

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

April 7, 2021

Elizabeth Runyon Elizabeth.runyon@unchealth.unc.edu

Exempt from Review – Replacement Equipment		
Record #:	3518	
Date of Request:	April 1, 2021	
Facility Name:	University of North Carolina Hospitals	
FID #:	923517	
Business Name:	University of North Carolina Hospitals at Chapel Hill	
Business #:	1900	
Project Description:	Replace existing CT Scanner	
County:	Orange	

Dear Ms. Runyon:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(7). Therefore, you may proceed to acquire without a certificate of need the Siemans.go CT scanner to replace the existing Siemans Emotion 6 CT scanner, serial number 3815490. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Um Mynandi

Kim Meymandi Project Analyst

fatumah Wilson for

Lisa Pittman Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR Construction Section, DHSR

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

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



April 1, 2021

VIA ELECTRONIC MAIL

Mike McKillip, 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 mike.mckillip@dhhs.nc.gov

Re: UNC Hospitals Notice of Exemption for Replacement Equipment and No Review Request/ Orange County

Dear Mr. McKillip,

University of North Carolina Hospitals ("UNCH") provides this notice regarding a replacement computed tomography (CT) scanner (the "CT Scanner"), 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 scanner was acquired in 2006 for \$328,067 and was not subject to CON review. The existing CT scanner, which is currently in use, will be replaced with the new CT Scanner which is "comparable medical equipment," as described in 10A NCAC 14C.0303. Additionally, UNCH plans to relocate the replacement scanner within the service area (and within the same licensed hospital) to its hospital-based Imaging Center location at 1350 Raleigh Road, Chapel Hill, at a total cost of under \$2 million. UNCH requests written confirmation that the project as described herein does not require a CON.

Replacement Equipment Exemption

Pursuant to NCGS § 131E-184(a)(7): "The department <u>shall</u> 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 equipment costs for the CT scanner are \$627,000 (see <u>Exhibit A</u>) and total project costs, including relocation and upfit necessary for the space to accommodate the CT scanner, are \$1,467,000 (see <u>Exhibit B</u>). The majority of the construction costs are due to the necessity for lead lining. Because these total costs for replacement and relocation are well below the \$2 million cost threshold for CON review, and because the acquisition of the CT scanner is "<u>replacement equipment</u>" that is exempt from CON review, UNCH does not believe this project requires a CON.

"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.

According to 10A NCAC 14C.0303, replacement equipment is "not comparable" if:

- 1. the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide;
- 2. the equipment to be replaced was acquired less than 12 months prior to the date the written notice... is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

The proposed acquisition of the replacement CT Scanner does <u>not</u> meet either of these criteria, and thus it is comparable medical equipment to the existing CT scanner.

Compliance

The acquisition of the replacement CT Scanner by UNCH is exempt from CON review because:

- The estimated project costs for the replacement CT scanner and its relocation to the hospital-based Imaging Center are less than \$2,000,000. The vendor quote for the CT Scanner shows equipment costs of approximately \$627,000 (see <u>Exhibit A</u>) and total project costs are estimated at \$1,467,000 (see <u>Exhibit B</u>).
- The replacement equipment will be purchased for the sole purpose of replacing comparable medical equipment currently in use, which will be traded in for disposal and removal from North Carolina. A comparison of the existing and replacement equipment is provided in <u>Exhibit C</u>.
- The replacement equipment is functionally similar to the existing equipment and will be used for providing the same health service as the equipment currently in use.

No Review Request

Finally, in addition to replacing the CT equipment as described above, UNCH also plans to relocate the CT scanner within the service area, from the main campus of the Medical Center in Chapel Hill to the hospital-based Imaging Center on Highway 54, also in Chapel Hill. This relocation is still within UNC Hospitals, and all costs associated with the relocation are contained in the total cost estimate of \$1,467,000. This relocation does not constitute the development of a new institutional health service.

Conclusion

UNCH requests that the Agency confirm in writing that its acquisition of the replacement CT Scanner and its relocation to the UNCH Imaging Center, 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 <u>elizabeth.runyon@unchealth.unc.edu</u> if you require further information or have any questions regarding this correspondence.

