibilities:

Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals)

Notes:

Training is non-refundable and non-transferable

1.33 INCL ED: CL222 Respiratory Gating

The Respiratory Gating course provides training for physicists and therapists, to obtain knowledge of principles and practices of respiratory gating in radiation oncology for clinical implementation.

Features:

- Includes support for TrueBeam Platform
- Includes Tuition and Materials for ONE person
- Length: 2 days
- Offer is valid for 18 months after installation of product

Customer Responsibilities:

Customer is responsible for all travel expenses (airfare, hotel, remail car, meals and travel incidentals).

Training is non-refundable and non-transferable

1.34 NLS: English

1.35 INCL ED: UAB TrueBeam SRS/SBRT Clin Sch

The SRS &SBRT Delivery with Edipse and Truebeam® clinical achool is taught by a multi-disciplinary team from the University of Alabama at Birmingham, including subspecially surgeons, radiation encologists and medical physicists. This team installed the first clinical TrueBeam STx in the world and has extensive experience with RapidArc® and High Intensity Mode beams. The course content can be individually focused on specific sites (e.g. neuro or thoracic) depending upon the interests of these enrolled. This course is designed for radiation physicists, radiation encologists, surgeons, and desimatrists.

Features:

Topics covered include:

Commissioning and QA4@ simulationRespiratory motion managementTriggered imagingRapidArc RadiosurgeryHigh intensity Mode (flattening filter free @2400 MU/min)Clinical implementation of advanced procedures in CNS, H/N, lung, liver, spine, and prostateNavigation bronchoscopy for fiducial placement

- Hands on laboratory experiences that mimic the clinical process including mock tumor board, contouring, and treatment planning
- Duration and Location: 3 day course at the Hazeing-Salter Radiation Oncology Center, The University of Alabama at Birmingham, Birmingham, AL.

Customer Responsibilities:

- Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals)

 Notes:
- Offer is valid for up to 18 months after installation of product
- Includes tuition and materials for 3 people
- Non-transferable to other products and services and non-refundable
- While this course is for 1 tuition, it is recommended that the customer purchase additional tuitions for the entire
 multi-disciplinary team of 3-4 individuals from the same site to attend the class together
- If the clinical school is not available, Varian will make all reasonable efforts to find a suitable replacement
- Eclipse is utilized extensively during the lab portion of the course so this clinical school is not ideal for institutions not planning to utilize Eclipse for treatment planning
- This course is offered and exclusively controlled by University of Alabama Birmingham, Varian is not responsible for and has not reviewed the course topic, content or materials. The student will be required to sign an agreement that disclaims all liability for Varian with respect to the content and training
- AMA, CAMPEP and MDCB Accreditation

