



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

VIA EMAIL ONLY

August 5, 2020

Elizabeth Runyon
Elizabeth.Runyon@unchealth.unc.edu

Exempt from Review – Replacement Equipment

Record #: 3327
Facility Name: Clayton Radiation Oncology
FID #: 080619
Business Name: Johnston Radiation Oncology, LLC
Business #: 1058
Project Description: Replace existing CT simulator
County: Johnston

Dear Ms. Runyon:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 31, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens SOMATOM go.Open Pro CT simulator to replace the existing GE Lightspeed Ultra model number 2281177 CT simulator. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction and Radiation Protection 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,

Kim Meymandi
Project Analyst

Martha J. Frisone
Chief

cc: Radiation Protection Section, DHSR

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

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



July 31, 2020

Ms. Martha Frisone, Chief
Kim Meymandi, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: JRO Request for Exemption for Replacement Equipment / Johnston County

Dear Ms. Frisone and Ms. Meymandi,

Johnston Radiation Oncology (“JRO”) intends to acquire a replacement computed tomography (CT) simulator (the “Simulator”), and requests confirmation that the acquisition of such replacement equipment is exempt from certificate of need (“CON”) review pursuant to NCGS 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303. The existing CT simulator owned by JRO received CON approval pursuant to Project ID No. J-10364-14. The CON for the simulator is attached as Exhibit A. The existing CT simulator currently in use will be replaced with the new Simulator which is “comparable medical equipment,” as that term is defined by 10A NCAC 14C.0303.

Exemption from Review

Pursuant to NCGS 131E-184(a)(7): “The department shall exempt from certificate of need review a new institutional health service if it received prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required for any of the following: ... To provide replacement equipment.” (emphasis added) The acquisition of an additional simulator is a new institutional health service pursuant to NCGS 131E-176(16)(f1)(9), but the acquisition of a simulator that is replacement equipment is exempt from review as described herein.

“Replacement equipment” is defined by NCGS 131E-176(22a) as equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

“Comparable medical equipment” is defined by 10A NCAC 14C.0303 as equipment that “is functionally similar and which is used for the same diagnostic or treatment purposes.” Replacement equipment is comparable if:

1. It has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
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; and
3. The acquisition of the equipment does 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

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project ID # J-10364-14

FID # 080619

ISSUED TO: Johnston Radiation Oncology
509 North Bright Leaf Boulevard
Smithfield, NC 27577

Pursuant to G.S. 131E-175, the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to G.S. 131E-189 for any of the reasons provided in that law.

SCOPE: Acquire a CT simulator/Johnston County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Clayton Radiation Oncology
2076 Highway 42 West, Suites 120 and 200
Clayton, NC 27520

MAXIMUM CAPITAL EXPENDITURE: \$336,259

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: July 1, 2015

This certificate is effective as of the 26th day of March, 2015

Martha J. Trisone for
Shelley Carraway, Chief

CONDITIONS:

1. Johnston Radiation Oncology, LLC shall materially comply with all representations made in the certificate of need application.
2. Johnston Radiation Oncology, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.
3. Johnston Radiation Oncology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on March 11, 2015.

TIMETABLE:

Contract Award _____ June 6, 2015
Occupancy/Offering of Services _____ October 1, 2015

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Jessica Barr
jessica.barr@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000007187

Date: 06/03/2020

JOHNSTON UNC HEALTH HEALTHCARE
509 N BRIGHTLEAF BLVD
SMITHFIELD, NC 27577

Ship to address:
UNC Radiation Oncology
Clayton 2076 Hwy 42 W
Clayton NC 27520

This quote is based upon standard delivery terms and conditions (e.g., standard work hours, first floor delivery, etc.), basic rigging, mechanical installation and calibration. Siemens Medical Solutions USA, Inc., Project Management shall perform a site-specific assessment to ascertain any variations that are out of scope and not covered by the standard terms (examples such as, but not limited to: larger crane, nonstandard work hours, removal of existing equipment, etc.). Any noted variations identified by Siemens Project Management shall remain the responsibility of the customer and will be subject to additional fees.

