

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

June 14, 2019

Lisa Griffin
2085 Frontis Plaza Drive
Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #: 2965
Facility Name: Novant Health Rowan Medical Center
FID #: 933436
Business Name: Rowan Regional Medical Center, Inc.
Business #: 1593
Project Description: Replacement of Linear Accelerator Equipment
County: Rowan

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 3, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Varian TrueBeam 2.7 Linear Accelerator to replace the Varian Linear Accelerator Model 2100C Serial #2937. 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,

Handwritten signature of Gregory F. Yakaboski
Gregory F. Yakaboski
Project Analyst

Handwritten signature of Martha J. Frisone
Martha J. Frisone
Chief

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

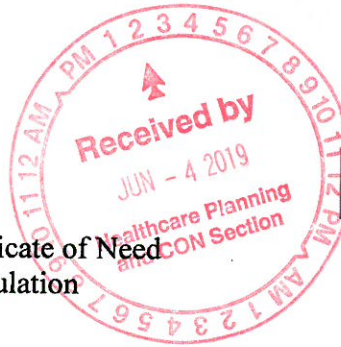
NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

June 3, 2019

Via Email

Greg Yakaboski, 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 Rowan Medical Center
Replacement of Linear Accelerator Equipment
Salisbury, North Carolina (FID # 933436; Rowan County)

Dear Mr. Yakaboski:

Novant Health Rowan Medical Center (NHRMC) intends to replace an existing linear accelerator (linac) currently located in the hospital's Radiation Oncology Department located at 229 Mocksville Avenue in Salisbury, North Carolina pursuant to N.C. Gen. Stat. 131E-184(f). The existing linac is over 10 years old and is in need of technological upgrading. Therefore, NHRMC will acquire a new Varian TrueBeam 2.7 system. See **Attachment A** for the equipment quote. As part of this project, the new linac is to be relocated to NHRMC's new, planned Cancer Center building under construction at the corner of Mocksville and Mahaley Avenues. The new linac will be installed in the new Radiation Oncology Department at the new Cancer Center location once the building is complete in 2020. The existing linac will then cease to operate and will be removed as part of the trade-in by the vendor (see the last page of the Equipment Quote). See **Attachment B** for Agency notice deeming the Cancer Center building construction as exempt from CON review.

The total capital costs are estimated at \$14,164,576. The construction costs were prorated and estimated for the area encompassing the linac only. See **Attachment C** – Project Capital Cost **Attachment D** for the Certified Architect's Letter. Also included is the Equipment Comparison Form in **Attachment E**.

NHRMC'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 existing and replacement linac are and will be located in hospital departments that are within 250 yards of Novant Health Rowan Medical Center, which is located at 612 Mocksville Avenue, Charlotte, North Carolina, 28144. In addition, Ms. Darise Caldwell, President, of NHRMC is located in Administration in the hospital's main building and has financial and administrative control over the entire facility and oversight of its clinical patient services. See a NHRMC Campus Map in **Attachment F** which shows the existing linac location and the new Cancer Center location in the lower left corner.

Re: NHRMC Replacement of Linear Accelerator
June 3, 2019
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Previous Certificate of Need:

The existing linac was acquired in April 2005 for total project costs of \$750,000 and replaced the original linac put in service in 2002 before linear accelerators were Need Determined in North Carolina. NHRMC has reported this linac on the hospital LRA and in the inventory of the annual State Medical Facilities Plan since it acquired a linac.

Prior Written Notice

This letter and supporting documentation are prior written notice that NHRMC's proposal to replace an existing linac meets the requirements of N.C.G.S. 131E-184(f).

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – NHRMC Cancer Center Construction Exemption Notice
- Attachment C** – Project Capital Costs
- Attachment D** – Certified Architects Letter
- Attachment E** – NC CON Equipment Comparison Form
- Attachment F** – NHRMC Campus Map

NHRMC's acquisition of the replacement equipment 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 \$14,164,576. 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 NHRMC's replacement equipment exemption request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me at (704) 384 - 3462.

Sincerely,



Lisa Griffin
Manager, Planning/Certificate of Need
Novant Health, Inc.