1

1

1

2020-245646 - February 19, 2020 - Page 9 of 18

Item	Description	Qty
1,36	6X High Intensity Mode	1
	40 cm x 40 cm maximum field size, dose rate range 400-1400 MU/Min in 200 MU/min steps.	
1.37	6 MeV HDTSE, 0-2500 MÜlmin	11
	6 MeV High Dose Total Skin Electron energy configuration, Dose rate 2500 MU/Min.	
	Prerequisites: High Dose Total Skin Electron Treatment Delivery license	
1,38	Enhanced Beam Conformance Specification	1,
	The Enhanced Beam Conformance Specifications provide tight tolerances for key X-ray and electron beam energy performance specifications.	
1.39	Additional In-Room Monitor System	1
	Additional in-room monitors that can be placed at customer discretion.	
	Customer Responsibilities: %%	
1.40	RapidArc Treatment Delivery	
1.41	RapidArc® Treatment Delivery is a volumetric modulated arc treatment delivery technique Features: Simultaneous modulation of MLC aperture shape, beam dose rate, and gantry angle and rotation speed during beam delivery. Supports dynamic jaw tracking and collimate rotation with supporting treatment planning system Prerequisites: 120 Multi Leaf Collimator or HD120 Multi Leaf Collimator Eclipse™ treatment planning system V110 or higher RapidArc treatment planning license TrueBeam with 120 Multileaf Collimator	1
	Treatment delivery system supporting X-Ray treatment delivery. Includes 120 leaf MLC with dual independent jaws, enhanced dynamic vicedge, 6 MVX ray treatment energy, 43 cm x 43 cm MV imager for radiographic, cine, and integrated imaging. Motion View(CCTV camera system, treatment console with integrated audio and video systems, back pointer tasers, front pointer sat and upper port film graticule to support basic quality assurance. Features: Basic X-Ray treatment delivery technique package, including Static Photon, Photon Arc, and Dynamic Conformal Arc treatment delivery techniques Intensity Modulated RadioTherapy (IMRT) treatment technique, including large field IMRT Total Body Treatment technique package 2pf MV Radiographic and Cine Image Acquisition, 2D/2D Radiographic Image Review and match, Cine image review Relative Portal Dosimetry Image and Integrated Image Acquisition Matching of 2D radiographs to 3D reference images Online addition of kV and MV imaging protocols to treatment fields, with automated generation of reference images Online Physician Approval of Images at Treatment Console (compatible with ARIA® only) Automated Machine Performance Check Testing, Online Machine Performance Check Review Offline Machine Performance: Check Review Prerequisites: ARIA® oncology information system for radiation oncology v11.0 MR4.1 or higher, or compatible third-party treatment planning system Eclipse Teatment planning system v11.0 MR3 or higher, or compatible third-party treatment planning system Customer Responsibilities: Verify compatibility with third-party oncology information systems if applicable Verify compatibility with third-party treatment planning systems if applicable If using a scale other than IEC 80601 or IEC 61217 in the rest of the department, it may be necessary to change scales on all other machines. This may require additional purchases.	ı:

Item	Description	Qty
1.42	10X High Intensity Mode	1
	40 cm x.40 cm maximum field size, dose rate range 400-2400 MU/min in 400 MU/min steps.	
1,43	Qfix™-kVue™-couch top	1
	Indexed Immobilization treatment table kVue TM couch top, by Qfix TM , treatment table with carbon fiber couch top, two locating bars, two removable accessory rails, patient straps.	
	Includes the following inserts: Standard indexing insert panel Dose-max insert panel Universal tip insert service panel. Note: Compatibility of specific 3rd party accessories, which are intended for use with kVue couch top, should be confirmed by the user directly with the 3rd party supplier before ordering this top.	
1.44	Integrated Collimator Verification & Interlock System (ICVI) for TrueBeam® platform	1
Section 2:	The Integrated Collimator Verification & Interlock (ICVI) system provides electronically-verified conical collimators for use in radiosurgical treatment delivery. Features: Conical collimator mounting system with integrated mount verification Set of 7 conical collimators with integrated verification Conical collimator set (in mm diameter): 4, 5, 7.5, 10, 12.5, 15, and 17.5 ICVI QA Toolkit Prerequisites: ARIA® oncology information systems for radiation encology v11,0 or higher or compatible third-party encology information system Eclipse Cone Planning v11,0 or higher or compatible third-party treatment planning systems Customer Responsibilities: Verify compatibility with third-party treatment planning systems if applicable Verify compatibility with third-party encology information systems if applicable Notes: Includes MPC ICVI isocenter license and MPC IGVI conical collimator alignment license. Machine Removal and Trade-In Remove/Dispose Exlating Equipment	1
	Remove and dispose existing Linux	1
.2.2,	Trade-In Discount for 2 Linacs	-1
	Trade-In Discount for Linac	
Section 3	Reserve and Travel and Lodging Obsolescence Reserve	1
	Obsolescence Reserve	

