



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 2, 2021

Lisa Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3653
Date of Request: August 19, 2021
Facility Name: Novant Health Huntersville Medical Center
FID #: 990440
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace an existing linear accelerator
County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project 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 Varian Truebeam linear accelerator to replace the Elekta Synergy 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.

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

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

August 19, 2021



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 Huntersville Medical Center (FID 990440)
Replacement of Existing Linear Accelerator
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 Huntersville Medical Center (“NHHMC”) intends to replace its existing fixed linear accelerator currently located in the Cancer Center on the ground floor of the Physicians Plaza building on the hospital campus. NHHMC’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

NHHMC is located at 10030 Gilead Road, Huntersville, North Carolina. The Radiation-Oncology Department is located on the ground floor in the Physicians Plaza building adjacent to the main hospital. See the enclosed campus maps in **Attachment A**. The main hospital building is the location at which NHHMC exercises financial and administrative control over the entire facility and the administrative suite is located on the first floor of NHHMC (see the indicated area First Floor Map in **Attachment A**).

Previous Certificate of Need

The existing linear accelerator is a replacement of the linear accelerator approved at Novant Health Presbyterian Hospital in Project ID #F-7518-06 to be relocated to NHHMC via a Declaratory Ruling approved in December 2013. This linear accelerator has been reported on the Annual License Renewal Application (“LRA”) since it became operational in 2015. The most recent LRA is included as support that this linear accelerator has been in use and is still in use. **See Attachment B** for an excerpt of NHHMC’s 2021 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 reasons found on the following page:

- (1) NHHMC 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 2015 and is in need of an upgrade. **Attachment C** contains the Equipment Comparison Form.

See **Attachment D** 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 as indicated on page 3 of the Varian quote. The total capital cost for the proposed replacement equipment project is estimated to be \$4,200,000. See **Attachment E** – Project Capital Cost Form.

In support of our request, please find attached:

- Attachment A** – NHHMC Campus Map
- Attachment B** – NHHMC 2021 LRA Excerpt
- Attachment C** – Equipment Comparison Form
- Attachment D** – Equipment Quote
- Attachment E** – Projected Capital Costs

NHHMC'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 \$4,200,000. 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 NHHMC'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

Lisa Griffin
Manager, Planning & CON
Strategic & Business Planning | Internal Consulting Group