Sincerely,

Clizabeth Runyon Elizabeth Runyon

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



PRELIMINARY PROPOSAL

Customer Number: 0000010805

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

Date: 02/05/2021

UNIV NORTH CAROLINA HEALTH CARE SYS 101 MANNING DR CHAPEL HILL, NC 27514

Quote Nr:	CPQ-311400 Rev. 0
Trade:	N/A – No trade
Terms of Payment	00% Down, 80% Delivery, 20% Turnover Free On Board: Destination
Purchasing Agreement	Vizient
Proposal Valid Until	9/30/2021
	Contingent on concurrent multi-modality purchase or POS (point of sale) Service agreement execution.

Siemens go.Top CT for UNC Health

Qty Part No. Item Description

14460603 SOMATOM go.Top

As a member of the SOMATOM go. platform, the SOMATOM go. Top supports all users to provide the best scan for every type of patient – no matter the clinical demands and challenges. The scanner features a unique tablet-based mobile workflow, user guidance with our GO technologies, and exclusive innovations such as Tin Filter low-dose technology. SOMATOM go.Top is built for personalization of processes and care, allowing every operator to optimally adapt to the individual patient and indication while interacting with patients in a more personalized way than ever before. Produce excellent results for the full clinical spectrum including Dual Energy imaging, and offer what others cannot – for a successful CT business.

14460600 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 Customer. 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

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and beyond the actual product (e.g. establish a broadband connection). 14460605 SW Base Package SW Base Package Scan&GO mobile workflow, including tablet, remote control, camera, and a new workplace design Check&GO flags problems with scan coverage or contrast distribution as they occur Recon&GO reduces post-processing to just one click, with: Inline Anatomical Ranges, Inline Table and Bone Removal, Inline Vessel Ranges and Multi Reconperforming multiple reconstructions in one step CT View&GO provides a variety of clinical applications and tools for smooth reading in just one workflow SAFIRE SOMATOM go. scanners achieve higher efficiency with in dose reduction with Sinogram Affirmed Iterative Reconstruction while maintaining excellent image quality Interleaved Volume Reconstruction Enhances spatial sampling in z-direction, independent of pitch CARE Dose4D, CARE kV, 10 kV Steps, CARE Child Personalized dose control tools that allow you to increase consistency of low dose CT scanning techniques across all technologists Endoscopic View Simulated views of e.g. the inside of bronchi, colon and any other hollow structures Dual Spiral Dual Energy and Dual Energy ROI syngo Single Source Dual Energy Scan mode option offers the possibility to acquire two spiral data sets in sequence at different energies HD FoV*' Enables a field of view up to 70 cm, which is optimal for visualization of obese patients and those that are positioned outside the CT isocenter *In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task ** The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned 14468644 SW Base Extension VA30 Check&GO Metal Detection Check&GO Metal Detection helps to prevent mistakes and rescans by alerting the user when metallic objects such as glasses, belts, chains, earrings or other are not removed and present on the scan area. The AI algorithm is extended to include the detection of the unwanted objects on the topogram image and informs the user both on the tablet and the console for their presence before the spiral or the sequential scan.

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Flex Dose Profile

Images of certain areas (e.g. heart or abdomen) require more dose than the rest of the scan. Flex Dose Profile allows a more optimal dose modulation in long scan ranges such as Chest Pain (where applicable) or regular Thorax-Abdomen examinations. Here different quality references might be needed along the scan range. FAST Planning automatically detects the two designated areas and Flex Dose Profile adjusts the tube current of the two different areas (heart and the abdomen) automatically. The Adaptive Dose Area (green area on the side of the image representing the dose) is displayed at the acquisition console and at the Scan&GO tablet with the same visual logic as any other procedures, so users of any level of experience can utilize it right away

Tilted spiral

Tilted spiral scan mode for additional clinical flexibility

1 14460624

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High-speed 0.33 s

This option provides a rotation speed of down to 0.33 sec per rotation, for outstanding image quality and very high scan speeds. Fast gantry rotation times are the prerequisite for highest temporal resolution and are therefore essential for brilliant, motion free cardiovascular imaging. With the temporal resolution of 165ms, this CT is especially suitable for cardiac examinations and fast scanning.

