

North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary  
January 20, 2012

[www.ncdhhs.gov/dhsr](http://www.ncdhhs.gov/dhsr)

Craig R. Smith, Section Chief  
Phone: 919-855-3875  
Fax: 919-733-8139

Robert V. Bode  
Bode, Call & Stroupe, L.L.P.  
Post Office Box 6338  
Raleigh, NC 27628-6338

RE: No Review/ Charlotte Radiology P.A. / Acquire a 2<sup>nd</sup> mobile mammography unit to be operated out of University Medical Park diagnostic center / Mecklenburg County  
FID# 070269

Dear Mr. Bode:

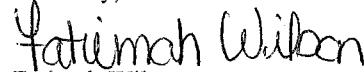
The Certificate of Need (CON) Section received your correspondence of December 30, 2011 regarding the above referenced proposal. Therefore, Charlotte Radiology P.A. may proceed to acquire a second mobile mammography unit to be operated out of its University Medical Park diagnostic center. The acquisition of new diagnostic equipment by an existing diagnostic center does not create a new diagnostic center requiring a Certificate of Need. Charlotte Radiology will own two mobile mammography units, but each will be operated from separate CON approved diagnostic centers. In addition, the estimated cost associated with this proposal is less than \$500,000 and less than the \$750,000 threshold for major medical equipment as defined in N.C.G.S. 131E-176(14o).

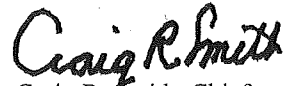
Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section.

In addition, you should contact the Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

  
Fatimah Wilson  
Project Analyst

  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR



**BODE, CALL & STROUPE, L.L.P.**

ATTORNEYS AT LAW

3105 GLENWOOD AVENUE, SUITE 300  
RALEIGH, NORTH CAROLINA 27612

TELEPHONE (919) 881-0338  
TELECOPIER (919) 881-9548

WWW.BCS-LAW.COM

*John V. Hunter III*

JOHN V. HUNTER III  
RETIRED

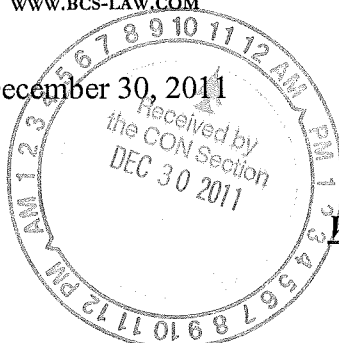
MAILING ADDRESS  
POST OFFICE BOX 6338  
RALEIGH, NORTH CAROLINA  
27628-6338

JOHN T. BODE  
W. DAVIDSON CALL  
ROBERT V. BODE  
ODES L. STROUPE, JR.  
S. TODD HEMPHILL  
MATTHEW A. FISHER

Writer's E-mail: RBODE@BCS-LAW.COM

Craig R. Smith, Chief  
CERTIFICATE OF NEED SECTION  
809 Ruggles Drive  
Raleigh, North Carolina 27603

December 30, 2011



VIA HAND DELIVERY

Re: No Review Request/Charlotte Radiology P.A./Mobile Mammography Equipment

Dear Mr. Smith:

Our firm represents Charlotte Radiology, P.A. ("Charlotte Radiology") with respect to the above matter. We would like to request a determination from the Certificate of Need ("CON") Section that the acquisition of mobile mammography equipment and a van for a mobile mammography unit by Charlotte Radiology at its Charlotte Radiology University Breast Center will not constitute a new diagnostic center that requires applying for a CON.

BACKGROUND

Charlotte Radiology owns 2 diagnostic centers pursuant to Certificates of Need issued in Project I.D. Nos. F-7734-06 ("University Medical Park") and F-6725-02 ("Morehead Medical Plaza"), attached hereto as Exhibit 1 and Exhibit 2.

Charlotte Radiology currently owns and operates one mobile mammography unit at its Morehead Medical Plaza diagnostic center, located at 6836 Morrison Boulevard. The total cost of that mammography unit was \$235,928, with \$30,428 attributed to the materials needed to upfit the van, \$16,500 attributed to the labor required to upfit the van, and \$189,000 attributed to the cost of the mammography equipment (see invoices, attached as Exhibit 3)<sup>1</sup>. This mobile mammography unit operates with a separate provider number as required by Medicare under the same billing address as the diagnostic center.

Charlotte Radiology now plans to acquire a second mobile mammography unit to be operated out of its University Medical Park diagnostic center. The estimated costs related to

<sup>1</sup> Per the Court of Appeals Decision in *Mission Hospitals, Inc. et. Al v. NC DHHS, DHSR, CON Section and Asheville Hematology and Oncology Associates, P.A.*, attached as Exhibit 6, only expenses directly related to the operation of the equipment need to be included. Similar to the initial construction cost of a room which is subsequently upfitted to house a CT scanner, the initial purchase price of the van is not essential to the operation of the mammography equipment. Therefore, that initial cost is not included. However, even if the entire purchase price of the van, with upfits, was added to the cost of the mammography equipment, that cost was only \$451,750.

upfit the van are \$32,857 for equipment and labor (see estimate, attached as Exhibit 4), and the estimated cost of the required mammography equipment is \$220,100.00 (see estimate, attached as Exhibit 5)<sup>2</sup>. Pursuant to Medicare requirements, Charlotte Radiology will acquire a new provider number for the mobile mammography unit, but will operate under the billing address of the existing diagnostic center at University Medical Park.