ATTACHMENT A

Campus map

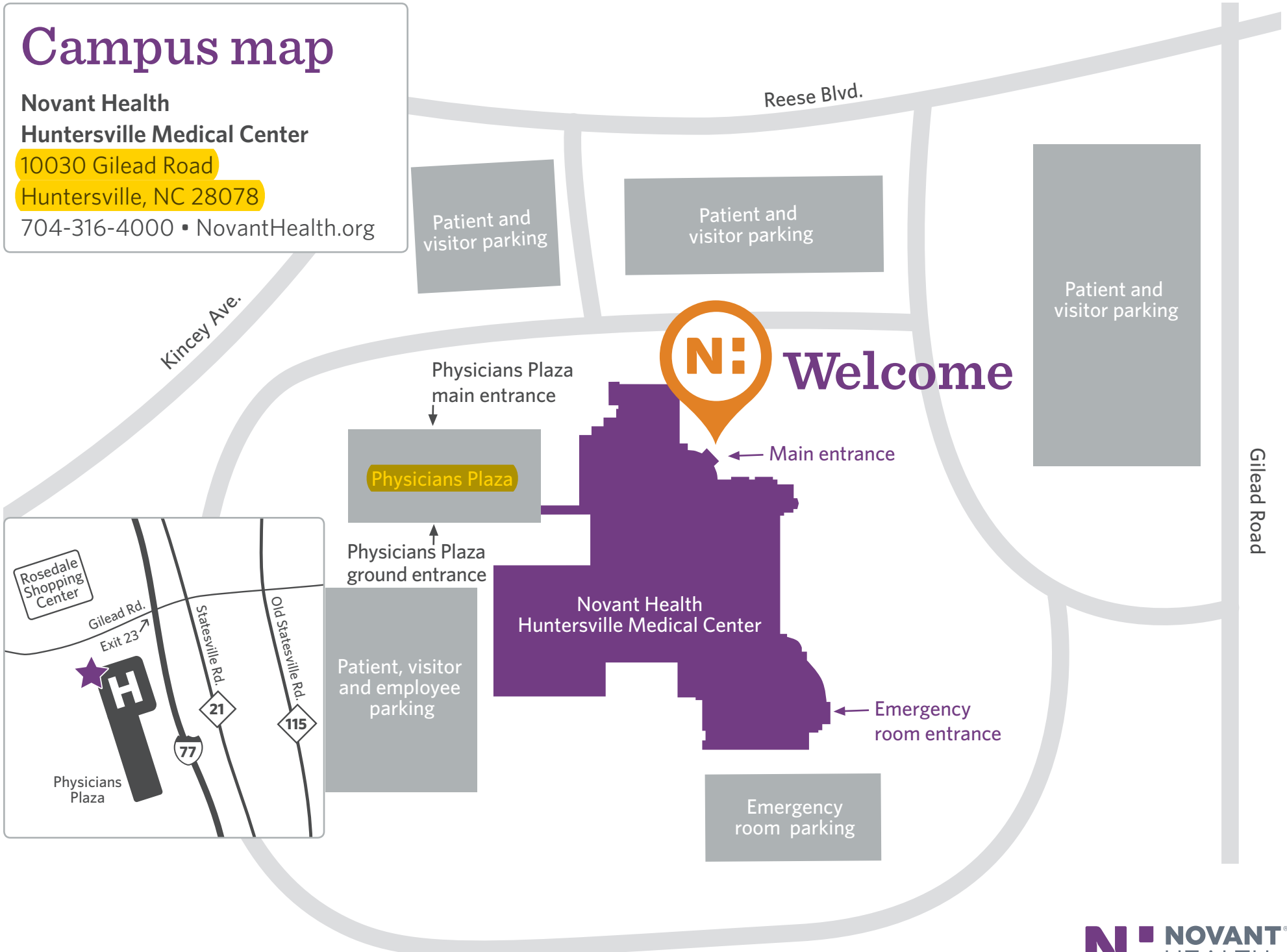
Novant Health

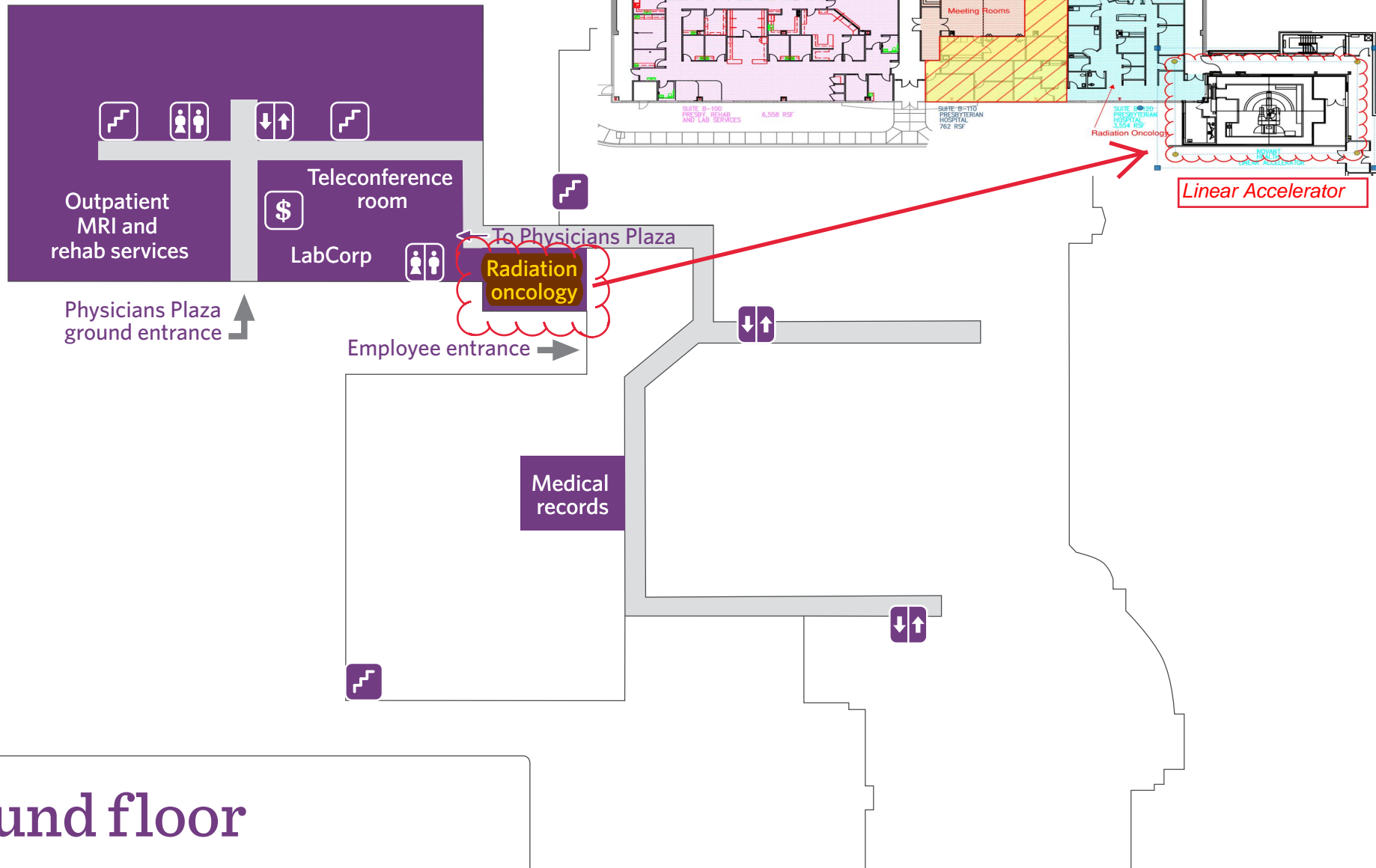
Huntersville Medical Center

10030 Gilead Road

Huntersville, NC 28078







704-316-4000 • NovantHealth.org





Ground floor

Novant Health Huntersville Medical Center

-  Information
-  Elevator
-  Vending
-  Stairs
-  Restrooms
-  ATM









Welcome

Main entrance
Admitting and discharge entrance



First floor

Novant Health Huntersville Medical Center

-  Information
-  Elevator
-  Vending
-  Stairs
-  Restrooms
-  ATM

ATTACHMENT B

All responses should pertain to **October 1, 2019 through September 30, 2020.**

11. Linear Accelerator Treatment Data *continued*

Campus – *if multiple sites:* _____

- a. Number of patients who received a course of radiation oncology treatments on linear accelerators (not the Gamma Knife®). Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three

Number of Patients 790

(This number should match the number of patients reported in the Linear Accelerator Patient Origin Table on page 32.)

- b. **TOTAL number of Linear Accelerators:**

1

Of the TOTAL above,

Number of Linear Accelerators configured for **stereotactic radiosurgery:**

1

Number of **CyberKnife®** Systems:

- 0 -

Number of **other specialized linear accelerators:**

- 0 -

- c. Number of **Gamma Knife®** units

- 0 -

- d. Number of **treatment simulators**

- 0 -

(“machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient.”(GS 131E-176(24b)))

- e. Number of grandfathered Linear Accelerators

- 0 -

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

- f. CON Project ID numbers for all non-grandfathered Linear Accelerators: One linac approved for

Novant Health Presbyterian Medical Center (Project ID F-7518-06)
was relocated to Novant Health Huntersville Medical Center per
Declaratory Ruling Request, December 2013.

