

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor

Richard O. Brajer Secretary DHHS

Mark Payne Assistant Secretary for Audit and Health Service Regulation

August 16, 2016

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

Exempt from Review - Replacement Equipment

Record #:

2026

Facility Name:

Novant Health Forsyth Medical Center

FID #:

Project Description:

Replace Existing Linear Accelerator at Novant Health Forsyth Medical Center

County:

Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letters dated July 28, 2016 and August 11, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to replace, without a certificate of need, the Varian 21EX linear accelerator located on the main campus at 3333 Silas Creek Parkway in Winston-Salem with an Elekta Infinity linear accelerator. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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,

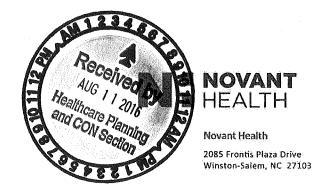
Project Analyst

Assistant Chief, Certificate of Need

cc:

Paige Bennett, Assistant Chief, Healthcare Planning, DHSR





August 11, 2016

Ms. Celia Inman, Project Analyst, Certificate of Need Healthcare Planning & Certificate of Need (CON) Section North Carolina Department of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

Re: Follow-up to Request for More Information Regarding Replacement Equipment Exemption Request Pursuant to N.C.G.S. 131E-184(f) — Linear Accelerator #3 at Novant Health Forsyth Medical Center (NHFMC); Forsyth County

Dear Ms. Inman:

This letter is a follow-up for a request for more information for NHFMC's notice of exemption concerning a project to replace an existing linear accelerator (Linear Accelerator 3) located in the hospital's cancer center with a new Elekta Infinity linear accelerator. As such, please refer to the original letter and attachments dated July 28, 2016, as referenced here. See Attachment A for the vendor quote from Elekta. The total project costs related to the replacement of the linear accelerator are \$3,206,787, including the new equipment cost of \$2,392,081. The project cost does not include: sales, property or excise taxes since NHFMC is a non-profit, tax-exempt organization and is not typically subject to these taxes. In addition, the expense for on-site training on the new linear accelerator for the radiation oncology staff is covered by the vendor quote on Page 14. The existing equipment is to be removed from NHFMC by RS&A Oncology Equipment Services (see Attachment B) and will then be sold to an equipment vendor or reconditioning specialist and removed from North Carolina and not returned to North Carolina without the appropriate CON approvals.

Both the existing equipment and the replacement equipment are comparable medical equipment as explained on the following page. This project should be approved by the Agency as exempt pursuant to N.C.G.S. Section 131E-184(f) which states that a project is exempt from Certificate of Need review if it is more than \$2 million and meets the following requirements:

1. The equipment is located on the main campus of the licensed acute care hospital. "Main campus" means: "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 entire facility, including the buildings and grounds adjacent to that main building and other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building."

Ms. Celia Inman August 11, 2016 Replacement Equipment Exemption – NHFMC Linear Accelerator #3 Page 3

in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

- 4. The existing equipment was not purchased second-hand nor was the existing equipment leased.
- 5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Attached for your convenience please find:

- 1) a vendor equipment price quote (Attachment A);
- 2) a vendor quote regarding the de-installation of the existing linear accelerator (Attachment B);
- 3) maps indicating the location of the campus and the cancer center (Attachment C);
- 4) a copy of the August 4, 2005 letter from the CON Section regarding the replacement of the current linear accelerator (Attachment D);
- 5) project/capital cost schedule which identifies the components of the total project costs (Attachment E);
- 6) a certified estimate of related construction costs from an independent licensed North Carolina architect (Attachment F); and,
- 7) the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (Attachment G).

NHFMC's acquisition of the replacement linear accelerator does not require a certificate of need because none of the definitions of "new institutional health service" set forth in N.C.G.S. Section 131E-176(16) is implicated. As discussed above, the total cost for the project is \$3,206,787. This includes the cost of the equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational (such as staff training).

In conclusion, based on the information described above, please confirm that NHFMC's replacement equipment request does not constitute a "new institutional health service" and does fit within the replacement equipment exemption definition. Therefore, the project is not subject to certificate of need review.

Please contact me at (704) 384 – 3462 if you need additional information to assist in your consideration of this request. Thank you for your prompt consideration of this request.

Sincerely,

Lisa Griffin

Manager, Certificate of Need

Novant Health, Inc.

File: FollowUp FMC LinAc V3 REER 081016.docx





Novant Health

2085 Frontis Plaza Drive Winston-Salem, NC 27103

July 28, 2016

Ms. Martha Frisone, Assistant Chief, Certificate of Need Healthcare Planning & Certificate of Need (CON) Section North Carolina Department of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

Re: Replacement Equipment Exemption Request Pursuant to N.C.G.S. 131E-184(f) – Linear Accelerator #3 at Novant Health Forsyth Medical Center (NHFMC); Forsyth County

Dear Ms. Frisone:

This letter outlines Novant Health Forsyth Medical Center's (NHFMC's) project to replace an existing linear accelerator (Linear Accelerator 3) located in the hospital's cancer center with a new Elekta Infinity linear accelerator. See **Attachment A** for the vendor quote from Elekta. The total project costs related to the replacement of the linear accelerator are \$3,206,787, including the new equipment cost of \$2,392,081. The project cost does not include: sales, property or excise taxes since NHFMC is a non-profit, tax-exempt organization and is not typically subject to these taxes. In addition, the expense for on-site training on the new linear accelerator for the radiation oncology staff is covered by the vendor quote on Page 14. The existing equipment is to be removed from NHFMC by RS&A Oncology Equipment Services (see Attachment B) and will then be sold to an equipment vendor or reconditioning specialist and removed from North Carolina and not returned to North Carolina without the appropriate CON approvals.

Both the existing equipment and the replacement equipment are comparable medical equipment as explained on the following page. This project should be approved by the Agency as exempt pursuant to N.C.G.S. Section 131E-184(f) which states that a project is exempt from Certificate of Need review if it is more than \$2 million and meets the following requirements:

1. The equipment is located on the main campus of the licensed acute care hospital, NHFMC;

The equipment, in this case, a linear accelerator, is located on the main campus in the Cancer Center of NHFMC, specifically in Vault (or Room) 3. The replacement linear accelerator will be located in the same location of NHFMC's main campus. See Maps documenting the location at NHFMC at 3333 Silas Creek Parkway, Winston-Salem, North Carolina in Attachment C.

Ms. Martha Frisone
July 28, 2016
Replacement Equipment Exemption – NHFMC Linear Accelerator #3
Page 2

2. The CON Department has previously issued a certificate of need for the equipment being replaced;

No Certificate of Need was required for the existing linear accelerator. It was an approved replacement equipment exemption per notice from the CON Section dated August 4, 2005 (See Attachment D.)

3. The facility proposing to acquire the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria.

This correspondence and supporting documentation serves as prior written notice to the CON Section that the linear accelerator replacement meets the exemption criteria.

This exempt project will replace a functionally similar operational equipment item on the main campus of NHFMC in the Cancer Center and will not increase the inventory of linear accelerators in Forsyth County. The proposed new linear accelerator is consistent with the replacement equipment definition at N.C.G.S. Section 131E-176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. The existing linear accelerator is used for radiation oncology procedures in the hospital Cancer Center and the replacement linear accelerator will be used for radiation oncology procedures in the hospital Cancer Center.