14460623 **iMAR**

The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This makes it possible to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants. Along with the algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts. iMAR can be combined with iterative reconstruction methods.

1 14468563 myExam Compass

Intelligence that works with you. myExam Companion launches the era of intelligent imaging. Using the new possibilities of digitalization, it turns data into built-in expertise. This helps technologists reduce unwarranted variations – by unlocking your modality's full potential automatically. myExam Companion guides users through any procedure, so they can interact easily and naturally with both the patient and the technology. No matter the patient, operator or throughput, it helps generate consistently excellent results – and improve diagnostic accuracy. Being a part of myExam Companion, myExam Compass is based on the condensed knowledge of thousands of scans and protocols from our installed base. Through AI, the most optimal patterns have been recognized and aggregated into clinical decision trees provided ex-factory.

1 14460606 Scan&GO wireless edition

Includes Scan&GO Tablet and Remote Scan Control. Built around a new mobile workflow, the SOMATOM go. platform features a line-up of innovative solutions – tablet, remote control, camera, and a new workplace design – that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also enhance patient comfort for potentially higher levels of patient satisfaction.

The lightweight, high-resolution tablet gives our customers total freedom over how they work: only a few steps for the entire scan.

1 14460885 676 lb (307 kg) Patient Table Patient table with 676 lb / 300 kg weight limit designed to accommodate virtually all

Patient table with 676 lb / 300 kg weight limit designed to accommodate virtually all patients with a long scan range of 2000 mm.

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1	14460613	Foot Switch for Pat.Table control Additional flexibility with a foot switch that controls patient table movements only.
1	14460614	Table Extension Comfortable table accessory to extend the maximum scan range.
1	14460615	Positioning & Fixation Set Including Pediatric Cradle, Arm support, Patient fixation with slider
1	14472322	UPS UPS. An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.
1	14460793	Computer Desk 1200 mm CT desk designed to accommodate the control components and color monitor(s).
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_STELL AR	Stellar Low Noise Technology Detector 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	CT_TIN_FILTER	SOMATOM go. Tin Filter Tin Filters block unnecessary low energy photons for non-contrast exams optimizing the X-ray spectrum increasing dose efficiency especially for applications with high air (or bone)-to-soft tissue contrast.
1	CT_LUNGIMAGI NGGO	Lung Imaging 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 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	HD_FOV_70CM	HD FOV Designed to enable visualization of the human body parts and skin line located outside of the 50cm standard field of view up to the bore size.
1	ACCESS_PROT ECT	Access Protection Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols



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- 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 4SPAS014 Low Contrast CT Phantom & Holder
- 1 PSPD250480Y3 Surge Protective Device (SPD)

1 CTSDEF01 CT Slicker

Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Shipped with main cover, a catheter bag holder, and 3 restraining belts unless otherwise noted.

Includes warranty from RADSCAN Medical.

1 CT_PM CT Project Management

A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemen's 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 rigging, as well as the initiation of on-site clinical education.

- 1 CT_ADDL_RIG Additional Rigging CT GING
- 1 CT_BTL_INSTA (

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CT Standard Rigging and Installation

CT_EDUOPTIO Clinical Education & Training: Option 3

Siemens offers multiple options for clinical education and training on your new system. These options enable a more personalized approach to the introduction to system operation, features, and benefits and will help ensure that your technologists and physicians have the opportunity to engage in the level of training that best meets your current clinical needs and business objectives.

The following items are the education and training modules are highly recommended for the operation of your new Siemens system and are most effective for sites where technologists and/or physicians have limited experience on Siemens' systems. With a focus on routine procedures, this option also provides additional opportunities to further increase efficiencies.