This offer is only valid if a firm, non-contingent order is placed with Siemens and a signed point of sale service contract must accompany the equipment order

This Quotation is specific to UNC Healthcare, and contains information which is confidential and proprietary to Siemens, including but not limited to discounts and pricing. The Customer may not distribute or disclose this quotation or any portion hereof to, or discuss any of the information (including pricing) contained herein with, any other customer or consultant, buying group, or other third party.

Respiratory gating hardware is listed as an optional add-on in the following proposal

Quote Nr. CPQ-165637 Rev. 0

SOMATOM go.Open Pro

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14461470	<p>SOMATOM go.Open Pro</p> <p>Precise CT simulation requires fail-safe, reproducible, and streamlined workflows. This 128-slice simulator was created for one reason - to potentially reduce time to treatment. The SOMATOM go.Open Pro helps minimize errors in a complex workflow using embedded hardware and software, such as the integrated lasers (option) with automated laser QA. This solution makes 4D techniques available for more patients by adapting to the patient's breathing pattern during the scan (option). By harnessing the power of its detector width and soft-tissue contrast capabilities it delivers clarity for confident treatment planning. Driven by intelligence and</p>

PRELIMINARY PROPOSAL

automation, the system simplifies your tasks and reduces the likelihood of errors allowing you to focus on what matters most: spending more time with your patients and improving what is, truly, most important – their therapy outcomes.

Package includes

- 0.5, 1.0 s rotation time
- Stellar Detector
- 85 cm bore size
- SAFIRE
- 75 kW (equivalent to 187 kW with SAFIRE)
- Athlon™ X-ray tube
- Adaptive Dose Shield
- Tin Filter
- Air cooling system
- Ring mood lighting
- Patient observation camera
- Dual 23" / 58 cm flat screen monitor with dual display functionality
- External USB 3.0 disks support
- syngo System Security

1 14461477

Identifier SRS

Smart Remote Service (SRS) is a secured data link that connects your medical system to Siemens service experts. Via SRS, the performance and condition of your equipment can be monitored in real time. SRS makes a broad range of proactive and interactive services available.

A VPN connection is to be provided by user.

The Customer agrees to allow connection to Siemens' remote service diagnostic equipment to the secured telecommunications link at his own expenses. The Customer bears the cost of any technical requirements for any such connection over and beyond the actual product (e.g. establish a broadband connection).

1 14467931

RT Identifier

Benefit from additional operational and clinical flexibility by configuring your SOMATOM go.Sim with the RT Standard package, the solid software and hardware

- FAST IRS
- FAST ICS
- 0.5, 1.0s rotation time
- CARE kV
- RT Image Suite basic
- Beam Placement
- Patient marking
- Basic contouring
- Patient Observation camera
- HD FOV (up to 85 cm)
- Diagnostic applications
- Physiological Measurement Module
- ECG cable

1 14467932

RT Performance Package

Benefit from additional operational and clinical flexibility by configuring your CT Sim with the RT Performance package, a bundle of software and hardware options to boost your performance.

- Ultra-FAST ICS
- Ultra-FAST IRS
- High-speed rotation time 0.35 s
- High Power 70
- 10kV Steps

PRELIMINARY PROPOSAL

- HD FoV (up to 85cm)
- SAFIRE
- CT View&GO
- Sim&GO
- Beam Placement tools
- Contouring tools
- Patient marking tools
- Vessel Extension
- Endoscopic View
- Diameter / WHO Area
- Lung Lesion Segmentation
- ROI HU Threshold
- Spine Ranges
- Check&GO
- Metal Detection
- Recon&GO:
- Inline Table Removal
- Inline Bone Removal
- Inline Vessel Ranges
- Inline Spine Ranges
- Inline Rib Ranges
- Multi Recon
- SureView
- WorkStream4D
- Adaptive Signal Boost
- FAST CARE
- CARE kV
- CARE Child
- FAST ROI
- DynSerio Scan
- syngo System Security
- myExam Compass
- Interleaved Volume Reconstruction (IVR)
- 2nd control-room monitor