ATTACHMENT C

EQUIPMENT COMPARISON

<i>NH Huntersville Medical Center Linear Accelerator Replacement</i>	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Linear Accelerator	Linear Accelerator
Manufacturer	Elekta	Varian
Model number	Synergy	Truebeam
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	3552	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2/2015	TBD
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 signed Projected Capital Cost form>	NA	\$2,645,000
Total cost of the equipment	NA	\$4,200,000
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	HMC Rad Onc Dept.	HMC Rad Onc Dept.
Document that the existing equipment is currently in use	See Enclosed LRA Excerpt	NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Radiation Therapy	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Radiation Therapy

Date of last revision: 5/17/19

ATTACHMENT D

Custom System Proposal

Quotation Number - 2021-308542

TrueBeam Price- \$2,650,000.

Draft Only

(Looking further)



Novant Health Huntersville Medical Center ("Customer")

Adam Worland
10030 GILEAD RD
Huntersville, North Carolina 28078 United States
Tel : (704) 920-7900
Fax : 336-718-9257
Email : acworland@novanthealth.org

VMS Inc, Oncology Systems

Jeff Boone
Sales Representative
Work from home
Charlottesville, VA 30327 US
Tel : 434-270-2144
Email : alexis.irizarry@varian.com

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

Quote Information

Quotation Number :	2021-308542	Sales PO Required :	No
Quotation Valid Until :	September 30, 2021	Customer Procurement Contact Name :	Needed
Customer Requested Delivery Date :	November 18, 2022		
Quotation Date :	April 16, 2021		

Sales

Incoterms :	DPU Site Insured
Payment Terms :	40 days net
Shipment :	80.00%
Acceptance :	20.00%

For orders equal or less than \$100k, 100% upon shipment, net 30.