CT_GOBASIC_ CT Go Basic Class, No Travel

Tuition for (1) imaging professional to attend a 2-day classroom course at Siemens Training Center in Cary, NC. The objectives of this course are to introduce the user to the Siemens SOMATOM go. platform, new patient-centric mobile workflow and technologies including Scan&Go, Check&Go, Recon&Go, CT View&Go, Guide&Go. Users will be able to understand the effect of choosing various parameters on image quality and dose. The instructor will combine didactic interactive discussions with hands-on training of key CT system operating hardware and workflow software functions. This class excludes airfare and lodging. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

CLS NTL



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1	CT_INITIAL_32	Initial onsite training 32 hrs Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	CT_FOLLOWUP _16	Follow-up training 16 hrs Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	CT_ADD_16	Additional onsite training 16 hours Up to (16) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	SY_PR_TEAMP LAY	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

System Total (excluding any optional items below) \$627,000

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PRELIMINARY PROPOSAL

Optional items (not included in system total above)

Qty	Part No.	Item Description	Extended Price
1	14468560	Cardio Base Package Cardio Base Package Item includes: Physiological Measurement Module, ECG cable, Cardio Spiral, BestPhase, Cardio Quick Sequence, syngo.CT CaScoring, Recon&GO CaScoring, Any kV CaScoring	+ \$ 14,000
1	14460659	 Advanced Cardio Package The Advanced Cardio Package allows for comprehensive cardiac assessment and clinical consistency in cardiac CT with ease. This option delivers an optimized, fully tablet-operated scan preparation, fast scanning, and standardized results in every cardiac case enabled by the integrated GO technologies that allow you to devote more time to your patient. During the scan, Check&GO monitors coverage and contrast in real time, allowing you to correct problems as you work and thus potentially avoiding repeat scans. Quality-control images are sent wirelessly to the tablet, so you can review them directly at the scanner. Adapt Cardio Sequence for adaptive prospective ECG-triggered sequence scanning. Inline Cardio Ranges for zero-click curved planar reformats (CPRs) of the main coronaries and radial VRT ranges of the coronary tree help you quickly rule out coronary artery disease. Cardio Ranges @ CT View&GO: CT View&GO supports you in challenging cases where you need to manually interact with the images. Its intuitive and customizable tools enable smooth, straightforward reading. 	+ \$ 36,000
1	14468207	Flex 4D Spiral - Neuro Flex 4D Spiral – Neuro applies a continuously repeated bi-directional table movement, moving the patient smoothly in and out of the gantry over the desired scan range. This allows dynamic CT imaging over a larger range than the physical detector size. These dynamic procedures are handled on the AWP with the same visual logic as any other procedure, so users of any level of experience can perform them right away. The optional tiltable head holder is recommended for optimal positioning of stroke patients.	+ \$ 12,000
1	14460625	Neuro Package The Neuro Package of your SOMATOM go. provides you with tools for the full stroke assessment: native neuro scanning, neuro DSA (Digital Subtraction Angiography) and neuro perfusion. Neuro DSA at CT View&GO allows for bone- free evaluation of the neuro vasculature. syngo.CT Neuro Perfusion provides dynamic 4D quantification and visualization of perfusion data. In addition, Recon&GO automatically produces standardized orientations to overcome challenging situations where patients might be wrongly positioned or unable to cooperate.	+ \$ 16,000
1	14461418	Tiltable Head Holder Tiltable Head Holder for the fixation of the patient's head. Tilt range between +30 till – 15 degree.	+ \$ 1,200