Enclosures

ATTACHMENT A –
• Equipment Quote

Item	Description	Qty
Section 1 Scalable TrueBeam		
1.1	TrueBeam Version 2.7	1
1.2	New Universal Baseframe 52" Fixed Floor	1
1.3	15/16 MV (BJR 11/17) 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.4	10/10 MV (BJR 11/17) 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.5	6/6 MV (BJR 11/17) 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.6	16 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.7	12 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.8	9 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.9	6 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.10	PerfectPitch 6DoF Couch Fully integrated 6-Degrees of Freedom (6DoF) couch system. Features: <ul style="list-style-type: none"> • Manual and automated positioning of the patient • Image-based 6DoF patient positioning with remote couch motion Prerequisites: <ul style="list-style-type: none"> • ARIA® Oncology Information System for Radiation Oncology v.11 or later 	1
1.11	Pivotal™ Prone Breast Solution	1

Item	Description	Qty
	<p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> • Right and left prone breast couch top inserts with foam cushions • Prone head cushion & contour pillow cushion • Dual hand grip and ipsilateral hand grip • Adjustable CT Risers (superior & inferior) for CT simulation • Storage Cart <p>Prerequisites:</p> <ul style="list-style-type: none"> • Qfix™ kVue™ Couch top <p>Notes:</p> <ul style="list-style-type: none"> • Available for small and large bore CT scanners 	
1.12	<p>6X High Intensity Mode</p> <p>40 cm x 40 cm maximum field size, dose rate range 400-1400 MU/Min in 200 MU/min steps.</p>	1
1.13	<p>6 MeV HDTSE, 0-2500 MU/min</p> <ul style="list-style-type: none"> • 6 MeV High Dose Total Skin Electron energy configuration. Dose rate 2500 MU/Min <p>Prerequisites:</p> <ul style="list-style-type: none"> • High Dose Total Skin Electron Treatment Delivery license 	1
1.14	<p>Low-X Imaging Energy</p> <p>Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam.</p>	1
1.15	<p>HyperArc Treatment Delivery Capability</p> <p>Frameless, MLC-based technique for multiple intracranial SRS targets. Automated non-coplanar treatment delivery with integral intrafraction imaging at specified couch angles.</p> <p>Features:</p> <ul style="list-style-type: none"> • HyperArc™ Delivery License <p>Prerequisites:</p> <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 iCART 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 <p>Notes:</p> <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
1.16	<p>kV Imaging System</p> <p>kV Imaging system, providing 2D radiographic and fluoroscopic and 3D CBCT imaging capability.</p> <p>Features:</p> <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	Triggered Imaging	1
	<p>Automated intrafraction 2D 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.</p> <p>Features:</p> <ul style="list-style-type: none"> Respiration Triggered Imaging MU Triggered Imaging Gantry Triggered Imaging Time Triggered Imaging Autobeam Hold <p>Prerequisites:</p> <ul style="list-style-type: none"> Respiratory Motion Management System 	
1.18	Advanced Resp Motion Management System	1
	<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 	
1.19	VCD Option, couch mounted	1
	<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 	
1.20	VCD w/Couch Mount - kVue	1
1.21	Gated CBCT	1
	<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. 	

Item	Description	Qty
	<ul style="list-style-type: none"> • 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 	
1.22	<p>4D CBCT Imaging Package</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> • 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 <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 <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> • Customer must verify compatibility with 3rd party systems & devices <p>Notes:</p> <ul style="list-style-type: none"> • TrueBeam v2.7 or higher is required to utilize 4D CBCT Match Review license 	1
1.23	<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
1.24	<p>LAP Apollo Green Room Laser Kit</p> <p>Features:</p> <ul style="list-style-type: none"> • 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
1.25	<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 • Two desktop LCD displays with built in camera controls • Adjustable viewing angle for patient privacy • Push button pan, tilt, zoom, and home position control <p>Prerequisites:</p> <ul style="list-style-type: none"> • Motion View camera system, provided with linac system. 	1