- | | | |
|---|----------|---|
| 1 | 14467935 | <p>Scan&GO wireless edition
Including Scan&GO Tablet and wireless Remote Scan Control</p> |
| 1 | 14468446 | <p>Additional Scan&GO tablet
Additional Scan&GO tablet</p> |
| 1 | 14467986 | <p>UPS
An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.</p> |
| 1 | 14467941 | <p>Long Patient Table RT
-Fully TG-66 compliant over the full scan range (without table extension)
-Max. table load 307 kg / 676 lbs
-Max. table feed speed 1-200 mm/s
-Vertical table travel range 47.5-90 cm / 18.7"-35.4" (at table top)
-Vertical travel speed 28.3 mm/s
-Scannable range up to 165cm (without table extension) and up to 200/78.7"(with table extension)
-Positioning mattress included
-RTP excellence package
The RTP excellence kit contains a high accuracy installation and adjustment procedure utilizing additional installation tools and a special laser QA phantom to</p> |

PRELIMINARY PROPOSAL

optimize the accuracy of the system.

1 14467976

Table Accessory Set

More table accessories for further flexibility based on the clinical needs. Includes table side rails, storage box and infusion holder.

1 14467948

Direct Laser Steering

Direct Laser steering allows for integrated control of the moveable laser system, without the need of an additional workstation. This functionality is compatible with Siemens Direct Laser (integrated moveable laser system on the gantry and associated mobile patient marking workflow) and with select LAP laser systems.

1 14467947

Direct Laser

Siemens unique integrated moveable laser system allows you to control the patient marking workflow with the RT dedicated tablet and avoid unnecessary switching between different devices. Mobile workflow with Direct Laser enables less error prone patient marking for optimized simulation process.

Item includes :

- Direct Laser
- Direct Laser QA

1 14467958

iMAR

The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This allows to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants.

iMAR is compatible with extended FoV, the extended CT scale as well as the newest dose reduction feature.

Along with the new algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts.

iMAR only requires to select the desired protocol from a drop down menu which contains the following type of implants:

- Dental fillings
- Neuro coil
- Thoracic coil
- Hip implants
- Extremity implants
- Pacemakers
- Spine implants
- Shoulder implants

1 14467961

DirectORGANS Contours

DirectORGANS (Optimized Reconstruction based Generative Adversarial NetworkS) is the world's first AI contouring solution embedded in a CT simulator. It leverages the power of dedicated reconstruction and deep learning to streamline organs-at-risk contouring. DirectORGANS eliminates variability and provides a consistent starting point for therapy planning.

1) Directly at the scanner

DirectORGANS makes autocontouring a part of the reconstruction process to eliminate manual interaction. Structure-set templates with autocontouring configurations can be configured directly on scan protocol.

2) OR(Optimized Reconstruction)

The quality of the autocontouring is depending on the quality of the images.

PRELIMINARY PROPOSAL

DirectORGANS leverages optimized and standardized reconstruction parameters to deliver input to the deep learning-based contouring solution. This process runs in parallel to the reconstruction of the image for target contouring.

3) GANS(Generative Adversarial Networks)
 After OR, autocontouring is applied trained by AI powered Deep Learning algorithm. A Deep Image-to-Image Network is employed. It consists of a convolutional encoder-decoder architecture combined with a multi-level feature concatenation. An adversarial network – a so called Generative Adversarial Network (GAN) – is selectively used to regularize the training process of DI2IN by discriminating the output of the DI2IN from the ground truth.
 -With the combination of AI powered OR and GANS, DirectORGANS enables a consistent starting point for OAR contouring independent from the image quality.