PROPOSED TOTAL CAPITAL COST OF PROJECT

A.	Site Costs			
	(1) Full purchase price of land		\$0	
	Acres Price per Acre \$			
	(2) Closing costs		\$0	
	(3) Site Inspection and Survey		\$0	
	(4) Legal fees and subsoil investigation		\$0	
	(5) Site Preparation Costs	¢o		
	Soil Borings	\$0 \$0		
	Clearing - Earthwork Fine Grade for Slab	\$0 \$0		
		\$0 \$0		
	Roads - Paving Concrete Sidewalks	\$0 \$0		
	Water and Sewer	\$0 \$0		
	Footing Excavation	\$0 \$0		
	Footing Backfill	\$0 \$0		
	Termite Treatment	\$0 \$0		
	Other (Specify)	\$0		
	Sub-Total Site Preparation Costs	\$0		
	(6) Other (Specify)	+-	\$0	
	(7) Sub-Total Site Costs		<i>+-</i>	\$0
В.	Construction Contract			
	(8) Cost of Materials			
	General Requirements	\$561,000		
	Concrete/Masonry	\$0		
	Woods/Doors & Windows/Finishes	\$0		
	Thermal & Moisture Protection	\$0		
	Equipment/Specialty Items	\$0		
	Mechanical/Electrical	\$0		
	Other (Unit Strut Support)	\$0		
	Sub-Total Cost of Materials		\$0	
	(9) Cost of Labor		\$0	
	(10) Other (Specify)		\$0	
	Firestopping		\$0	
	Asbestos Abatement		\$0	
	Window Upgrade		\$0 \$0	
	HVAC Upgrade		\$0 \$115.000	
	Construction Contingency (11) Sub-Total Construction Contract		\$115,000	\$0
c	Miscellaneous Project Costs			φΟ
0.	(12) Building Purchase			\$0
	(12) Building Fulchase (13) Fixed Equipment Purchase			\$0 \$0
	(14) Movable Equipment Purchase			\$0
	(15) Furniture			\$0
	(16) Landscaping			\$0
	(17) Consultant Fees			+-
	Architect and Engineering Fees	\$124,000		
	Legal Fees	\$0		
	Market Analysis	\$0		
	Other (Structural fee)	\$0		
	Other (Specify)	\$0		
	Sub-Total Consultant Fees		\$0	
	(18) Financing Costs (e.g. Bond, Loan, etc.)		\$0	
	(19) Interest During Construction		\$0	
	(20) Other (Specify)		\$0	
	Contingency		\$40,000	* -
	(21) Sub-Total Miscellaneous			\$0
	(22) Total Capital Cost of Project (Sum A-C	above)		

\$0

\$840,000

UNC Hospitals CT Replacement EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Туре	Computed	Computed
(e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor,	Tomography	Tomography
MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Scanner	Scanner
Manufacturer	Siemens	Siemens
Model number	Emotion 6	Siemens.go
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN3815490	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	3/7/2006	TBD
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project < Attach a signed Projected Capital Cost form>	N/A	
Total cost of medical equipment	\$328,067	\$627,000
Location of the equipment < Attach a separate sheet for mobile equipment if necessary>	N/A	N/A
Document that the existing equipment is currently in use		N/A
Will the replacement equipment result in any increase in the average charge per procedure?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the average operating expense per procedure?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	See Exhibit D	N/A
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	N/A	See Exhibit D

UNC Hospitals

Dept: 1000-224310 - UNCH CT Scan IC CH (1)