Item	Description	Qty
1.26	<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
1.27	<p>Power Cond., 3phase 50KVA</p> <p>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.</p> <p>Notes:</p> <ul style="list-style-type: none"> Supports voltage configurations from 208 to 600 VAC and in 50 or 60 Hz for US and ROW applications. 	1
1.28	<p>SuperFAST Install - New Base</p> <p>Accelerated 12-day installation of TrueBeam®, TrueBeam STx, VitalBeam™, or Edge®.</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
1.29	<p>RPC Lung Phantom Service</p> <p>A service provided through the MD Anderson Dosimetry Lab (MDADL) to supply a Radiological Physics Center (RPC) lung phantom for QA and commissioning of advanced technologies.</p> <p>Features:</p> <ul style="list-style-type: none"> 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 <p>Report of analysis from MDADL</p> <p>Prerequisites:</p> <ul style="list-style-type: none"> Acceptance of TrueBeam® or Edge™ system with which the lung phantom will be used <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Login to www.myvarian.com to access the Customer Technical Bulletin CTB-GE-930 for instructions on redeeming the lung phantom service <p>Non-printing</p>	1
1.30	<p>SRS Encompass IMB Qfix Couchtop</p> <p>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.</p> <p>Features:</p> <ul style="list-style-type: none"> kVue Encompass Intracranial Insert (quantity: 1) Encompass Intracranial Standalone Device for CT (quantity: 1) Encompass mask system (quantity: 10) Locating bar (quantity: 1) <p>Prerequisites:</p> <ul style="list-style-type: none"> Qfix kVue or Calypso kVue couch top TrueBeam® v2.0 and higher 	1

Item	Description	Qty
	<ul style="list-style-type: none"> VitalBeam® v2.5 (China only) and higher <p>Notes:</p> <ul style="list-style-type: none"> Training will be provided by Qfix 	
1.31	<p>Calypso</p> <p>The Calypso® system enables Real-time direct tumor localization and tracking using implanted transponders based on user-defined motion thresholds.</p> <p>Features:</p> <ul style="list-style-type: none"> Automated coplanar and non-coplanar patient set up, patient repositioning, target tracking, and treatment beam gating based on user-defined motion thresholds Starter kit for prostate Beacon Transponders and implant training <p>Prerequisites:</p> <ul style="list-style-type: none"> Motion Management Interface Qfix™ kVue™ Couch top, Calypso compatible 	1
1.32	<p>Beacon Care Pkg – Surface</p> <p>Calypso Beacon® Transponder for Surface</p> <p>Features:</p> <ul style="list-style-type: none"> Enables use of the Calypso® System for localization and real-time monitoring of respiratory motion and other patient motion during radiation therapy Each Beacon Care Package includes one surface transponder assembly and storage case <p>Prerequisites:</p> <ul style="list-style-type: none"> Calypso System v2.0 or higher <p>Notes:</p> <ul style="list-style-type: none"> Each Beacon Care Package is designed for one patient 	5
1.33	<p>Beacon® Care Pkg - Soft Tissue 17G</p> <p>The Beacon® Care Package - Soft Tissue (17G) Beacon transponder is intended for use with the Calypso® System. The Beacon transponders are indicated for permanent implantation in the body, specifically in the prostate and prostatic bed, and in soft tissue. Each Beacon Care Package consists of three (3) Beacon transponders, a set of three (3) 17G introducer needle assemblies, Instruction for Use (IFU) pamphlet and a patient identification wallet card. One (1) Beacon Care Package is required per patient.</p> <p>Prerequisites:</p> <ul style="list-style-type: none"> Calypso System 3.0 Soft Tissue Implant Training <p>Customer Responsibilities:</p> <ul style="list-style-type: none"> Customer to provide 17G needle guide if devices are to be implanted under ultrasound guidance 	10
1.34	<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
1.35	<p>INCL ED: UAB TrueBeam SRS/SBRT Clin Sch</p> <p>The SRS & SBRT Delivery with Eclipse and Truebeam® clinical school is taught by a multi-disciplinary team from the University of Alabama at Birmingham, including subspecialty surgeons, radiation oncologists 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)</p>	1