1 14467962

DirectORGANS Contours Advanced
 DirectORGANS Contours Advanced is an extended organ package to support the more organs for advanced therapy outcome.

1 14467949

Respiratory Motion Management
 Various acquisition modes and protocols accommodate for a wide range of respiratory patterns and workflows. Following functionalities are supported.

- Extended scan time capabilities up to 300 seconds in respiratory motion management acquisition.
- Supports retrospective modes including phase and amplitude reconstructions
- Supports the automatic creation of
 - Average CT (tAverage)
 - temporal MIP (tMIP)
 - temporal MinIP (tMinIP),
 - temporal MaxIP (tMaxIP)
 - the easy generation via reconstruction
- Quantitative 4D assessment of 3D tumor trajectory and amplitude and semi automatic calculation of the midventilation phase
- Contouring propagation to each phase via deformable registration.

1 14467953

Open Interface
 Interface kit and software license to connect an external respiratory device that supports Open Interface.

1 14467954

TwinSpiral Dual Energy
 A new holistic solution for spectral imaging is introduced. The TwinSpiral scan mode offers the possibility to acquire two consecutive spiral data sets at different energies. Item includes ;
 -TwinSpiral acquisition protocols
 - DE_ROI
 - SPP_BASIC
 - DE Monoenergetic Plus

1 CT_PM

CT Project Management
 A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and

PRELIMINARY PROPOSAL

rigging, as well as the initiation of on-site clinical education.

- 1 CT_BTL_INSTALL **CT Standard Rigging and Installation**
- 1 PSPD250480Y3K **Surge Protective Device (SPD)**
- 1 4SPAS014 **Low Contrast CT Phantom & Holder**
- 1 CARE_BOLUS **CARE Bolus**
Operating mode for CM-enhancement-triggered data acquisition.
- 1 SYNGO_VRT **syngo VRT**
Advanced 3D functionality as an extension to the basic 3D viewer, containing volume rendering technique (VRT) and advanced editing functions.
- 1 SYNGO_BONE_REMOVAL **syngo Bone Removal**
Simple, automated bone removal functionality for the syngo 3D application. Preconfigured algorithms for angiography and hip/pelvis fracture scenarios are included to facilitate fast removal of bone structure for three dimensional presentation and analysis of CT data.
- 1 WORKSTREAM_4D **Workstream4D**
WorkStream 4D further enhances the already superb workflow of SOMATOM CT scanners by offering direct generation of sagittal, coronal, oblique or double-oblique reconstructed images directly from CT raw data as part of the CT protocol.
- 1 CARE_DOSE4D **CARE Dose4D**
CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction
- 1 CARE_DOSE_CONFIG **CARE Dose Configurator**
CARE Dose Configurator: Enhancement of Siemens' renowned real-time dose modulation CARE Dose4D, introducing new reference curves for each body region and for each body habitus allowing to adjust the configuration even more precisely to the patient's anatomy.
- 1 DICOM_SR **DICOM SR Dose Reports**
DICOM structured file allows for the extraction of dose values (CTDIvol, DLP)
- 1 DOSELOGS **DoseLogs**
Whenever a dose limit exceeds the established reference dose levels (Dose Notification and Dose Alert) a report is automatically created on the system, enhancing your ability to track radiation dose.
- 1 DOSE_ALERT **Dose Alert**
Dose Alert: Dose Alert automatically adds CTDIvol and DLP values depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.
- 1 DOSE_NOTIFICATION **Dose Notification**
Dose Notification: Dose Notification provides the ability to set dose reference values (CTDIvol, DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user.
- 1 NEMA_XR-29 **NEMA_XR-29 Standard**
This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose.
- 1 CT_LUNGIMAGI **Lung Imaging**