Pursuant to 10A NCAC 14C.0303 the proposed linear accelerator constitutes replacement equipment because:

- 1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to the technological improvements.
- 2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service.
- 3. The acquisition of the new 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.
- 4. The existing equipment was not purchased second-hand nor was the existing equipment leased.
- 5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Ms. Martha Frisone
July 28, 2016
Replacement Equipment Exemption – NHFMC Linear Accelerator #3
Page 3

Attached for your convenience please find:

- 1) a vendor equipment price quote (Attachment A);
- 2) a vendor quote regarding the de-installation of the existing linear accelerator (Attachment B);
- 3) maps indicating the location of the campus and the cancer center (Attachment C);
- 4) a copy of the August 4, 2005 letter from the CON Section regarding the replacement of the current linear accelerator (Attachment D);
- 5) project/capital cost schedule which identifies the components of the total project costs (Attachment E);
- 6) a certified estimate of related construction costs from an independent licensed North Carolina architect (Attachment F); and,
- 7) the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (Attachment G).

NHFMC's acquisition of the replacement linear accelerator does not require a certificate of need because none of the definitions of "new institutional health service" set forth in N.C.G.S. Section 131E-176(16) is implicated. As discussed above, the total cost for the project is \$3,206,787. This includes the cost of the equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational (such as staff training).

In conclusion, based on the information described above, please confirm that NHFMC's replacement equipment request does not constitute a "new institutional health service" and does fit within the replacement equipment exemption definition. Therefore, the project is not subject to certificate of need review.

Please let us know as soon as possible if you need additional information to assist in your consideration of this request. Thank you for your prompt consideration of this request.

Sincerely,

Lisa Griffin

Manager, Certificate of Need

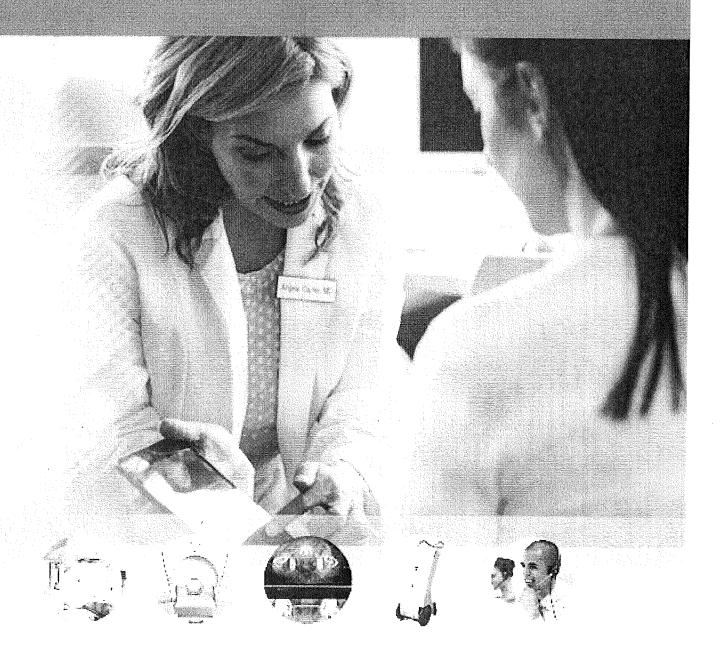
Novant Health, Inc.

Enclosures

cc: Barbara Freedy, Director, CON, Novant Health
Laura MacFadden, Vice President, Design & Construction, Novant Health

Attachment A





ONCOLOGY | BRACHYTHERAPY | NEUROSCIENCE | SOFTWARE | SERVICES

Elekta is pioneering significant innovations and clinical solutions for treating cancer and brain disorders. We provide intelligent and resource-efficient technologies that improve, prolong and save patient lives.



Quotation Date: June 24, 2016

Valid Until: October 31, 2016

Prepared For:

Novant Health ACCOUNTS PAYABLE PO BOX 25686 WINSTON SALEM, North Carolina 27114-5686 US (t) (336) 718-8599 (f) (336) 718-9257 Prepared By: Chris Broyles North Carolina Sales Client Manager

400 Perimeter Center Terrance, Suite 50 Atlanta, GA 30346 (t) 704.322.3493 (c) +1 7046998788 chris.broyles@elekta.com

Currency: USD

Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Elekta Infinity Bundle (Incudes MOSAIQ Connectivity & VisionRT System)

Total Offer Price:

\$2,392,080.80

The price under this Quotation reflects a discount of \$4,862,891.16 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency. A reportable discount may be set out above or exist in the form of undertakings made by Supplier elsewhere in this Agreement.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation



Quotation Date: June 24, 2016

Valid Until: October 31, 2016

Scope of Supply

Qty	Description	License Term
1	MOSAIQ IGRT Connectivity for Elekta Connectivity kit including the RTD and Elekta delivery platform, interface to Elekta MLC/ IMRT, interface to IViewGT electronic portal imaging device and connectivity to the XVI including volumetric imaging.	Perpetual
1	Connectivity to Elekta VMAT Support for Elekta VMAT treatment techniques.	Perpetual
1	SYNERGISTIQ SYNERGISTIQ integrates MOSAIQ and Elekta IGRT devices into a consolidated and synchronized user interface that brings together, in a coordinated manner, the various systems that are required for Image Guided Radiotherapy.	Perpetual
1	KVM Extender Kit for In-Room SEQUENCER Monitor Contract pass-through 3rd party product. Includes: 1 x ACS4001A-R2 Black Box ServSwitch Single DVI-D CATx KVM Extender, USB 1 x A3L980-150-BLUS Belkin CAT6 150' patch cable, RJ45 1 x 26911 Cables to Go DVI-D M/M Display Cable - 6.6 ft	NA
1	HP LCD Monitor for MOSAIQ Workstations Contract pass-through 3rd party product. Includes: 1 x C9V76A8#ABA HP EliteDisplay E221 21.5-inch LED Backlit Monitor	NĄ
1	HP Keyboard and Mouse for MOSAIQ Workstation Contract pass-through 3rd party product. Includes: 1 x KF885AA#ABA HP USB MOUSE AND KEYBOARD KIT	NÁ
1	Barcode Scanner Kit for MOSAIQ Contract pass-through 3rd party product. Includes: 1 x MK9540-72A38 Metrologic MS9540 VoyagerCG Barcode Scanner USB.	NA

Description Qty

Elekța Infinity™

Dual modality digital accelerator provides:

- a choice of up to three different x-ray energies and up to 9 electron energies
 Agility™, Elekta's integrated multi-leaf collimator, that provides full field high resolution beam shaping (5mm at isocentre), a
 40 x 40cm treatment field and effective leaf tip speed of up to 6.5cm/sec, capable of covering multiple targets with
 interdigitation and island shapes

Elekta, Inc., 400 Perimeter Center Terrace, Suite 50, Atlanta, GA 30346 Phone: 770 300 9725 | Fax: 770 670 2323 | www.elekta.com



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- A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT, VMAT-VMAT enables simultaneous and dynamic movement of the MLC while rotating the gantry in combination with varying the dose rate, gantry speed and or collimator angle to deliver a highly conformal dose.
- XVI, offering 2D and 3D kV image guidance for advanced soft tissue visualization supporting image guided treatment workflows . XVI Software options VolumeView™, MotionView™ and PlanarView™ are included. IViewGT™, offering 2D MV imaging capability supporting image guided treatment workflows
- remote system diagnostic ready and will function with the optional Elekta IntelliMax™ service monitoring and support system. IntelliMax is enabled through software and is available during the original system warranty period or through purchase of an Elekta Advanced Service Agreement
- Precise Treatment Table™ which comprises a vertical lift mechanism, couch base and the control system
- low isocentric height of 124cm.
- Goalpost Assembly 1

Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™, Elekta Axesse™ and Versa HD™ compatible standard goalposts.