REQUEST

A diagnostic center is defined in N.C.G.S. 131E-176(7a) as “a freestanding facility, program, or provider, including mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000).” In this case, Charlotte Radiology will own 2 mobile mammography units, but each will be operated from separate CON approved diagnostic centers.

It is our opinion that the acquisition of new diagnostic equipment by an existing diagnostic center does not create a new diagnostic center requiring a Certificate of Need. Such an acquisition is merely the purchase of equipment for the existing diagnostic center. In addition, the estimated cost associated with this project is less than \$500,000 and less than the \$750,000 threshold for major medical equipment as defined in N.C.G.S. 131E-176(14o).

We respectfully request that the Agency determine that Charlotte Radiology may proceed with the project without a certificate of need under N.C.G.S. 131E-178 and further that second mobile mammography unit operated as part of the University Medical Park diagnostic center does not constitute a new diagnostic center.

Thank you for your consideration of this Request. Please feel free to contact us if you have any questions.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.

  
Robert V. Bode

Enclosures  
RVB/jc

cc w/ enclosures: Mark Farmer

---

<sup>2</sup> Even if the total cost of the van were considered, the total cost of the equipment would not exceed the \$750,000 major medical equipment cost threshold, which is applicable here since University Medical Park already is a diagnostic center.



**STATE OF NORTH CAROLINA**  
Department of Health and Human Services  
Division of Health Service Regulation

**CERTIFICATE OF NEED**  
for  
**Project Identification Number F-7734-06**  
**FID#070269**

**ISSUED TO:** Charlotte Radiology, P.A.  
1701 East Boulevard  
Charlotte, NC 28203

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., 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. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 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 N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

**SCOPE:** Charlotte Radiology shall acquire digital mammography equipment to replace an existing analog mammography unit and establish a diagnostic center at Charlotte Radiology University Breast Center/Mecklenburg County

**CONDITIONS:** See Reverse Side

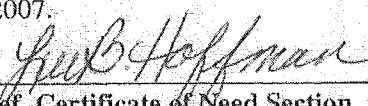
**PHYSICAL LOCATION:** Charlotte Radiology University Breast Center  
101 W. T. Harris Boulevard  
Suite 2122-A  
Charlotte, NC 28262

**MAXIMUM CAPITAL EXPENDITURE:** \$746,900

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** December 31, 2007

This certificate is effective as of the 20th day of September, 2007.

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Health Service Regulation

**EXHIBIT**  
**1**

Conditions

1. Charlotte Radiology, P.A. d/b/a Charlotte Radiology University Breast Center shall materially comply with all representations made in the certificate of need application and the supplemental documents provided to the Agency on September 12, 2007. In those instances in which any of these representations conflict, Charlotte Radiology, P.A. d/b/a Charlotte Radiology University Breast Center shall materially comply with the last-made representations.

2. Charlotte Radiology, P.A. d/b/a Charlotte Radiology University Breast Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.

3. Charlotte Radiology, P.A. d/b/a Charlotte Radiology University Breast Center shall remove and dispose of by sale or trade-in to another unrelated party, the existing mammography unit, upon installation of the replacement equipment.

Timetable

Ordering of equipment.....	September 24, 2007
Arrival of equipment.....	October 1, 2007
Operation of equipment.....	November 1, 2007
Offering of service.....	November 1, 2007



# STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

## CERTIFICATE OF NEED

for

Project Identification Number F-6725-02

FID#021188

**ISSUED TO:** Charlotte Radiology, PA  
d/b/a Charlotte Radiology Breast Center  
1701 East Boulevard  
Charlotte, NC 28203-5823

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., 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. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 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 N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

**SCOPE:** Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Center/Acquire a dedicated breast magnetic resonance scanner (MRI) and establish a new diagnostic center/Mecklenburg County

**CONDITIONS:** See Reverse Side


**PHYSICAL LOCATION:** Charlotte Radiology Breast Center  
6836 Morrison Boulevard  
Charlotte, NC 28211

**MAXIMUM CAPITAL EXPENDITURE:** \$1,273,565

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** January 2, 2004

This certificate is effective as of the 24<sup>th</sup> day of September, 2003.