Travel and Lodging for training Travel and Lodging for training Section 4 Advantage Credits Travel and Lodging is purchased through Varian can only be used for attendance of education courses at a Varian Education Center and Varian chical schools. A Travel and Lodging cannot be used to attend tradeshows or any event not related to Varian education and training courses. Allowance is applied only to the travel and lodging expenses, including either, lotal accommodations at a Varian preferred fixetia, and a rend for Afri and captions are expenses outside of the allowance is applied only to the travel and lodging expenses, including either, lotal accommodations at a Varian preferred fixetia, and a rend for Afri and several expenses outside of the allowance preferred fixetia, and a rend for Afri and several expenses outside of the allowance of the several expenses outside of the allowance and the travel agents used to varian Mackad Systems only. The automore history travel agency is a first prefer and prefer the read agency to the several provide Bulbook held Varian adapted number. The customer must provide Bulbook held Varian adapted number. The Travel and Lodging allowance expires 24 months from the acceptance dated, the equiphiest. Any tenturing before a market of number. The Travel and Lodging allowance expires 24 months from the acceptance dated, the equiphiest. Any tenturing education, and thirty-agent services including these services are disclosed in that are purchased through Varian. 4.2 Advantage Contract Credits Advantage Contract Credits Advantage Contract Credits Advantage Contract Advantage credits (Opticional Advantage credits (Contract Credits and Contract Credits (Contract Credits and Contract Credits and Contract Credits (Contract Credits (Contract Credits (Contract Credits (Contract Credit	Item	Description	Qty
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Commissioning report		 Sample of various plans for end to end testing with Portal Dosimetry Review of TPS configuration and settings Data book 	



Qty Description ltem Prereq: Customer site physicist must be present for deliverables and approvals Must have acceptance of accelerator and Eclipse before Advantage Commissioning can start Full access to the accelerator, accessories and the control room Secured Internet access Not included: This service does not include any commissioning for Hard Wedge. Customer must purchase Hard Wedge commissioning separately 16.0 4.6 ED: TB201 TrueBeam Platform Physicists (Qty. 1, Credit per Qty: 16.0) Includes Tuition and Materials for ONE Person This course provides training for Medical Physicists responsible for commissioning and administration of the TrueBeam machine. The course consists of combination of lectures, demonstrations, and hands-on exercises carried out in a lab equipped with fully functioning TrueBeam system. The course provides an overview of TrueBeam hardware, software and control system, to a depth sufficient for the user to prepare the system for clinical use. The course also includes demonstration of common IGRT, Motion Management and treatment plan delivery techniques. PLEASE NOTE: For more in-depth calibration and maintenance training, see TrueBeam Technical Maintenance I & II. Designed for Medical Physicists Pre-Requisites: Masters degree in Medical Physics, or equivalent Duration and Location: 4.0 days Varian Education Center Las Vegas, Nevada, USA Application has been made to CAMPEP credits Advantage Credits Eligible Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals), unless otherwise stated. Section 5 Extended Warranty for Scalable TrueBeam (1 Year) 1 5.1 TrueBeam Rapid Arc/VVMAT **ICBCT** 4D CBCT G/SA_CBCT VCD-TBM ARMM Triggered Imaging KV Imager ejvotal Prone Breast PerfectPitch Couch



Summary of Advantage Contract Credits Quoted Above

Section 4

Year 1 Total	252.0
Total Credits	252.0



Quotation Total

Quotation Total

US \$3,711,472.00



ATTACHMENT C

ATTACHMENT D

All responses should pertain to October 1, 2018 through September 30, 2019.

License No: <u>H0010</u>
Facility ID: <u>943501</u>

11.	. Linear Accelerator Treatment Data continued	
Ca	ampus – if multiple sites: PMC	_
a.	Number of <u>patients</u> who received a course of radiation oncology to Knife®). Patients shall be counted once if they receive one course courses of treatment. For example, one patient who receives one course who receives three courses of treatment counts as three	se of treatment and more if they receive additional
	Number of Patients 1758 (This number should match the number of patients reported ipage 32.)	in the Linear Accelerator Patient Origin Table on
b.	. TOTAL number of Linear Accelerators: 2	
	Of the TOTAL above,	
	Number of Linear Accelerators configured for stereotactic radiosurgery:	
	Number of CyberKnife® Systems:	<u> </u>
	Number of other specialized linear accelerators:	⊅ ⊅
c.	. Number of Gamma Knife® units	<u> </u>
d.	1. Number of treatment simulators ("machine that produces high quality diagnostic radiographs and megavoltage radiation therapy equipment to the patient." (GS 13)	I precisely reproduces the geometric relationships of 1E-176(24b)))
e.	e. Number of grandfathered Linear Accelerators	<u> </u>
	For questions, please contact Healthcare Planning and Certific	cate of Need at 919-855-3873.
f.	f. CON Project ID numbers for all non-grandfathered Linear Acce	elerators:
	unable to locate CON Project ID a	t this time