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, Services, Software-as-a-Service and/or SubscriptionService 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 : Adam Worland
Title : VP Supply Chain
Date : April 16, 2021

Varian Medical Systems, Inc.

Authorized Representative : Jeff Boone
Title : Sales Representative
Date : April 16, 2021

Offered Products (Sales)

TrueBeam to Replace Elekta

Eclipse HyperArc Planning License

Removal/Disposal and Trade-In VersaHD

Commissioning Services

TPS Eclipse - HW

Draft Only

Item	Description	Qty
Section 1 TrueBeam to Replace Elekta		
1.1	<p>TrueBeam Base System 120 MLC</p> <p>Treatment delivery system supporting X-Ray treatment delivery. Includes 120 leaf MLC with dual independent jaws, enhanced dynamic wedge, 6 MV X-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 lasers, front pointer set and upper port film graticule to support basic quality assurance.</p> <p>Features:</p> <ul style="list-style-type: none"> • 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 • 2D 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 • Access to online marketing kit that contains a broad range of advertising, educational, promotional, and public relations materials targeted to referring physicians, patients, and the media, contact Marcom@varian.com for access <p>Prerequisites:</p> <ul style="list-style-type: none"> • ARIA® oncology information system for radiation oncology v11 MR4.1 or higher or compatible third-party oncology information system • Eclipse™ treatment planning system v11 MR3 or higher or compatible third-party treatment planning system • Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> • Verify compatibility with third-party oncology information systems • Verify compatibility with third-party treatment planning systems • If using a scale other than IEC 60601 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. 	1
1.2	TrueBeam Version 2.7	1
1.3	New Universal Baseframe 52" Fixed Floor	1
1.4	<p>15/16 MV (BJR 11/17)</p> <p>40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.</p>	1
1.5	<p>10/10 MV (BJR 11/17)</p> <p>40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.</p>	1
1.6	<p>6/6 MV (BJR 11/17)</p> <p>40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.</p>	1
1.7	<p>16 MeV, 0-1000 MU/Min</p> <p>25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.</p>	1
1.8	<p>12 MeV, 0-1000 MU/Min</p> <p>25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.</p>	1

Item	Description	Qty
1.9	9 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.10	6 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.11	10X High Intensity Mode 40 cm x 40 cm maximum field size, dose rate range 400-2400 MU/min in 400 MU/min steps.	1
1.12	6X High Intensity Mode 40 cm x 40 cm maximum field size, dose rate range 400-1400 MU/Min in 200 MU/min steps.	1
1.13	Low-X Imaging Energy Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam.	1
1.14	HyperArc Treatment Delivery Capability Frameless, MLC-based technique for multiple intracranial SRS targets. Automated non-coplanar treatment delivery with integral intrafraction imaging at specified couch angles. Features: <ul style="list-style-type: none"> HyperArc™ Delivery License Prerequisites: <ul style="list-style-type: none"> TrueBeam™ or Edge® system v2.7 or higher RapidArc® 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 RapidArc® planning license ARIA® oncology information system for radiation oncology v15.1 or higher Notes: <ul style="list-style-type: none"> Use of external devices connected to Motion Management or ADI interfaces with HyperArc are not validated or supported by Varian. It is recommended that the patient CT scan used for treatment planning be acquired at a slice thickness of 1.25 mm or better 	1
1.15	RapidArc Treatment Delivery RapidArc® Treatment Delivery is a volumetric modulated arc treatment delivery technique. Features: <ul style="list-style-type: none"> Simultaneous modulation of MLC aperture shape, beam dose rate, and gantry angle and rotation speed during beam delivery Supports dynamic jaw tracking and collimator rotation with supporting treatment planning system Prerequisites: <ul style="list-style-type: none"> 120 Multi Leaf Collimator or HD120™ Multi Leaf Collimator Eclipse™ treatment planning system v11.0 or higher RapidArc treatment planning license Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs 	1
1.16	kV Imaging System kV Imaging system, providing 2D radiographic and fluoroscopic and 3D CBCT imaging capability. Features: <ul style="list-style-type: none"> kV CBCT image acquisition, review, and match to 3D reference image Radiographic image acquisition, with 2D/2D and 2D/3D image matching to reference image 	1