Department	EDIC CDM Code	EPIC CDM Code Description
Department CDM Codes included in Dept Statistics	EPIC CDM Code	EPIC CDM Code Description
1000-224310 - UNCH CT Scan IC CH	73200008	HC CT LUNG CANCER SCREENING-INACTIVE
1000-224310 - UNCH CT Scan IC CH	73200045	HC CT THORAX LW DOSE LUNG CANCER SCREEN WO CONTRAST
1000-224310 - UNCH CT Scan IC CH	73500004	HC CT HEART WO CONT W COR CAL SCORE
1000-224310 - UNCH CT Scan IC CH	73500008	HC CTA ABD AORTA AND BIL ILIEOFM W CONT
1000-224310 - UNCH CT Scan IC CH	73500016	HC CT HEAD OR BRAIN WO CONT
1000-224310 - UNCH CT Scan IC CH	73500017	HC CT HEAD OR BRAIN W CONT
1000-224310 - UNCH CT Scan IC CH	73500018	HC CT HEAD OR BRAIN WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500019	HC CT ORBIT SELLA PF WO CONT
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500020 73500021	HC CT ORBIT SELLA PF W CONT HC CT ORBIT SELLA PF WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500021	HC CT ORBIT SELLA FF WO FLD W CONT HC CT MAXILLOFACIAL WO CONT
1000-224310 - UNCH CT Scan IC CH	73500022	HC CT MAXILLOFACIAL W CONT
1000-224310 - UNCH CT Scan IC CH	73500024	HC CT MAXILLOFACIAL WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500025	HC CT NECK SOFT TISSUE WO CONT
1000-224310 - UNCH CT Scan IC CH	73500026	HC CT SOFT TISSUE NECK W CONT
1000-224310 - UNCH CT Scan IC CH	73500027	HC CT SOFT TISSUE NECK WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500028	HC CTA HEAD W CONT INCL NON CONT
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500029 73500030	HC CTA NECK W CONT INCL NON CONT HC CT THORAX DIAGNOSTIC WO CONT
1000-224310 - UNCH CT Scan IC CH	73500030	HC CT THORAX DIAGNOSTIC W CONT
1000-224310 - UNCH CT Scan IC CH	73500032	HC CT THORAX DIAGNOSTIC WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500033	HC CTA CHEST NONCOR WO W CONT
1000-224310 - UNCH CT Scan IC CH	73500034	HC CT CERVICAL W O CONT
1000-224310 - UNCH CT Scan IC CH	73500035	HC CT CERVICAL W CONT
1000-224310 - UNCH CT Scan IC CH	73500037	HC CT THORACIC W O CONT
1000-224310 - UNCH CT Scan IC CH	73500038	HC CT THORACIC W CONT
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500040	
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500041 73500043	HC CT LUMBAR W CONT HC CTA PELVIS W CONT INCL NON CONT
1000-224310 - UNCH CT Scan IC CH	73500043	HC CT PELVIS W CONTINCE NON CONT HC CT PELVIS W O CONT
1000-224310 - UNCH CT Scan IC CH	73500045	HC CT PELVIS W CONT
1000-224310 - UNCH CT Scan IC CH	73500046	HC CT PELVIS WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500047	HC CT UE W O CONT
1000-224310 - UNCH CT Scan IC CH	73500048	HC CT UE W CONT
1000-224310 - UNCH CT Scan IC CH	73500049	HC CT UE WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500050	HC CTA UE W CONT W NON CONT
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500051 73500052	HC CT LE WO CONT HC CT LE W CONT
1000-224310 - UNCH CT Scante CH	73500052	HC CT LE WO FLD W CONT
1000-224310 - UNCH CT Scan IC CH	73500054	HC CTA LE W CONT AND INCL NON CONT
1000-224310 - UNCH CT Scan IC CH	73500055	HC CT ABDOMEN WO CONT
1000-224310 - UNCH CT Scan IC CH	73500056	HC CT ABDOMEN W CONT
1000-224310 - UNCH CT Scan IC CH	73500057	HC CT ABDOMEN WO W CONT
1000-224310 - UNCH CT Scan IC CH	73500058	HC CTA ABD PELVIS W CONT W NON CONT
1000-224310 - UNCH CT Scan IC CH	73500060	HC CT ABD PELVIS WO CONT
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500061 73500062	HC CT ABD PELVIS W CONT HC CT ABD PELVIS WO W CONT
1000-224310 - UNCH CT Scan IC CH	73500062	HC CT ABD PELVIS WOW CONT HC CTA ABDOMEN W CONT W NONCONT
1000-224310 - UNCH CT Scan IC CH	79900003	HC SCREENING CARDIAC CALCIUM SCORE
Total - CDM Codes included in Dept Sta		
CDM Codes Not included in Dept Statistics		
1000-224310 - UNCH CT Scan IC CH	32500017	HC WASTE CONTRAST Q9966
1000-224310 - UNCH CT Scan IC CH	32540001	HC CONTRAST FOR DIAGNOSTIC SERVICES
1000-224310 - UNCH CT Scan IC CH	6300002	HC GLUCOSE BLD BY MONITOR DEVICE POC
1000-224310 - UNCH CT Scan IC CH	73500009	HC 3D RECON NOT REQ INDEP WORKST
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	73500010 74000005	HC 3D RECON REQUIRE INDEP WORKST HC CDSM NATIONAL DECISION SUPPORT COMPANY AS DEFINED BY THE MCAR AUCP
1000-224310 - UNCH CT Scan IC CH	83000386	HC CDSM NATIONAL DECISION SUPPORT COMPANY AS DEFINED BY THE MCAR AUCP HC CREATININE
1000-224310 - UNCH CT Scan IC CH	83001563	HC URINE PREGNANCY QUALITATIVE
1000-224310 - UNCH CT Scan IC CH	92540001	HC WASTE IOHEXOL 350 MG IODINE ML IV SOLUTION
1000-224310 - UNCH CT Scan IC CH	ACTCOST_39	SupplyCostVariance_1000-224310
1000-224310 - UNCH CT Scan IC CH	NDCI0407-1412-30	OMNIPAQUE 240 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCI0407-1414-03	OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCI0407-1414-91	OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0019-1333-75	OPTIRAY 350 MG IODINE-ML INTRAVENOUS SYRINGE
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	NDCO0270-5164-12 NDCO0270-5164-14	MULTIHANCE 529 MG-ML (0.1 MMOL-0.2 ML) INTRAVENOUS SOLUTION MULTIHANCE 529 MG-ML (0.1 MMOL-0.2 ML) INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0270-5164-14 NDCO0407-1411-10	OMNIPAQUE 180 MG IODINE-ML INTRATHECAL SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1411-20	OMNIPAQUE 180 MG IODINE-ML INTRATHECAL SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1412-10	OMNIPAQUE 240 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1412-20	OMNIPAQUE 240 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1412-30	OMNIPAQUE 240 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1413-10	OMNIPAQUE 300 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1413-63	OMNIPAQUE 300 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH 1000-224310 - UNCH CT Scan IC CH	NDCO0407-1413-65 NDCO0407-1414-03	OMNIPAQUE 300 MG IODINE-ML INTRAVENOUS SOLUTION OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1414-03	OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO0407-1414-91	OMNIPAQUE 350 MG IODINE-ML INTRAVENOUS SOLUTION
1000-224310 - UNCH CT Scan IC CH	NDCO67684-2000-2	DOTAREM 0.5 MMOL-ML (376.9 MG-ML) INTRAVENOUS SOLUTION
Total - CDM Codes Not included in Dep	t Statistics	