- Elekta Infinity Standard Cover Set
- Elekta Infinity Drum and Ring Cover Set

Agility - fully integrated 160 leaf Beam Shaping Device with fine resolution leaves (0.5 cm wide) across the full 40x40 cm field size. The MLC comes with a Treatment Control System Rack Cabinet and Integrity R3.X software which includes integral leaf calibration workflows. Agility is designed to support high resolution stereotactic radiation therapy and volumetric arc therapy (VMAT), providing high conformance beam shaping for these advanced delivery techniques. It also supports conventional and electron based radiation techniques.

- 1 Agility ™ - Linac Parts
- Agility™ Headcover and Touchguard (new white).
- . Agility™ Beam Arm Cover (new white)
- Integrity™ R3.2 control system software 1

Integrity is the latest generation of Elekta's fully digital treatment control system software for systems with Agility™. Integrity is built on the latest LynX OS platform and is the monitoring and control foundation of Elekta treatment delivery systems. Integrity additionally supports Continuously Variable Dose Rate, dynamic and VMAT deliveries.

MOSAIQ Sequencer PC

This option provides a MOSAIQ Sequencer PC that can be mounted in the Agility Treatment Control system cabinet.

- 6 MV Low Energy Photon
- 10 MV Mid Energy Photon
- 15 MV High Energy Photon
- 6 MeV Electron Energy



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- 1 9 MeV Electron Energy
- 1 12 MeV Electron Energy
- 1 15 MeV Electron Energy
- 1 18 MeV Electron Energy
- 1 U.S.A. Electron Flatness

Electron flatness according to U.S.A. standards, optimized at 100 cm.

Standard Set of Aperture Plate Electron Beam Applicators

Field sizes:

- 6 x 6 cm, SSD 95 cm
- 10 x 10 cm, SSD 95 cm
- 14 x 14 cm, SSD 95 cm
- 20 x 20 cm, SSD 95 cm

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator latch mounting system enables easy and rapid attachment.

1 Factory Data Match

The option of matching one or more new Elekta machines to each other and/or to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to the factory data recorded in production for the existing Elekta machine.

1 Wedge Factor Match

The option of matching the wedged profiles and wedge output factors of one or more new Elekta machines to each other and to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to customer data supplied from the existing Elekta machine.

1 PreciseBEAM™ VMAT

Provides Volumetric Intensity Modulated Arc Therapy which offers simultaneous dynamic control of the MLC, diaphragms, gantry and collimator. It allows continuous variable MU/degree along the arc.

1 Combined Interdigitation & CVDR license

License providing interdigitation and Continuously Variable Dose Rate (CVDR) functionality.

- 1 VMAT Treatment Planning System Manual
- 1 VMAT CAT (Volumetric Arc Therapy Customer Acceptance Test)
- 1 Response™ Gating Control System for Digital Accelerators

Response provides a seamless interface that supports automated gated treatment delivery for a range of delivery techniques on the Elekta Digital Accelerator. The gating signal can be provided by a validated external motion management system, such as the Active Breathing CoordinatorTM.



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SYNERGISTIQ ™ Software License

Enables the XVI functionality to support SYNERGISTIQ. SYNERGISTIQ integrates MOSAIQ® and XVI into a consolidated and synchronized user interface.

Software Media Pack, SYNERGISTIQ™ Clients

1 SYNERGISTIQ ™ Monitor kit

Specification for Extender/Receiver and cable for a remote monitor. Required for sites that use SYNERGISTIQ with a remote monitor in the treatment room.

1 kiloVoltage Cone-beam CT Hardware for Elekta Infinity™

40kW kV generator - 480V 1

The integrated 40kW kV generator provides multiple settings control via the XVI software. Acquisition parameters are configured within the preset protocol function in the XVI software, and is user configurable. The generator and X-ray tube have been optimized for the 3D VolumeView™ imaging, as well as the 2D radiographic type exposures of PlanarView™ and MotionView™.

Control System hardware for XVI R5.0.3

The XVI control system is a high specification PC which supports all aspects of the IGRT process including 2D, 3D and 4D kV image acquisition, reconstruction, and analysis using a suite of registration functionality.

Base XVI License

The XVI 5.x base license includes the following features as standard:

- PlanarView™: 2D kV radiograph mode
- MotionView™: 2D kV fluoroscopic mode VolumeView™: 3D kV volumetric imaging mode
- Segmental MotionView™ and VolumeView™: Pause/Restart 2D fluoro or 3D volumetric acquisitions manually.

. Intrafraction Imaging License

Provides the ability to acquire kV images during the delivery of an MV treatment field. Intra-fraction imaging allows you to:

- Acquire images (2D fluoro) for a specified time, and then move directly into a 3D volumetric acquisition.
- Acquire a 3D volumetric image during conformal, IMRT or VMAT MV deliveries to measure intrafraction movement.
- Perform Intra-fraction 3D or 4D volumetric imaging and registration per arc during dual (or multiple) arc procedures, allowing table corrections in between arcs.

Symmetry™ License

Symmetry is primarily indicated for respiratory motion management, it offers a unique 4D IGRT online solution that is correlated to internal organ movement. It facilitates for the planned dose to be delivered to the volume where the target spends most of its time in. This allows for margin reduction and baseline shift compensation, supporting treatment deliveries during free-breathing with no surrogates. The use of Symmetry does not require planning on a 4D reference CT.

Critical Structure Avoidance

Critical Structure Avoidance allows the registration of two separate areas of anatomy, utilizing both the clipbox and the Shaped Registration Region of Interest. XVI software will calculate the relationship of both areas of anatomy to the proposed correction vectors and alert the user if the target has moved closer to the critical structures due to anatomical changes. The user can then choose to select a compromise between the two areas, or send the patient for re-planning.

3D Shaped Registration Region of Interest



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The 3D Shaped Registration Region of Interest can be generated from any structure imported from the treatment planning system, or created manually using tools in the software. This allows generation of a 3D registration volume that conforms to anatomical structures.

1 3D Automated Seed Match License

Offers an optimized 3D registration algorithm to register implanted markers, without compromising on 3D volumetric information.

1 Hounsfield Units

Hounsfield Unit (HU) Scaling uses calibration measurements to calculate the HU mean accuracy to ±40 HU for the small field of view for specified imaging conditions. HU Scaling changes the pixel values for the 3D VolumeView images. HU calibration provides greater soft tissue detail, ensuring a more accurate picture of where dose is being delivered, aiding in critical structure avoidance.