Item	Description	Qty
	<ul style="list-style-type: none"> 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. 	
1.17	<p>Advanced Resp Motion Management System</p> <p>Stereoscopic optical system for managing patient respiration motion during treatment delivery and imaging.</p> <p>Features:</p> <ul style="list-style-type: none"> Stereoscopic optical imager, including marker block for tracking patient respiration motion Respiratory gated treatment delivery 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
1.18	<p>VCD Option, couch mounted</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> 2 rechargeable batteries and charging system Video interface for optional use of customer-provided video goggles Wireless display system with adjustable count mount <p>Prerequisites:</p> <ul style="list-style-type: none"> TrueBeam® v2.7 or higher One of the following: <ul style="list-style-type: none"> Advanced Respiratory Motion Management System Basic Respiratory Motion Management System Respiratory Motion Management System Optical Imager 	1
1.19	<p>Gated CBCT</p> <p>Provides the ability to acquire CBCT images synchronized with patient respiration (free-breathing or breath hold).</p> <p>Features:</p> <ul style="list-style-type: none"> Gated CBCT Imaging License: CBCT image acquisition, image review, and image match to respiratory gated reference image. Short Arc CBCT Imaging License: CBCT 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. <p>Prerequisites:</p> <ul style="list-style-type: none"> One of the following: <ul style="list-style-type: none"> Advanced Respiratory Motion Management System Basic Respiratory Motion Management System Respiratory Motion Management System Optical Imager kV Imaging System 	1
1.20	<p>Iterative CBCT</p> <p>Iterative CBCT provides improved detectability of stationary or gating-immobilized soft tissue anatomy.</p> <p>Features:</p> <ul style="list-style-type: none"> Iterative CBCT license Reconstruction computer with GPU hardware 	1
1.21	<p>Additional MotionView CCTV Camera System</p> <p>Additional set of two Motion View CCTV cameras and displays. Camera placement is at customer discretion.</p> <p>Features:</p> <ul style="list-style-type: none"> Two pan, tilt, zoom CCTV cameras 	1

Item	Description	Qty
	<ul style="list-style-type: none"> • Two desktopLCD displays with built in camera controls • Adjustable viewing angle for patient privacy • Push button pan, tilt, zoom, and home position control Prerequisites: <ul style="list-style-type: none"> • Motion View camera system, provided with linac system. 	
1.22	<p>Main Circuit Breaker Panel</p> <p>Main circuit breaker panel, interfacing to a single power input feed from the facility Mains. Circuit breakers provide independent over-current protection for equipment at the console and in the treatment room. UL and IEC/CE certified.</p>	1
1.23	<p>SuperFAST Installation - Existing Basefr</p> <p>Accelerated 12-day installation of TrueBeam®, TrueBeam STx, VitalBeam™, or Edge® on existing base frame with prior system rigging and network availability.</p> <p>Features:</p> <ul style="list-style-type: none"> • Completion of installation of all features required for commissioning readiness <p>Prerequisites:</p> <ul style="list-style-type: none"> • Recently ordered new system that has not yet been installed • Eclipse™ Treatment Planning System • 24/7 access to the facility • All items on pre-installation checklist complete • Customer agreement to scope of work <p>Notes:</p> <ul style="list-style-type: none"> • Varian will complete installation to a minimum of beam, collimator, and MV imaging system readiness for commissioning activities. • Varian will return within 30 days from completion of customer commissioning to complete installation and acceptance of all remaining items that were not required for system commissioning, including kV imaging, Rapid Arc, respiratory motion management system. • This service does not include additional construction or commissioning support. 	1
1.24	<p>CatPhan Phantom</p> <p>Phantom for measuring CBCT image contrast, spatial resolution, and uniformity.</p> <p>Features:</p> <ul style="list-style-type: none"> • Modules for measuring CBCT image contrast, spatial resolution, and uniformity <p>Prerequisites:</p> <ul style="list-style-type: none"> • kV Imaging system with CBCT 	1
1.25	<p>Supp. Phantom Kit</p> <p>Supplemental imaging phantom kit for measuring resolution and contrast of kV and MV imaging systems.</p> <p>Features:</p> <ul style="list-style-type: none"> • Leeds TOR 18FG phantom for measuring spatial resolution and contrast of kV imaging system • MV contrast phantom for measuring contrast performance of MV imaging system • Geometric phantom, mounted on IGRT couch top-compatible lock bar. Can be used for quality assurance of image guidance workflow. <p>Prerequisites:</p> <ul style="list-style-type: none"> • MV imaging system 	1
1.26	<p>Motion Management Interface</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> • 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
1.27	<p>STD TRNG: TB Platform On-Site</p> <p>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.</p>	1