Item	Description	Qty
	<p>depending upon the interests of those enrolled. This course is designed for radiation physicists, radiation oncologists, surgeons, and dosimetrists.</p> <p>Features:</p> <ul style="list-style-type: none"> • Topics covered include: Commissioning and QA4D 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 Hazelrig-Salter Radiation Oncology Center, The University of Alabama at Birmingham, Birmingham, AL. <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"> • 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 	
1.36	Implant Trng Mod–Prostate/Prostatic Bed	1
1.37	STD TRNG: TB Platform On-Site	1
	<p>The on-site review of the TrueBeam/Edge/HiBeam 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> <p>Features:</p> <ul style="list-style-type: none"> • Includes support for TrueBeam/Edge/HiBeam • 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 	
1.38	STD TRNG: Calypso	1
	<p>Training plan details will be provided by the training management team as part of the product implementation process.</p> <p>Features:</p> <ul style="list-style-type: none"> • Offer is valid for 18 months after installation of product. <p>Notes:</p> <ul style="list-style-type: none"> • Training is non-refundable and non-transferable 	
1.39	INCL ED: TB201 TB Platform Physicists	1
	<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</p>	

Item	Description	Qty
	<p>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 • 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 	
1.40	<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 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
1.41	<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
1.42	<p>NLS: English</p>	1
1.43	<p>TrueBeam with 120 Multileaf Collimator</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>	1

Item	Description	Qty
	<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 <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. 	
1.44	<p>Qfix™ kVue™ CouchTop, Calypso compatible</p> <p>Carbon fiber composite treatment table top, featuring indexed immobilization, two locating bars, two removable accessory rails, patient straps, and movable carbon fiber support beams. Metal-free and non-conductive.</p> <p>Features:</p> <ul style="list-style-type: none"> • Standard insert: Carbon fiber composite insert with indexing every 14 cm • Universal tip insert: Carbon fiber composite insert allowing mounting of QA and treatment devices at the head of the couch top, 14 cm indexing • Service overlay: A protective surface designed to be placed on the couch tops to protect the surface during maintenance, QA measurements, and commissioning measurements <p>Notes:</p> <ul style="list-style-type: none"> • Customers must confirm with 3rd party suppliers of accessories for compatibility. 	
1.45	<p>10X High Intensity Mode</p> <p>40 cm x 40 cm maximum field size, dose rate range 400-2400 MU/min in 400 MU/min steps.</p>	1
1.46	<p>RapidArc Treatment Delivery</p> <p>RapidArc® Treatment Delivery is a volumetric modulated arc treatment delivery technique.</p> <p>Features:</p> <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 <p>Prerequisites:</p> <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
1.47	<p>Filtrine Water Chiller for 2 Systems</p>	1

Item	Description	Qty	Offer Price
	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.		
1.48	SBRT IMB for existing Qfix couchtops	1	
1.49	Beacon Care Package - Lung Calypso Anchored Beacon® Transponders for Lung Features: <ul style="list-style-type: none"> • Each Beacon Care Package for Lung includes three custom, single-use delivery catheters preloaded with anchored Beacon transponders • Each Beacon Care Package for Lung is designed for one patient • Enables use of Calypso® System for localization and real-time monitoring of treatment targets in the lung • Supports free breathing and breath-hold protocols • Permanent implantation in small airways in the lung • 5 Nitinol legs anchor the Beacon transponders upon deployment • Implanted via bronchoscopic procedure Prerequisites: <ul style="list-style-type: none"> • Calypso System v3.0 Customer Responsibilities: <ul style="list-style-type: none"> • Completed or scheduled Calypso System Lung Usage training for radiation therapy department prior to product delivery • Completed or scheduled Anchored Beacon Transponder Lung Implantation training for implanting physician prior to product delivery 	2	
1.50	20 MeV, 0-1000 MU/Min 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1	
			Offer Price
			Section Total : US \$9,094,430.00 US \$9,094,430.00
Section 2 Removal and Disposal with Trade-In Allowance			
2.1	Remove/Dispose Existing Equipment Remove/Dispose Existing Equipment	1	
2.2	Trade-In for existing Linac Trade-In for existing Linac	1	

Offer Price

Item	Description	Qty
Section Total :		US \$25,000.00
		US \$15,000.00

Section 3 Advantage Credits

3.1 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.