Department Total

From:	Mckillip, Mike		
То:	<u>Waller, Martha K</u>		
Subject:	FW: [External] UNC Hospitals Notice of Exemption for Replacement Equipment and No Review Request		
Date:	Monday, April 5, 2021 9:39:34 AM		
Attachments:	UNCH CT Exemption Request April 2021.pdf		
	Exhibit A - Siemens go.Top CT Quote 2-5-21.pdf		
	Exhibit B - Imaging Center CT Scanner Cost Estimate.XLS.pdf		
	Exhibit C - Equipment Comparison Form.pdf		
	Exhibit D - UNCH Imaging Center CT Procedures.pdf		

For you. Happy Monday, Martha!

Mike

Michael McKillip

Project Analyst Division of Health Service Regulation, Healthcare Planning and Certificate of Need <u>NC Department of Health and Human Services</u>

Office: 919-855-3877 mike.mckillip@dhhs.nc.gov

809 Ruggles Drive, Edgerton 2704 Mail Service Center Raleigh, NC 27699

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From: Delong, Natasha <Natasha.Delong@unchealth.unc.edu>

Sent: Thursday, April 1, 2021 4:38 PM

To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>

Cc: Runyon, Elizabeth <Elizabeth.Runyon@unchealth.unc.edu>

Subject: [External] UNC Hospitals Notice of Exemption for Replacement Equipment and No Review Request

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Mike,

Please see the attached documents for the UNC Hospitals notice of exemption for replacement equipment and no review request.

Let us know if you have any questions.

Natasha Bonett DeLong | Strategy Analyst Strategic Planning UNC Health 211 Friday Center Drive, Chapel Hill, NC 27517 p (984) 974-1205 | m (919) 961-1706 natasha.delong@unchealth.unc.edu

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