ATTACHMENT D

Projected Capital Cost Form

Project Name

HVI-CI Linac 2

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 1,500,000
Landscaping	
Architect / Engineering Fees	\$ 74,000
Medical Equipment	\$ 3,711,472
Non-Medical Equipment	\$ -
Furniture	
Consultant Fees (Engineering Fees)	\$ -
Financing Costs	
Interest during Construction	
Other (contingency)	\$ 45,000
Total Capital Cost	\$ 5,330,472

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected construction cost for the projected cost for the projected cost for the projected cost for the projected cost for t

Signature of Licensed Architect or Engineer

Date Signed: 6/8/2020

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that is our intent to carry out the proposed project as described.

Docusigned by: Matthew Stiene 9BCFAC883518459	Date Signed:	08/28/2020	2:57:16	EDT
Signature of Officer/Agent Vice President, Construction & Engineering Novant Health, Inc.				
Title of Officer/Agent				

ATTACHMENT E

EQUIPMENT COMPARISON

PMC Linac #2 Relocation & Replacement	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Khife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI: PET. Simulator, CT Scanner, Other Major Medical Equipment)	Linear Accelerator	Linear Accelerator
Manufacturer	Elekta	Varian
Model number	MRT10771	True Beam
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	135267	ŢBĎ
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	10/31/2007	~Oct. 2020
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="" capital="" cost="" form="" projected="" signed=""></attach>	\$1,820,396	\$5,330,472
Total cost of the equipment	\$1,635,110	\$3,711,472
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	PMC Rad-Onc Dept.	PMC HVI-CC
Document that the existing equipment is currently in use	2020 LRA	n/a
Will the replacement equipment result in any increase in the average charge per procedure?	No	No
If so, provide the increase as a percent of the current average charge per procedure	n/a	n/a
Will the replacement equipment result in any increase in the average operating expense per procedure?	No	No
If so, provide the increase as a percent of the current average operating expense per procedure	n/a	n/a
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	Linac Radiation Treatments	
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	1.	Linac Radiation Treatments

Date of last revision: 5/17/19

From: Flores, Disraeliza

To: Waller, Martha K

Subject: Fw: [External] NH Presbyterian Med Ctr Linac Replacement Equipment Exemption Notices

Date: Friday, September 4, 2020 3:27:23 PM
Attachments: PMC Linac1 REER to Agency 09.04.20.pdf
PMC Linac2 REER to Agency 09.04.20.pdf

From: Griffin, Lisa L < llgriffin@novanthealth.org>

Sent: Friday, September 4, 2020 3:21 PM

To: Faenza, Julie M < Julie. Faenza@dhhs.nc.gov> **Cc:** Flores, Disraeliza < Disraeliza. Flores@dhhs.nc.gov>

Subject: [External] NH Presbyterian Med Ctr Linac Replacement Equipment Exemption Notices

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

Hi Julie,

Attached are 2 replacement equipment exemption notices for the 2 linacs located at NH Presbyterian Medical Center in Charlotte.

Please confirm receipt of both files and let me know if you have any questions upon review.

Have a nice long weekend!

Lisa Griffin

Manager, Operational Planning Novant Health, Inc. (704) 351 - 1132

We are here to help you get the care you need. Visit <u>Novant Health</u> or <u>Novant Health UVA</u> for upto-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite <u>Novant Health</u> o <u>Novant Health UVA</u> para información actualizada.

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