Item	Description	Qty
1.28	<p>INCL ED: TB201 TB Platform Physicists</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> Includes support for TrueBeam/Edge/VitalBeam Offer is valid for 18 months after installation of product <p>Prerequisites:</p> <ul style="list-style-type: none"> TrueBeam Platform classroom trainings <p>Notes:</p> <ul style="list-style-type: none"> Training is non-refundable and non-transferable 	1
1.29	<p>INCL ED: TB101 TB Platform Operations</p> <p>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 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.</p> <p>Features:</p> <ul style="list-style-type: none"> 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 <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) <p>Notes:</p> <ul style="list-style-type: none"> Training is non-refundable and non-transferable 	1
1.30	<p>INCL ED: CL222 Respiratory Gating</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> 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 <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) <p>Notes:</p> <ul style="list-style-type: none"> Training is non-refundable and non-transferable 	1

Item	Description	Qty
1.31	NLS: English	1
1.32	20 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.33	Filtrine Water Chiller A closed loop water cooling system, providing clean water at a constant flow, pressure, and temperature for cooling a high energy medical linear accelerator. Ideal for sites where a dependable source of clean water for cooling is not available.	1
1.34	Additional In-Room Monitor System Additional in-room monitors that can be placed at customer discretion.	1
1.35	Power Cond., 3phase 50KVA Transtector 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
1.36	IGRT Couch Top Image Guided RadioTherapy (IGRT) carbon fiber treatment couch top, free of metal or other radiation-opaque materials. Features: • Indexed Immobilization® for compatible accessories • Couch top interface for mounting patient immobilization and quality assurance devices at the head of the couch • Lock bar for indexed positioning of equipment or immobilization devices on the couch top • Handrail for couch positioning, with hooks for temporary pendant placement during patient set up	1
1.37	VCD w/Couch Mount - IGRT	1
1.38	4D CBCT Imaging Package 4D Cone-Beam Computed Tomography (CBCT) Package. Provides the ability to acquire an 4D CBCT images for patient positioning and review target motion analysis at the time of treatment delivery or review 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 Prerequisites: • TrueBeam® v2.7 • One of the following: ◦ Advanced Respiratory Motion Management System ◦ Basic Respiratory Motion Management System ◦ Respiratory Motion Management System ◦ Optical Imager • kV Imaging System • ARIA® oncology information system v11.1 MR1 (11.0.55) or higher or compatible third-party oncology information system • ARIA oncology information system for radiation oncology or Eclipse™ treatment planning system • v11 MR3 (11.0.47) or higher • ARIA oncology information system v15.1 or higher is required for review of 4D kV CBCT images in ARIA Offline Review	1

Item	Description	Qty
	<ul style="list-style-type: none"> Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Verify compatibly third-party oncology information system Initiate Smart Connect application to allow remote monitoring 	
1.39	<p>SRS Encompass IMB IGRT Couchtop</p> <p>The SRS Encompass™ Immobilization package from Qfix™ is a dedicated SRS immobilization package specifically tailored for use with the IGRT couch top.</p> <p>Features:</p> <ul style="list-style-type: none"> Encompass Intracranial Standalone Device (quantity: 2) Encompass mask system (quantity: 10) Direct Indexing™ Adapter for Varian IGRT couch top (quantity: 1) Locating bar (quantity: 1) <p>Prerequisites:</p> <ul style="list-style-type: none"> IGRT couch top TrueBeam® v2.0 and higher VitalBeam® v2.5 (China only) and higher <p>Notes:</p> <ul style="list-style-type: none"> Training will be provided by Qfix 	1
1.40	<p>PerfectPitch 6DoF Couch</p> <p>The PerfectPitch™ 6-Degrees of Freedom couch system</p> <p>Features:</p> <ul style="list-style-type: none"> Image-based 6DoF patient positioning <p>Prerequisites:</p> <ul style="list-style-type: none"> TrueBeam® v2.5 MR2 or higher ARIA® oncology information system v11.1 MR1 (11.0.55) and ARIA radiation therapy management v11 MR3 (11.0.47) or higher or compatible third-party oncology information system <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Verify compatibly of third-party oncology information system 	1
1.41	<p>Gammex Micro+ Fixed Laser System (Green)</p> <p>The MICRO+™ Fixed Laser System (Green) is comprised of three crosshair lasers, one sagittal laser and one remote control.</p> <p>Features:</p> <ul style="list-style-type: none"> One (1) MICRO+ Green Remote-Controlled Ceiling Crosshair Laser Two (2) MICRO+ Green Remote-Controlled Lateral Crosshair Lasers One (1) MICRO+ Green Remote-Controlled Sagittal Line Laser <p>Prerequisites:</p> <ul style="list-style-type: none"> TrueBeam® v2.5 MR2 or higher 	1
Section 2	Eclipse HyperArc Planning License	
2.1	Install on Existing/Customer Server	1
2.2	<p>HyperArc Planning</p> <p>Eclipse external beam planning for frameless, MLC-based delivery technique for single or multiple intracranial SRS targets in support of HyperArc™ delivery.</p> <p>Features:</p> <ul style="list-style-type: none"> HyperArc™ Planning License for one user <p>Prerequisites:</p> <ul style="list-style-type: none"> HyperArc delivery license TrueBeam® or EDGE™ system software v2.7 or higher Eclipse RapidArc Planning License 	1
2.3	<p>STD TRNG: HyperArc Consultant Suprt</p> <p>Standard Training HyperArc™ Consultant Support</p>	1