1 Distributed Review

Distributed Review allows the sending of XVI CBCT data to MOSAIQ® for review at any MOSAIQ® workstation, as well as the primary XVI workstation.

Pre-regulaites:

- Distributed Imaging/Treatment
- DICOM CT Export (+/- Auto DICOM CT Export).

1 Distributed Imaging

Distributed Imaging allows the transfer a patient between XVI systems without having to prepare the registration settings on the secondary XVI system, through MOSAIQ®.

1 Elekta XVI Basic Calibration Kit - Bearing Phantom Assembly

Specially designed geometric calibration phantom for kV to MV isocentre alignment. Suitable for the XVI system with the BEAM® evo couch too.

1 Couch top Adaptor kit for QA Phantom

Single ball phantom table top adapter kit. This attachment supports the single ball bearing phantom which is used to calibrate the XVI imaging software to the mechanical isocenter. Fits the iBEAM®, iBEAM® evo, HexaPOD™ evo and Connexion™ couch tops.

1 XVI Daily QA Phantom Kit

Daily QA Phantom for kV and MV projection imaging and kV VolumeView™. Checks the laser and light field coincide and additionally provides a spreadsheet for recording and analyzing trend results.

1 CIRS Dynamic Thorax Phantom

Respiratory Motion Phantom 4D Phantom allows study of Symmetry functionality. Motion can be performed in 3D, which allows simulation of both rotational and translational target motion.

1 2D Image Quality Phantom

Image quality phantom use for 2D kV image quality to determine the low contrast and spatial resolution of XVI 2D images (PlanarView™ images). This test tool is used for the 2D image quality of the Customer Acceptance Test for XVI and can be used to monitor image quality over a period of time.

1 Annulus, Oval Body

Optional Annulus, required if the user wishes to calibrate for Hounsfield Units (HU) for Medium and Large FOV. Option to calibrate for HU introduced with XVI R5.X.

This annulus has an oval shape with a 35cm by 25cm outer diameter and a 20cm length. The oval shape of the body annulus simulates the non-uniform attenuation created by a patient torso shape. The annulus weighs 8kg. This annulus is cast from the Catphan Phantom uniformity material which combines excellent material uniformity with a density in the tissue range. The annulus is designed to slide over the outside of the 20cm Catphan Phantom housings.



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1 Automated DICOM CT export license

This tool uses DICOM Auto-Push for 3D images. DICOM Auto-Push automatically exports the CBCT image when you accept or save a 3D VolumeView reconstruction.

Manual DICOM RT Image Export

This tool uses DICOM to export 2D PlanarView images manually from XVI.

1 Auto DICOM RT Image Export

This tool uses DICOM Auto-Push for 2D images. DICOM Auto-Push automatically exports the image when you acquire a 2D PlanarView image.

1 DICOM CT export license

This tool uses DICOM to export the 3D images manually from XVI to MOSAIQ®, or any 3rd party DICOM-based tool.

1 DICOM 4D export

4D DICOM export allows the user to export to a third party system the CBCT data as generated by Symmetry™ of:

- Average phases
- · All phases
- · Single phase.

1 Extra Collimators

Provision of additional XVI collimators for imaging. Includes:

- VolumeView cassettes: L10, M2, L2.
- 1 Elekta Infinity™ iViewGT™

This kit contains all of the components for iViewGT including;

- A MK 6 imaging control system cabinet with the iViewGT software R3.4.1. pre-installed.
- A rigid and fully retractable slim line MV imaging detector arm with a large, square active detector area and wide lateral and longitudinal movement adjustments. The arm has automatic and manual arm movements and is fully interlocked.
- 1 iViewGT™ Amorphous Silicon detector panel
- 1 iViewGT™ R3.4.1 Installation Kit
- 1 iViewGT™ R3.4.1 Software License
- 1 iViewGT ™ R3.4.1 Software License Collation

Third Party License toolkit necessary for supporting iViewGT.

1 Remote Retraction of the iViewGT™ detector - 30M

This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.

1 DICOM 3.0 software interface for image transfer

The international standard interface protocol for network transfer of medical images.



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1 iViewGT™ IMRT Verification Software License

This software expands existing iViewGT functions to verify multiple segment beams for IMRT. The iViewGT image acquisition is triggered automatically and the image taken depends on whether the user selects single, multiple or movie image.

1 Template Matching Software License

The template matching option enables the user to compare the portal image with a nominated reference image for any set-up error. The set-up error is measured by matching visible anatomy and the field edge on the referenced image with the portal image. The user can move the templates to provide an image displacement.

1 Patient Auto Select Software License

This enables the prescription selected on the Linac to automatically select or create that patient record on iViewGTTM or iViewCTM using the iCom-Vx protocol. In addition, images will automatically be acquired and stored in the iViewGT / iViewC database without further operator intervention.

1 Software License Image Approval

This allows the user, assigned with the 'review' permission, to approve or disapprove any image within iViewGT™ or iViewC™.

1 Las Vegas Calibration Phantom

The Las Vegas phantom is a device that is used to check image quality of a portal imaging device at different megavoltage energies both at acceptance and as part of the corrective maintenance procedure.

1 iBEAM® evo Couchtop

The iBEAM evo Couchtop has no metallic components apart from the rails. The Couchtop comes complete with the following extensions:

- iBEAM evo Extension 415
- · indexing bar
- iBEAM evo Extension removable rails EP (aluminum).

The table top comes with a fixed rail at the foot end of the couch and a removable, light weight rail for the superior couch end.

1 iBEAM® evo Extension 650

The iBEAM evo Extension 650 is designed to support the patients upper body and extends off the end of the iBEAM evo Couchtop by 650 mm, thus allowing for treatment of the prostate of very tall patient's.

1 iBEAM® evo Couch Adapter

Allows mounting head fixation system with a hook & latch mechanism.

1 Precise Treatment Table™ or Pedestal Pit Kit

This kit provides the necessary fixings, floor boards and template to install a Precise Treatment Table into a custom built pit or a modified Pedestal pit.

1 Independent X/Y movement of table top

To save time, in reaching the desired position, this kit allows the X/Y brakes to be released independently.

1 Beam Block Tray - Star Pattern

Lexan beam block tray with holes in a star pattern. Trays are designed with threaded, removable plugs for the coding of each block. Specially designed for use with the Elekta shadow tray assembly.

1 Hook and Latch Magnification Graticule

Solid Frame Port Film magnification graticule that attaches directly to the linac, taking the place of the coded shadow tray, thus providing more clearance between the patient and the accessory. Used in treatment verification for situations where simultaneous filment of blocking tray is not required.



Quotation Date: June 24, 2016

Valid Until: October 31, 2016

4 19-inch Control Room LCD Monitor

1 IMKM

The In-room Monitor and Keyboard function provides the operator with access to all clinical and service functions available at the control console from inside the treatment room.

Comprising:

- Cable switching connectors for attaching the in-room monitor to the treatment control system.
- 1 In-room Monitor, Keyboard and Mouse Local Procurement Specification

1 Table ASU License

In addition to normal linac ASU, the user is able to separately request the auto setup of the table isocenter from inside and outside the room.