3.2 Additional Advantage credits

40.0

(Qty: 40, Credit per Qty: 1.0)
Undefined Advantage credits

3.3 LMP4a Comm custom 5X+SRS

183.0

(Qty: 1, Credit per Qty: 183.0)

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 access Not included. This service does not include any commissioning for Hard Wedge. Customer must purchase Hard Wedge commissioning separately

3.4 ED: TB101 TrueBeam Platform Operations

16.0

(Qty: 1, Credit per Qty: 16.0)

Includes Tuition and Materials for ONE Person

This course provides training for Radiation Therapists responsible for the operation of the TrueBeam, providing an overview of the TrueBeam system, hands-on training to include: system components, shutdown procedure, startup with basic morning QA procedures, startup after an emergency shutdown and power failure, basic administrative information and treatment and imaging scenarios to include: basic 2D and 2D-2D imaging, treatment with automation, LaserGuard II and Machine Protection, imaging and treatment with custom blocks, Cone-Beam CT , gated imaging and treatment with intra-fraction motion review, auto-beam hold and emergency treatment.

Designed for Radiation Therapists who will treat patients on a daily basis and will be able to teach TrueBeam others users in the department

Pre-Requisites: Clinical training in Radiation Therapy. Clinical experience if treating patients on Varian machines. Clinical experience of IGRT, OBI and Cone-Beam CT.

Application has been made for MPCEC credits

Duration and Location:

4.0 days

Varian Education Center

Las Vegas, Nevada, USA

Item	Description	Qty
	<p>Advantage Credits Eligible</p> <p>Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals), unless otherwise stated.</p>	
3.5	<p>Travel and Lodging</p> <p>Allowance is applied only to the travel and lodging expenses, including airfare, hotel accommodations and rental car.</p> <p>The customer is responsible for any expenses outside of the allowance. Travel and lodging charges will be direct billed and are not reimbursable if travel is booked outside of Balboa Travel. The hotel must be Varian preferred. Any remaining balance is non-refundable.</p> <p>Please contact Balboa Travel Agency at 877-593-7220 in order to make the necessary travel arrangements once you complete the online registration at www.variantraining.com and receive an email confirmation for the course. Be sure to provide Balboa your Varian sales order number.</p> <p>The Travel and Lodging allowance expires 24 months from the acceptance date of your equipment. Any unused portion will not be available, cannot be traded for other products or services and will not be returned.</p>	
3.6	<p>Product Applications MMI (per hour)</p> <p>(Qty: 1, Credit per Qty: 1.0)</p> <p>Additional Motion Management onsite training is available for previously trained Varian products. Sold and delivered by hours.</p> <p><u>Total Advantage Credits for this Section: 240.0</u></p>	1.0
		<p>Section Total : US \$192,000.00 Offer Price US \$192,000.00</p>
Section 4 One-year Extended Warranty for Scalable TrueBeam (1 Year)		
4.1	<p>TrueBeam RapidArc/M/MAT MLC 120 MV Imager Calypso iCBCT 4D CBCT C/SA CBCT VCB-TBM ARMM Triggered Imaging KV Imager PerfectPitch Couch</p>	1
		<p>Section Total : US \$316,523.00 Offer Price US \$9,694.00</p>
Section 5 humediQ IDENTIFY RT/SGRS & CT/DIBH Package		
5.1	<p>Allowance</p> <p>humediQ - New System</p>	1

Item	Description	Qty
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	Offer Price
Section Total :	US \$429,000.00 US \$429,000.00

Section 6 humediQ Light & Sound/Welcome Desk Package

6.1	Allowance	1
	humediQ - New System	

	Offer Price
Section Total :	US \$55,000.00 US \$55,000.00

Draft Only

Sales Price Table

Trade-in →	TradeIn-Cancellations	-US \$10,000.00
	Sales Total	US \$9,795,124.00
	Quotation Total	US \$9,795,124.00

Draft Only

ATTACHMENT B –

- **Cancer Center Building Exemption**



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

May 6, 2019

Lisa Griffin
2085 Frontis Plaza Drive
Winston-Salem, NC 27103

Exempt from Review

Record #: 2927
Facility Name: Novant Health Rowan Medical Center
FID #: 933436
Business Name: Rowan Regional Medical Center, Inc.
Business #: 1593
Project Description: Construct a cancer center on its main campus
County: Rowan

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 11, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g). 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 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.