Item	Description	Qty
2.4	<p>STD TRNG: HyperArc- Onsite</p> <p>Standard Training for HyperArc™ Planning. Intended audience includes physicists, dosimetrist/treatment planners and other staff as appropriate.</p> <p>Features:</p> <ul style="list-style-type: none"> • Consultant will provide clinical support to establish a Stereotactic Radiosurgery (SRS) Program at customer site. The consultant will cover the necessary workflow for the following: <ul style="list-style-type: none"> ◦ patient selection ◦ positioning and imaging ◦ treatment planning ◦ dose prescriptions and organ at risk sparing ◦ quality assurance ◦ treatment imaging and delivery ◦ patient follow up • Duration and Location: 2 days at customer site plus 4 hours of remote support <p>Prerequisites:</p> <ul style="list-style-type: none"> • HyperArc v15.5 or higher installed • Truebeam v2.7 or higher installed <p>Notes:</p> <ul style="list-style-type: none"> • Offer is valid for up to 18 months after installation of product • Non-transferable to other products and services and non-refundable • This entitled training is for up to 3 users. The intended audience includes physicists, physicians, dosimetrists, treatment planners and other staff as appropriate 	1
2.5	<p>STD TRNG: HyperArc Follow Up Trng</p> <p>Standard Training HyperArc™ Follow Up Training Onsite</p> <p>Features:</p> <ul style="list-style-type: none"> • Training Plan details will be provided by the training management team as part of your product implementation process. Topics covered can include: <ul style="list-style-type: none"> • Workflow treatment planning from CT protocol • Plan generation • Fixation device • Optimization • Plan preparation for imaging and treatment • Duration and Location: 1 day at customer site <p>Prerequisites:</p> <ul style="list-style-type: none"> • HyperArc installed <p>Notes:</p> <ul style="list-style-type: none"> • This entitled training is for up to 3 users • Offer is valid for up to 18 months after installation of product • Non-transferable to other products and services and non-refundable 	1
2.6	<p>Non-Clinical HyperArc</p> <p>Eclipse™ external beam planning for frameless, MLC-based delivery technique for single or multiple intracranial SRS targets in support of HyperArc™ delivery.</p> <p>Features:</p> <ul style="list-style-type: none"> • Non-Clinical HyperArc Planning License for one (1) user <p>Prerequisites:</p> <ul style="list-style-type: none"> • Eclipse T-Box Software Package or Eclipse Educational/Research SFW Package • Non-Clinical RapidArc Planning 	1