1 Delivery Parameters Log File Convertor

Enables a user to upload log files and have them converted into csv format.

1 Software License Linac Record

The Daily Record Function allows the Treatment System radiation beam information to be recorded on a continuous basis. Every time the beam is turned on it records the incidence: patient treatments or port films. This can be used as a back up for record and verify systems or for billing purposes.

1 Software license Linac Record to file

The Software license Linac record to file offers the user the option to configure the Linac (in Service Mode) to send the data to network file rather than to a printer.

1 IntelliMax™ Intelligent Agent

This License provides only the IntellilMax Intelligent Agent license. Any provision of services relating to the use of data collected by the Agent (via the IntellilMax Enterprise) should be negotiated as part of the Service Contract between the Customer and the BU/distributor. IntellilMax Intelligent Agent requires a dedicated PC. Provision of this PC must be negotiated between the Customer and the Elekta BU/Distributor. A specification of the PC can be obtained from your Elekta representative. IntellilMax Intelligent Agent also requires a direct internet connection to the Agent PC opening secure port 443 (https).

1 Extended Service License

This license allows the user extra service tools/functionality.

Extender Cards

Extender cards for fault diagnosis on the Electrical Interface Module (EIM).

- 1 Linear Accelerator Manual Set
- Order two sets of pre defined terminated cable kits

Pre installation treatment room and Inter bay terminated cable kits.

1 Customer Interface Terminal Board



Quotation Date: June 24, 2016

Valid Until: October 31, 2016

1 Turbo Starter Kit for Linear Accelerators

Ancillary equipment required for the installation and maintenance of any Precise Digital Accelerator, Comprising:

- Rotary vacuum pump
- Turbo molecular pump attachment for rapid pump down times and higher roughing vacuum.

General Function Key Pad

The Function Key Pad provides the following features:

- MV Start, Interrupt and Terminate
- LEDs to indicate radiation on / off status
- Linac Assisted Setup (ASU) facilitating automatic gantry and diaphragm rotations
- Table ASU facilitating automatic table translations and isocentric setup
- Imaging ASU facilitating automatic remote retraction of the iViewGT™ detector.

1 XVI cable reeling

1 Remote Automatic Table Movement License

This license enables the user to make the translation correction movements remotely and automatically at the Precise Treatment Table™. This movement can either take place following a registration as part of an on-line VolumeView imaging workflow or the table can be moved remotely and automatically to coordinates entered into MOSAIQ®.

1 Agility™ Service Tool

Tool to support maintenance of the Agility beam shaping device.

1 Agility Upgrade Cable Kits

Treatment room and Interbay terminated cable kits for Elekta delivery systems upgrading to the Agility Beam Shaping Device only.

1 Room Lasers, Green, Remote

Set of 4 green room lasers with remote control adjustment. Comprising 3 crosshair and 1 line sagittal laser. Featuring fine lines (< 1mm), high precision adjustment at the isocenter and stable mounting bracket. Inclusive of switchable (110v to 240v) power supply and universal main adaptor.

1 Applications Training for Standard Therapy on the Desktop

The 2-day Standard Precise Desktop Course (travel time inclusive) provides training for 4 Radiation Therapists in the clinical use of the Precise Desktop Digital Linear Accelerator. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy.

1 Applications training for iViewGT™

The 3-day iViewGT training course (travel time inclusive), provides training for 4 radiation therapists in the clinical use of the iViewGT imaging system. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 XVI Applications Training

The 4-day XVI training course (travel time inclusive) provides training for Radiation Therapists in the clinical use of the X-ray Volume Imaging portion of the Elekta Digital Accelerators. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy, CT, or Diagnostic Imaging. This course is given at the customer site for a maximum of 4 users.

1 Weekend Rigging & Handling

Basic rigging of Linac to first floor or ground floor location outside of Elekta's normal working hours. Elekta will provide the necessary crew to offload, uncrate, rigging and machinery moving required to set system as per plan, and remove debris. Basic rigging excludes use of a crane or rigging down an elevator shaft.

Elekta, Inc., 400 Perimeter Center Terrace, Suite 50, Atlanta, GA 30346

Phone: 770 300 9725 | Fax: 770 670 2323 | www.elekta.com



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Standard Rigging includes:

- Make one pre-installation site visit and delivery project management.
- Drill holes for equipment fasteners
- Supply a 12,000 lb capacity forklift during the off loading procedure.
- Stage and uncrate the linac machine, move all components into the facility, and set as directed.
- Remove and dispose of all packaging that will not be reused.
- Transport the base, gantry and beam arm into the facility/bunker on transport trolleys supplied by Elekta.
- Set the base frame in place (Elekta will level).
- Set the gantry drum onto the base frame.
- · Set beam arm into the gantry.
- Install counterweight holder and stack the counterweights.
- Supply a manual gantry lifting system to perform aforementioned setting activities and all necessary tools.
- Supply a crew, including a rigging supervisor.
- Include the cost of all associated resource and expenses, including related travel time.
- Complete all rigging activities in a single day.

Standard Rigging excludes:

- Crane service.
- · Elevator, or shaft deliveries.
- No clear access to the building (exterior).
- Interior obstruction en route to treatment room.
- · Any shoring needed to protect the structure from the weight of the system.
- Any shoring and/or plating needed to build temporary dock or landing area for the unit.
- Extra long delivery routes, distances in excess of 150' from offload site to the treatment room.
- Overtime, weekend, premium time, unless Weekend Rigging selected.
- Additional travel expenses should the project exceed the time allotted in this scope for reasons beyond Elekta or our contractor's control.
- Additional man-hours, manpower, travel expenses, or equipment required due to delays caused by incorrect site preparation, waiting time, or delays not caused by Elekta or our contractor will be itemized and billed to the customer at then current rates.

1 Open Air Graticule

The Open Air Graticule is intended to be used for Radiation Therapy to project a scale of defined increments on port film images which can aid in treatment setup and verification. The Open Air Graticule does not require the use of a shadow tray holder and can be attached directly to the head of the Precise Treatment System or SL Linac. It consists of two wires delineating the X & Y axis of the treatment field. This model of graticule is ideal for MLC customers and especially those using Elekta's iView & iViewGTTM. Because the open air graticule has a minimal transmission factor, with Physic's approval, the customer does not have to re-enter the treatment room after the port film to deliver the treatment. Please see product User manual for specific treatment information.

1 Elekta Site Marketing Program

Elekta's Strategic Marketing and Referral Techniques (SMART) program provides a comprehensive array of general and technologyspecific marketing tools and resource materials to help you cultivate your investment. If purchased separately via a third party, this package could be valued at \$12,000.00 USD. Following is a content overview of the program:

- Elekta Site Marketing Templates & Materials Package CD-ROMs contain PowerPoint presentations, suggested copy, brochures, videos and templates to help your center market to patient populations and referring physicians, as well as product images that can be used to produce brochures, patient education pieces, advertising, etc. Templates and design source files may be customized by your center to align with your specific outreach or branding.
- Secure Website Following a brief registration process, you will have 24-hour marketing support via secure online access to the most current SMART images, video materials, tools and templates, guidebooks and tutorial material. Download design files or templates to facilitate customization and meeting time-sensitive deadlines, or video files for use in consultation, on targeted website landing pages, or as calls-to-action. Quickly reference guidebooks, suggested marketing timelines and strategies, when and where you need them.
- Educational Outreach Periodic WebEx presentations offer virtual learning opportunities that support practice growth
 objectives within evolving market strategies. Email publications keep you informed on best practices within traditional and
 virtual marketing channels. Additional opportunities include live events to coincide with regional / national meetings, such as



Quotation Date: June 24, 2016

Valid Until: October 31, 2016

Elekta's Oncology Users Meeting, to provide updates on getting the most out of your SMART tools, as well as evolving market trends.