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


NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873


AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Ms. Griffin
May 6, 2019
Page 2

Sincerely,



Gregory F. Yakaboski
Project Analyst



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

cc: Construction Section, DHR
Acute and Home Care Licensure and Certification Section, DHR

ATTACHMENT C –
• Project Capital Costs

**RMC Linear Accelerator Replacment
Projected Capital Cost Form**

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 4,191,566
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$ 9,805,124
Non-Medical Equipment	
Furniture	
Consultant Fees: Architects & Engineer.	\$ 147,337
Financing Costs	
Interest during Construction	
Other: DHSR Review	\$ 20,549
Total Capital Cost	\$ 14,164,576

< \$9,795,124 + \$10,000 TradeIn

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

*** See Signed Architect's Letter Included ***

Date Signed: _____

Signature of Licensed Architect or Engineer _____

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.

Darise D Caldwell

Date Signed: 6-3-19

Signature of Officer/Agent _____

President, Novant Health Rowan Medical Center

Title of Officer/Agent _____

ATTACHMENT D –
• Certified Architects Letter



200 West Tremont Avenue | Suite 200
Charlotte, North Carolina 28203

704.364.3400 Office

ksq.design

March 12, 2019

Mr. Todd Howard
Novant Health, Inc.
Corporate Design Services
200 Hawthorne Lane
Charlotte, NC 28204

Re: Novant Health | Rowan Medical Center – Cancer Center Linear Accelerator, Salisbury, NC

Dear Todd,

I have prepared the estimate for the Rowan Medical Center – Cancer Center Linear Accelerator construction cost. I estimate the total construction cost to be \$4,191,566.00

The architectural and engineering design fees shall be \$141,980.00 and estimated project reimbursables are approximately \$5,357.00. The DHSR review fee is estimated to be \$20,549.00. Therefore, the total estimated cost of construction, including A&E fees and reimbursables, and DHSR review fee is \$4,359,452.00.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

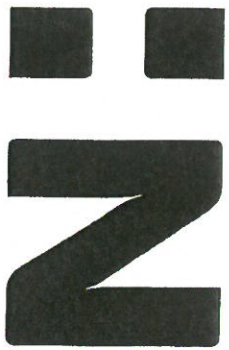
Nelson C. Soggs, AIA, LEED® AP
Senior Associate
KSQ Design



ATTACHMENT E –
• Equipment Comparison Form

Novant Health Rowan Medical Center Linear Accelerator Replacement		EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)		Linear Accelerator	Linear Accelerator
Manufacturer of Equipment		Varian	Varian
Tesla Rating for MRIs		n/a	n/a
Model Number		2100C	TrueBeam
Serial Number		2937	TBD
Provider's Method of Identifying Equipment		Internal # System	Internal # System
Specify if Mobile or Fixed		Fixed	Fixed
Mobile Trailer Serial Number/VIN #		n/a	n/a
Mobile Tractor Serial Number/VIN #		n/a	n/a
Date of Acquisition of Each Component		April 2005	TBD
Does Provider Hold Title to Equipment of Have a Capital Lease?		Own	Own
Specify if Equipment Was/Is New or Used When Acquired		Used	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>		\$11,700	\$14,164,576
Total Cost of Equipment		\$738,300	\$9,795,124
Fair Market Value of Equipment		\$10,000	\$9,795,124
Net Purchase Price of Equipment		\$10,000	\$9,795,124
Locations Where Operated		RMC Rad-Onc Department	RMC Cancer Center
Number Days In Use/To be Used in N.C. Per Year		365	365
Percent of Change in Patient Charges (by Procedure)		No change	No change
Percent of Change in Per Procedure Operating Expenses (by Procedure)		No change	No change
Type of Procedures Currently Performed on Existing Equipment		Radiation Therapy treatments	
Type of Procedures New Equipment is Capable of Performing			Radiation Therapy Treatments

ATTACHMENT F –
• NHRMC Campus Map



Campus Map

Novant Health Rowan Medical Center

612 Mocksville Avenue
Salisbury, NC 28144
704-210-5000
NovantHealth.org

Proposed Cancer Center area