Item	Description	Qty
Section 3 Removal/Disposal and Trade-In VersaHD		
3.1	Remove/Dispose Existing Equipment	1
	Remove/Dispose Existing Equipment	
3.2	Trade-In Discount	1
	Trade-In Discount	
3.3	Discount for VTX	1
	Discount for VTX	
Section 4 Commissioning Services		
4.1	Advantage Contract Credits	
	Advantage Credits can be utilized for Varian's Professional Services, such as consulting, on-site applications training, education, and third-party services including physics services and clinical schools that are purchased through Varian. For further details, please reference the attached Terms and Conditions.	
4.2	LMP4a Comm custom 5X+SRS	208.0
	(Qty: 1, Credit per Qty: 208.0)	
	Advantage Commissioning of TrueBeam with custom Models and SRS and Eclipse Treatment Planning System Landauer Medical Physics will commission TrueBeam accelerator for up to 3 flattened and 2 unflattened X-ray and up to 6 electrons energies. This group will also commission SRS for MLC and cones for one photon energy. The service will be performed by 2 physicists and is estimated to be 9 calendar days.	
	Scope of Work:	
	• SRS Cone configuration for one energy ,	
	Deliverables:	
	• Commissioning Review with Customer physicist	
	• Sample of various plans for end to end testing with Portal Dosimetry	
	• Review of TPS configuration and settings	
	• Data book	
	• Commissioning report	
	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 accessNot included: This service does not include any commissioning for Hard Wedge. Customer must purchase Hard Wedge commissioning separately	
Section 5 TPS Eclipse - HW		
5.1	GPU Enabled Framework Agent Server (FAS)	1
	A Framework Agent Server (FAS) that includes the necessary GPU (Graphics Processing Unit) cards required to support the Framework Agent Server GPU Algorithm license. The FAS is a high-performance server dedicated	

Item	Description	Qty
	<p>exclusively to running Varian's Eclipse Distributed Calculation Framework (DCF). FAS with DCF leverages specialized Grid Clustering power (network-based parallel processing) to optimize throughput for Eclipse planning and dose calculation in both native client/server topologies and Citrix environments. Multiple Framework Agent Servers may be configured to create a FAS Array.</p> <p>Features:</p> <ul style="list-style-type: none">• Includes GPU cards <p>Prerequisites:</p> <ul style="list-style-type: none">• Eclipse 15.5 and higher <p>Customer Responsibilities:</p> <ul style="list-style-type: none">• A properly networked environment connected at 1Gbps• Server rack equipped with power supply input voltage 208V/240V AC @50/60Hz 10A• Power Distribution Unit (PDU) or supply rail which outputs 208V/240V (1600W)• Computer Uninterruptible Power Supply (UPS) 220V• Installation of the server into the rack• Installation of server into existing customer domain <p>Notes:</p> <ul style="list-style-type: none">• Server will not run on low-line 110V/120V AC• Does not support Windows Server 2008R2	

Draft Only

ATTACHMENT E

Projected Capital Cost Form

NH Huntersville Medical Center Linear Accelerator Replacement

Building Purchase Price	\$	-
Purchase Price of Land	\$	-
Closing Costs	\$	-
Moblie Site Preparation	\$	-
Construction/Renovation Contract(s)	\$	779,652
Cost of Temporary Moblie CT	\$	-
Architect / Engineering / DHSR Fees	\$	105,597
Medical Equipment	\$	2,650,000
Non-Medical Equipment	\$	337,015
Furniture	\$	-
DPS/IT Systems	\$	26,180
Financing Costs	\$	-
Interest during Construction	\$	-
Other: Contingency	\$	301,556
Total Capital Cost	\$	4,200,000

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected construction costs for the proposed project is complete and correct.

DocuSigned by:
TJ Connors, AIA License No. 8017
2ED9CFE8541E48F...

Date Signed: 08/18/2021 | 1:00:29 EDT

Signature of Licensed Architect or Engineer
TJ Connors, HDR Inc.

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
9BCFAC883516459...

Date Signed: 08/18/2021 | 5:32:40 EDT

Signature of Officer/Agent

Senior Vice President, Construction & Facilities Svcs, Novant Health
Title of Officer/Agent

Faenza, Julie M

From: Griffin, Lisa L <lgriffin@novanthealth.org>
Sent: Thursday, August 19, 2021 3:58 PM
To: Faenza, Julie M
Cc: Hale, Gloria
Subject: [External] Replacement Equipment Exemption for NH Huntersville Linear Accelerator
Attachments: NH HMC Linac REER Letter to Agency 08.19.21.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Good afternoon, Julie,

Attached is an exemption letter regarding the replacement of the linear accelerator at Novant Health Huntersville Medical Center.

Please let me know if you have any questions or need any further information.

Thank you,

Lisa Griffin

Manager, Planning & Certificate of Need
Strategic & Business Planning | Internal Consulting Group
Novant Health, Inc.
(704) 351 – 1132

We are here to help you get the care you need. Visit [Novant Health](#) or [Novant Health UVA](#) for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite [Novant Health](#) o [Novant Health UVA](#) para información actualizada.

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