1 Aperture Plate Electron Beam Applicator 25 x 25 cm

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator. The X-ray diaphragms are then set automatically to the optimum position.

A unique hook and latch mounting system enables easy and rapid attachment.

1 iBEAM Indexing Bar (set of 3)

The iBEAM Indexing Bar is designed for the BodyFIX® 14 Indexing system and allows indexing and positioning of compatible surface mounted accessories.

1 Closed Circuit TV System - Color

The standard CCTV system consists of two Samsung SNP-5321 (1.3 Megapixel HD) dome-shaped color cameras and two pan/tilt/zoom control mounts allowing the operator full control of both cameras, An 18.5 inch flat screen monitor is also provided and supports a resolution of up to 1360 x 768.

1 Intercom system for patient and radiographer communication

The ASK-4® 501-TLI-CF is a single zone audio monitoring system with 2-way talk/listen capabilities. It consists of a remote speaker/microphone and audio base station with built-in microphone and speaker.

1 Medical Gases SF6 for Installation and Service

Includes:

- 44-liter cylinder for SF6 gas
- 115 lbs of SF6 gas
- Regulator
- Delivery.

1 Medical Gases Nitrogen for Installation and Service

Includes:

- · 16-liter cylinder for Nitrogen (N2) gas
- Nitrogen (N2) gas
- Regulator
- Delivery.

1 Physics 1: Medical Accelerator Introduction Objective

After completing this course, attendees will:

- Identify different components of an Elekta linear accelerator.
- Operate the linear accelerator's controls.
- Summarize the system communication and the different protocols used.
- Operate the accelerator in service and clinical modes.
- Perform calibration of dosimetry system.
- Understand fundamentals of MLC control system, optical tracking, and calibration.
- Outline the operation of imaging systems for IGRT and perform basic quality assurance.

Course Content

- Theory of Operation
- Control Sytem and System Communication

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Quotation Date: June 24, 2016

Valid Until: October 31, 2016

- Beam Measurement and Dosimetry
- Agility Beam Limiting Device
- Imaging Systems and Introduction to IGRT

The application has been made to CAMPEP for 31.2 Medical Physics Continuing Education Credits (MPCEC.) Duration

5-day training at Elekta's Region North America LINC **Target Group**

- Medical Physicists
- Medical Physics Students

Pre-requisites

None

Medical Accelerator Quality Assurance

After completing this course, attendees will:

- List all AAPM TASK GROUP 142 REPORT report tests and their recommended frequency.
- Perform Dosimetry, mechanical, safety, respiratory gating, universal wedge, MLC, and imaging tests and evaluate results of these tests.
- Evaluate all AAPM TG 142 report tests and determine applicability of each test to their clinical setting.
- Analyze potential causes of test failures in order to assist in determining necessary corrective actions in conjunction with Elekta and/or Field System Engineer.
- List Elekta linear accelerator characteristics and how they apply to TASK GROUP 142 REPORT accelerator QA.

Course Content

- During this course, participants will learn about the philosophy and purpose of the recommendations given in the AAPM TASK GROUP 142 REPORT report: Quality assurance of medical accelerators.
- The recommended tests listed in the AAPM TASK GROUP 142 REPORT report will be presented and evaluated during this course in order for medical physicist to understand the clinical rational of each test, evaluate the necessity of each test for their specific clinical setting, and how to execute the tests in their clinical setting.
- The application has been made to CAMPEP for Medical Physics Continuing Education Credits (MPCEC).

Duration

3-day training at Elekta's Region North America LINC

Target Group Certified Medical Physicists Medical Physics Students

Pre-requisites

None

Volumetric Modulated Arc Therapy (VMAT) QA

After completing this course, attendees will:

- Explain the clinical rational for the VMAT treatment technique.
- Evaluate the key factors influencing the quality of VMAT plans. List advantages and limitations of VMAT treatment technique.
- Explain the method by which VMAT is delivered by an Elekta linear accelerator.
- List the constraints required by the delivery system to ensure optimal treatment planning. Evaluate which aspects of VMAT must be tested prior to clinical use.
- Perform Picket Fence with Gantry Rotation, synchronization of dose rate and gantry speed, and synchronization of dose rate and MLC speed tests to evaluate proper performance of the Elekta medical accelerator.
- Develop and execute commissioning benchmark tests to determine baseline system performance for routine quality control testing post future repairs, upgrades, or cal checks.

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Discuss implementation strategies for patient specific measurement to determine gamma pass rate of the delivered plan.

Content

During this one-day course, attendees will learn the rationale for VMAT as a treatment technique and the different methods for creating VMAT treatment plans. The course will also cover VMAT delivery, commissioning, and quality assurance for the Elekta medical accelerator as well as advantages and limitations for VMAT as a treatment technique. The application has been made to CAMPEP for 7.75 Medical Physics Continuing Education Credits (MPCEC).

Duration

1 day

Target Audience

- Certified Medical Physicists
- Medical physics students

Prerequisites

- Physics 1: Medical Accelerator Introduction
- Quality Assurance of Elekta Medical Accelerators.

1 Elekta Stereotactic Radiosurgery and Stereotactic Body Radiotherapy Physics Course

During this 4-day course, participants will learn the physics behind the operation of an Elekta Medical Accelerator with Agility MLC, APEX MLC, and Stereotactic Cones.

Students will build on the principles of operation of the accelerator as addressed in Elekta Medical Accelerator Physics 1 and the quality assurance aspects taught in Elekta Machine QA. Students will learn about the principles of each of the systems in regards to their Commissioning, Quality Assurance and Application for SRS and SBRT.

Objectives

After completing this course, attendees will:

- Be able to accept, commission and QA the SRS/SBRT solution
- · Perform small field dosimetry
- Perform commissioning measurements
- Describe the relationship of various isocenters in the accelerator
- Perform Winston Lutz tests
- Explain patient immobilization options
- Describe IGRT options for patient positioning verification
- Explain appropriate routine QA tests
- Perform End to End testing
- Understand requirements of AAPM TG54, TG 101 and ASTRO Target Safety reports

Target Audience

- · Certified Medical Physicists
- Medical Physics students

Prerequisites

- Physics 1: Medical Accelerator Introduction
- Elekta Medical Accelerator Quality Assurance

Pricing Includes

Tuition for one student

Pricing Does Not Include

- Airfare
- Hote
- Travel-related expenses

Your eligibility for this course expires:

Purchased with new equipment - twenty-four (24) months after Acceptance or first clinical use, whichever occurs first.

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Purchased directly - 24 months after Purchase Order is accepted.