PRELIMINARY PROPOSAL

- NGGO Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy visualization task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Siemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D™, automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies.
- 1 SURE_VIEW **SureView**
Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality
- 1 CT_GO_STELLAR **Stellar Low Noise Technology Detector**
AR The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.
- 1 ACCESS_PROTECT **Access Protection**
ECT Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
- 1 AS11154902 **iBEAM evo CT Overlay for MPT**
The iBEAM® evo CT Overlay Siemens MPT is supporting the patient during CT imaging procedures for radiation therapy applications with overlays. It is designed to be attached on top of the original cradle of Somatom Definition AS MPT table.
- 1 AS10847258 **iBeam evo Head-Neck Extension**
This extension is required for the iBeam evo CT overlay with head-neck-examinations if HeadFIX system is used. It extends the iBeam evo overlay with additional 400mm.
- 1 RO_EDU_PKG_2A **RO Clinical Edu Training Pkg: Option 2A**
The Radiation Oncology education assurance package provides a comprehensive, blended learning approach to meet both the initial and ongoing training needs of the RO-dedicated customer. This package includes:
 - Initial onsite 4-hour didactic workshop with lectures and simulated hands-on to introduce the Radiation Therapist, Dosimetrist, and/or Physicist to Siemens Computed Tomography as it is used in the Oncology environment. The workshop is delivered in conjunction with an additional 8 hours of onsite applications for protocol building and physicist commissioning support.
 - 24-hour onsite handover training with a dedicated focus on CT in radiation therapy protocols and workflow.
 - 16-hour onsite follow-up training to cover syngo.via RTiS
 - 24-hour onsite follow-up training to cover additional customized applications (e.g. Respiratory Gating/4D CT, DirectDensity, Dual Energy)



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Jessica Barr
jessica.barr@siemens-healthineers.com

PRELIMINARY PROPOSAL

• 1-hour x 2 virtual follow-up to ensure confidence and adoption of system features, applications, and workflow.
Education must be completed by the later of (12) months from install end or purchase date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

1 SY_PR_TEAMPLAY

teamplay Welcome & Registration Package

teamplay is a cloud-based network that brings together your imaging modality users, the systems' dose and utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.

To register: <http://teamplay.siemens.com/#/institutionRegistration/1>

1 CT_ADDL_RIGGING

CT_ADDL_RIGGING (\$10,221)

1 CT_TRADE_IN_ALLOW

CT Trade-in-Allowance, project 2020-1272 valid through 10/2020 (\$6,200)

System Total \$ 697,021

PRELIMINARY PROPOSAL

OPTIONS on Quote Nr : CPQ-165637 Rev. 0

OPTIONS for SOMATOM go.Open Pro

Qty	Part No.	Item Description	Extended Price
1	BFLEXOCS_S	<p>Stellant Flex injector-ceiling Stellant Flex ceiling mounted injector with workstation, NO Informatics, but is Informatics ready.</p> <p>Includes Stellant Flex ceiling mounted injector w/short post (580 mm) and ceiling plate; workstation; installation and warranty through Bayer.</p> <p>This post length is recommended for rooms with a floor to structural ceiling height of approximately 9 or 9.5 feet.</p>	+ \$ 37,000
1	14467952	<p>ANZAI Interface Cable to connect to Anzai belt.</p>	+ \$ 1,000
1	14467950	<p>Direct i4D During respiratory gated acquisitions, 75% of the patients breathe irregularly, which leads to artifacts. Direct i4D is Siemens' answer to this untackled challenge. Direct i4D is an intelligent 4D CT algorithm that adapts to the patient's breathing pattern in real time under free breathing. It helps every user achieve accurate visualizations of moving tumors. Prerequisites: - Respiratory motion management - Online mode required (Anzai or Varian RGSC required)</p> <p>Requires: - Respiratory Motion Management</p> <p>Not compatible with Open Interface</p>	+ \$ 0
1	AS11154967	<p>Anzai Respiratory Gating (VI) With the Respiratory Gating system, the respiratory data is synchronized with the CT acquisition in order to minimize motion artifacts. The system is comprised of load cell with breast belt and a PC based evaluation console that is connected to the CT system, for capture and storage of a signal representing the patient's respiratory cycle. All components can be placed on a trolley for mobile positioning in the examination room. This Respiratory Gating hardware only works together with the respiratory gating software option integrated in the CT system.</p>	+ \$ 36,923



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Jessica Barr
jessica.barr@siemens-healthineers.com

PRELIMINARY PROPOSAL

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare
Jessica Barr

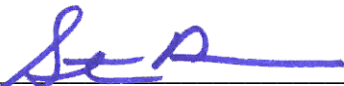
jessica.barr@siemens-healthineers.com

Projected Capital Cost Form

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$56,000.00
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$853,021.00
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (specify)	
Total Capital Cost	\$909,021.00

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.


NC License #13331
Date Signed: 7/31/2020
 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 it is our intent to carry out the proposed project as described.

 Signature of Officer/Agent
 Date Signed: _____

 Title of Officer/Agent

EXHIBIT D: EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Simulator	CT Simulator
Manufacturer	GE	Siemens
Model number	2281177	
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Suite CT02 Lightspeed Ultra S/N 351275CN3	
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	Installed Nov 10, 2015	
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$909,021
Total cost of the equipment	\$336,259	\$771,944
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Johnston Radiation Oncology (Clayton)	Johnston Radiation Oncology (Clayton)
Document that the existing equipment is currently in use		NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Treatment simulations in support of radiation therapy	NA

Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Treatment simulations in support of radiation therapy
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Date of last revision: 5/17/19

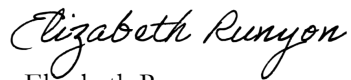
Compliance

The acquisition of the replacement Simulator by JRO is exempt from CON review because:

- The estimated project costs for the replacement Simulator are less than \$2,000,000. See [Exhibit B](#) for the vendor quote for the CT simulator, showing costs of approximately \$771,944, and [Exhibit C](#) for the project cost certification, reflecting total estimated costs of \$909,021.
- The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in [Exhibit D](#).
- The replacement equipment is functionally similar to the existing equipment and will be used for the same radiation oncology treatment planning procedures as the equipment currently in use. Although it has expanded capabilities due to technological advances, the replacement Simulator uses the same technology as JRO's existing simulator.
- No increase in charges will occur within the first twelve months after the replacement equipment is acquired.
- The average cost per procedure will not increase as a result of the equipment replacement.

JRO requests that the Agency confirm in writing that its acquisition of the replacement Simulator, as described herein, does not constitute a new institutional health service and is exempt from certificate of need review. Please don't hesitate to contact me at elizabeth.runyon@unchealth.unc.edu if you require further information or have any questions regarding this correspondence.

Sincerely,



Elizabeth Runyon
System Director of Regulatory Affairs and Special Counsel
UNC Health

From: [Runyon, Elizabeth](#)
To: [Meymandi, Kimberly](#); [Waller, Martha K](#)
Subject: [External] JRO Exemption Request
Date: Friday, July 31, 2020 3:52:11 PM
Attachments: [2020.7.31 JRO CT Sim Replacement Exemption.pdf](#)
[Ex. A - CON J-10364-14 JMH rad onc simulator March 2015.pdf](#)
[Ex. B - Siemens Quote UNC Clayton CT Sim Quote Revised 6-3-20.pdf](#)
[Ex. C - JRO CT Sim Replacement Exemption Projected Capital Cost Form - JJCA Signature.pdf](#)
[Ex. D for JRO CT Sim replacement exemption.pdf](#)

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Kim and Martha,

Please see attached correspondence and exhibits regarding a Replacement Equipment Exemption for Johnston Radiation Oncology. Please let me know if you have any questions or require further information. I hope you both have a wonderful weekend.

Thanks,
Elizabeth

Elizabeth Frock Runyon
System Director of Regulatory Affairs and Special Counsel
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elizabeth.runyon@unchealth.unc.edu

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