3 Education & Training Travel Support (4-6 day course)

Elekta will provide reasonable and necessary travel to support completion of the Off-Site Education & Training course(s) purchased under this Agreement. This Travel Support includes reasonable and necessary airfare and accommodations booked at least three (3) weeks in advance through Elekta's approved travel agent, proof of course registration at the time of booking is required. Extended airfare and accommodations beyond the duration required to travel and attend the course(s) is not permitted. This Travel Support also includes reasonable and necessary local transportation costs and up to \$100 (USD) per person per day to cover reasonable and necessary meals, which will be paid by Elekta directly to Customer (not to Customer employees) upon receipt of invoice, proof of course completion and supporting receipts. This Travel Support is available for up to two (2) years after date of Acceptance, no exceptions permitted. Price - \$2,000.00 USD (ea)

UIM Extension Kit

The UIM Extension Kit enables the user to displace the UIM from the front to the side to enable more clearance for the Agility head.

Qty Description

AlignRT System

Attachment B



Equipment: Machine Removal Proposal

EXECUTIVE SUMMARY

Client Contact

Marty Haynes | mhaynes@novanthealth.org Novant Health 3333 Silas Creek Parkway Winston-Salem, NC 27103

RS&A Contact

David Stith | dstith@rsainc.net 465 Forum Parkway Rural Hall, NC 27045 P: (800) 320-4332

Statement of Work

Objective:

Inspect, remove, and dispose of Novant's linear accelerator (listed below).

Equipment:

Varian 21EX (S/N 2808) with MLC, PV, IGRT table, and 4DiTC

Location:

Derrick L. Davis Cancer Center | 3333 Silas Creek Pkwy | Winston-Salem, NC

Approach:

As part of this project, RS&A will:

- Assign a dedicated project coordinator to oversee all activities.
- Assign a qualified engineer team to perform all activities.
- Coordinate all activities with facility staff.
- Provide all equipment needed to complete the work.
- Perform a pre-job site walk down and machine inspections prior to beginning removal/install activities.

Start Date:

To be added

Reference #:

OP-005570

Pricing

Below is a pricing breakdown by activity - these may vary and are provided for budgeting purposes only.

Lin	e Item		Amount
1	Complete pre-inspection of facility.	\$	Included
2	De-install and remove existing machine.	\$	Included
3	Baseframe Removal	\$	Included
4	Travel and expenses	\$	Included
	Sub-Total	\$ (27,500
-	Adjustments: Machine Credit	(\$	8,000)
		4	40 500

Total \$ 19,500

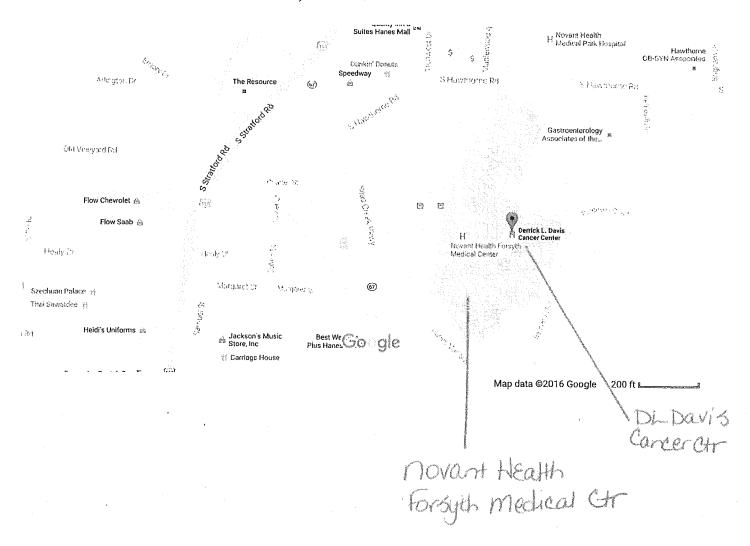
Note: Does not include applicable taxes.

Attachment C

Gogle Maps

Derrick L. Davis Cancer Center

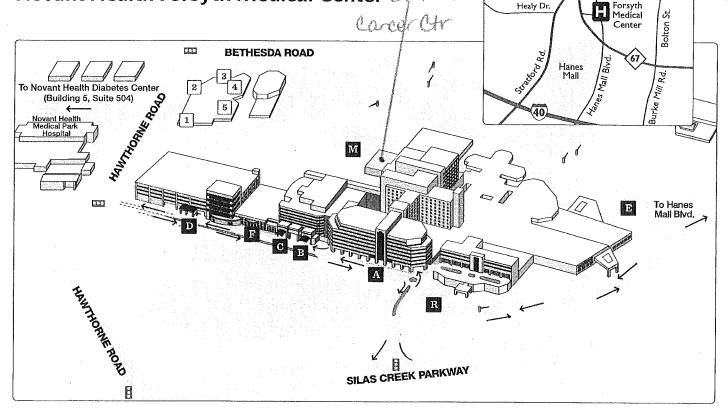
Novant Health Forsyth Medical Center





Campus map

Novant Health Forsyth Medical Center Dipan's



Entrance A

- Administration
- Cashier/business office
- EKG
- Endoscopy lab
- EOPS
- Lab services
- Outpatient day center
- Patient registration
- Radiology
- SPPU (Day of surgery)
- Valet parking

Entrance B

All registration from 7 p.m.-5:30 a.m. and weekends (after 5:30 a.m.)

- · Birthing center
- Community rooms
- · Gyn anesthesia unit
- Gyn surgery
- Prenatal care
- Novant Health Maya Angelou Women's Health & Wellness Center
- Valet parking

Entrance ©

- Cardiac procedures
- · Preanesthesia visits
- Valet parking

Entrance D

- Handicapped
- · Public parking deck

Entrance

Emergency Services

Entrance IP

Conference center

Entrance M

- Novant Health
- Cancer Center
- Patient parking (Radiology and Cancer Center only)
- PET/CT, nuclear medicine & MRI
- Novant Health Imaging
- Novant Health Oncology Specialists
- Valet parking

Entrance R

- · CHF clinic
- Infant audiology
- Heart & Wellness
- Rehabilitation services
- · Wellness programs
- Novant Health
 Hawthorne
 Outpatient Surgery

Hawthorne Rd.

Novant Health

- 2 Novant Health Rehabilitation Center
- 3 Novant Health Wound Care
- Forsyth
 Nutrition Center
- 5 Salem Room



Ground floor visitor information

Elevators

Stairways

্র Waiting Area

Novant Health Forsyth Medical Center

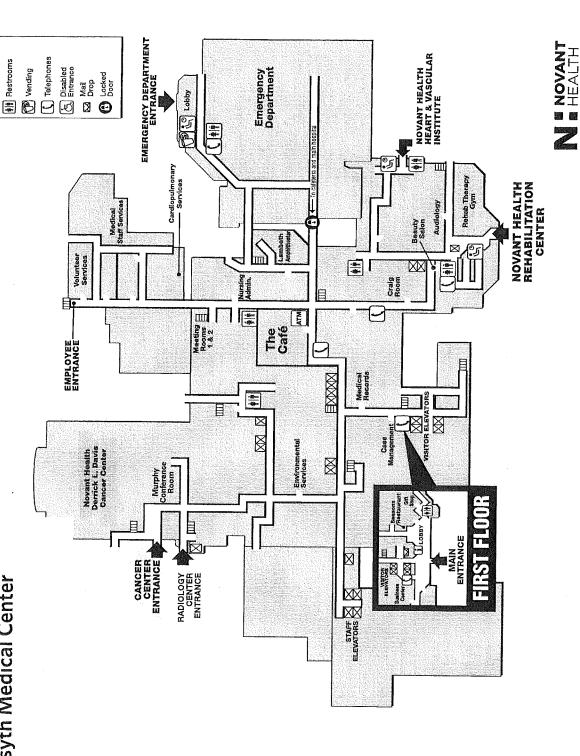
Ground floor access

To access the ground floor from floors 2-9, from patient rooms ending in 151-180 you will need to:

- Travel to the first floor
- Follow signs for restaurants
- At the information desk, take gold elevators to ground floor
- Follow signs to reach your destination

To access the ground floor from patient rooms ending in 101-148 or 202-554, you will need to:

- Take any elevator to the ground floor
- Follow signs to reach your destination



Attachment D



North Carolina Department of Health and Human Services **Division of Facility Services** Certificate of Need Section

2704 Mail Servic Center Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor Carmen Hooker Odom, Secretary

http://facility-services.state.nc.us

Lee Hoffman, Section Chief

Phone: 919-855-3873 Fax: 919-733-8139

August 4, 2005

Barbara L. Freedy Financial Planning & Analysis Novant Health, Inc. 2085 Frontis Plaza Boulevard Winston-Salem, NC 27103

RE:

Exempt from Review - Replacement Equipment/ Forsyth Medical Center/ Replace existing Siemens

linear accelerator/ Forsyth County

FID#: 923174

Dear Ms. Freedy:

In response to your letter of July 18, 2004, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian High Energy Clinac iX linear accelerator to replace the existing Siemens KD 2 linear accelerator, Serial Number 2183-2/92. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely.

Certificate of Need Section

cc:

Medical Facilities Planning Section, DFS

Construction Section, DFS

MJF:LBH:mif

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

Attachment E

PROPOSED CAPITAL COSTS

Project Name:

FMC Linear Accelerator 3 Equipment Replacement

July 27, 2016

Proponent:

Forsyth Medical Center (FMC)

Α.	Site C	Posts .				
	(1)	Full purchase price of land			\$	
	, ,	AcresPrice per Acre			\$	
	(2)	Closing Costs			\$	
	(3)	Site Inspection and Survey			\$	
	(4)	Legal fees and subsoil investigation			\$	· · · · · · · · · · · · · · · · · · ·
	(5)	Site Preparation Costs			Ψ	
	(0)	Soil Borings	9			
		Clearing Earthwork			-	
		Fine Grade For Slab	\$		-	
			\$		-	
		Roads Paving	\$		-	
		Concrete Sidewalks	\$		_	
		Water and Sewer	\$			
		Footing Excavation	\$	***************************************		
		Footing Backfill	\$			
		Termite Treatment	\$		_	
		Sub-Total Site Preparation Costs			\$	0.00
	(6)	Other (specify)			\$	
	(7)	Sub-Total Site Costs			\$_	0.00
3.	Const	truction Contract				
	(8)	Cost of Materials (55% of estimated const	truction cost)		\$	246,000.00
	(9)	Cost of GC Labor (45% of estimated cons			\$	201,350.00
	(10)	(Other)			\$	
	(11)	Sub-Total Construction Contra	act		\$	447,350.00
5.	Misce	Ilaneous Project Costs				
	(12)	Building Purchase			\$	
	(13)	Fixed Equipment Purchase/Lease	14		\$	2,393,680.80
	(14)	Movable Equipment Purchase/Lease			\$	2,000,000.00
	(15)	Furniture			\$	
	(16)	Removal of Existing Linear Accelerator			\$	27,500.00
	(17)	Consult Fees			Ψ	27,300.00
	(,	Architect and Engineering Fees	\$	39,800.00		
		A&E reimbursable expenses	Ψ	2,900.00	•	
		DHSR review fee		1,755.25	•	
		Legal Fees	\$	1,700.20		
		Market Analysis	Ψ \$			
		Other*	φ \$	4 775 00		
				4,775.00		
		*Med gas testing, special inspections Sub-Total Consultant Fees	s, ut tapelini	j, i & b	\$	49,230.25
	(18)	Financing Costs (e.g. Bond Loan, etc)			\$,
	(19)	Interest During Construction	V.		\$	
	(20)	(Other) 10% Project contingency			\$	289,026.11
	(21)	Sub-Total Miscellaneous Proje	ct Costs		\$-	2,759,437.16
	(22)	Total Capital Cost of Project (Sum A-C			\$	3,206,787.16
	()				Ψ	0,200,707.10

Attachment F

ksqdesign

2115 Rexford Road, Suite 500 Charlotte, North Carolina 28211

704.364,3400 Office

ksq.design

June 21, 2016

Mr. Jeff Bailey Project Manager Novant Health, Inc. Corporate Design Services 3600 Country Club Road, Suite 102 Winston-Salem, NC 27104

Re: Novant Health | Forsyth Medical Center | Linear Accelerator Vault #3 Equipment Replacement | Winston-Salem, NC

Dear Jeff:

We have prepared out cost estimate for the Forsyth Medical Center – Linear Accelerator Vault #3 Equipment Replacement. The renovation shall consist of 1,021 S.F. We certify the following projected cost estimate and related architectural engineering fees:

Construction Cost

Construction Material Cost:	\$246,000.00
Construction Labor Cost:	\$201,350.00
Total Construction Cost:	\$447,350.00

 A/E Fees:
 \$39,800.00

 Estimated Reimbursable Expense:
 \$ 2,900.00

 TOTAL COST:
 \$490,050.00

Sincerely,

Nelson C. Soggs, AIA, LEED® AP, Associate | Senior Project Manager

KSQ Architects, PC dba KSQ Design

nsoggs@ksq.design

Attachment G

Replacement of Linear Accelerator (V3) at Novant Health Forsyth Medical Center	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Elekta
Tesla Rating for MRIs	n/a	n/a
Model Number	21EX	Infinity
Serial Number	#2808	TBD
Provider's Method of Identifying Equipment	Internal Asset Number	Internal Asset Number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	n/a	n/a
Mobile Tractor Serial Number/VIN #	n/a	п/а
Date of Acquisition	2005	TBD
Does Provider Hold Title to Equipment of Have a Capital Lease?	Yes	Hold Title upon Acquisition
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" for="" form="" new=""></use>	\$1,974,689	\$2,392,081
Total Cost of Equipment	\$1,604,148	\$3,206,787
Fair Market Value of Equipment	\$8,000	\$2,392,081
Net Purchase Price of Equipment	\$1,974,689	\$2,392,081
Locations Where Operated	FMC DL Davis Cancer Ctr (Vault 3)	FMC DL Davis Cancer Ctr (Vault 3)
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	None	None
Percent of Change in Per Procedure Operating Expenses (by Procedure)	None	None
Type of Procedures Currently Performed on Existing Equipment	Radiation Therapy Procedures	
Type of Procedures New Equipment is Capable of Performing		Radiation Therapy Procedured