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Facility Services

EXHIBIT

2



## CONDITIONS

1. Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Clinic shall materially comply with all representations made in the certificate of need application and supplemental documents provided to the Agency on June 11 and August 7, 2003. In those instances in which any of these representations conflict, Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Center shall materially comply with the last-made representations.
2. Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Clinic shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. The facility's charges for the first three years of operation following completion of its project shall be limited to the following:

Procedure	ICD-9 Code	Year One	Year Two	Year Three
Unilateral	76093	\$1,483	\$1,483	\$1,483
Bilateral	76094	\$1,613	\$1,613	\$1,613

## TIMETABLE

Obtaining funds necessary to undertake project	November 1, 2003
Completion of final drawings and specifications	December 7, 2003
Contract award	February 21, 2004
25% completion of construction	March 15, 2004
50% completion of construction	April 1, 2004
75% completion of construction	April 21, 2004
Completion of construction	May 14, 2004
Offering of service	June 1, 2004

*December 5 2005*

*2006*

*2007*

*2008*





**OSHKOSH  
SPECIALTY  
VEHICLES**

December 21, 2012

MR. Michael Vachino  
Charlotte Radiology

Dear Mr. Vachino:

The breakdown in price for the prior mobile unit is as follows:

Total Sell Price		\$262,750.00
Labor to upfit motor coach:	\$38,082.00	
Components	\$57,453.00	
Motor Coach:	\$167,215.00	

The breakdown for coach work dedicated to the medical system installation is:

\$15,240.00 electrical components  
\$16,500.00 Labor  
\$15,188.00 (10Kva UPS and Radiation Shield)

Please let me know if you require additional information.

Regards

*Tom Biwan*  
Tom Biwan  
Vice President Sales  
Oshkosh Specialty Vehicles



**From:** Moushey, Dave [mailto:dmoushey@ArmorMobile.com]  
**Sent:** Wednesday, December 07, 2011 4:09 PM  
**To:** Michael Vachino  
**Subject:** Revised Mobile Mammography Coach Proposal

Hi Mike,

Per your request, attached is a revised Mobile Mammography Coach configured as we discussed.

This plan (Mammo II) includes the rear Staff Entrance with electric steps (no wheel chair lift), the Hologic-required UPS and Shield, Graphics Allowance, and Delivery with Training.

The total new cost of this coach is \$347,100. Of that, there is \$32,857 in items necessary to convert one of our standard-build coaches into a Mammography Coach. These items are itemized on page 12 of the proposal (I did not include Graphics or Delivery in this figure although they are listed for reference).

Please let me know if you need any additional information.

I look forward to hearing from you.

Best regards,  
Dave

**Dave Moushey**  
Director of Sales

Armor Mobile Systems  
4600 North Mason-Montgomery Rd.  
Mason, OH 45040  
Office 513-923-5647  
Mobile 513-673-6125  
Fax 513-923-5473  
[DMoushey@ArmorMobile.com](mailto:DMoushey@ArmorMobile.com)  
[www.ArmorMobile.com](http://www.ArmorMobile.com)

CONFIDENTIALITY DISCLAIMER: This email message and any attachments are considered confidential and may be legally privileged and is intended only for the addressee to view. If you are not the intended recipient of this email, you are prohibited from disclosing, copying, or distributing the materials in this message, or any action in reliance of the material. If you have received this email message in error, please contact the sender immediately and discard this transmission. Thank

EXHIBIT  
4

## Armor Mobile Mammography Coach Pricing Information

**Premier Series Mammography Coach Base Price ..... \$ 347,100\***

- \* Pricing is based upon Layout Drawing Title "40' Premier Series Mammography Coach #2" and is subject to change pending final layout and design of your coach.
- \* Digital mammography equipment installation to be provided by the manufacturer or their authorized partner and is not included in the price above. Armor will support the equipment installation as needed.
- \* Price excludes applicable tax, VAT, licensing and registration.

**Major Options INCLUDED in the above quotation and their value:**

✓ Hologic-required UPS and Acrylic Lead Shield	\$ 12,500
✓ Back-up HVAC System (for Mammo Suite only)	\$ 2,300
✓ Cargo Door for Loading X-Ray Machine	\$ 2,449
✓ Changing Room Walls, Cabinets and Doors	\$ 8,975
✓ Supplemental Heater/Fan Combo at Entrance	\$ 635
✓ Supplemental Lighting and Electrical	\$ 2,565
✓ Automatic Transfer Switch for Generator	\$ 1,948
✓ Additional Interior Finishes	\$ 2,565
✓ Exterior Graphics Allowance	\$ 10,000
✓ Delivery and Training in Charlotte, NC	\$ 2,300

Accepted by: \_\_\_\_\_ Date: \_\_\_\_\_  
Authorized Signature

Name and Title: \_\_\_\_\_  
Armor Mobile Systems

Accepted by: \_\_\_\_\_ Date: \_\_\_\_\_  
Authorized Signature

Name and Title: \_\_\_\_\_  
Charlotte Radiology

This document contains information that is confidential and the property of Armor Mobile Systems. It may not be copied, published, or used, in whole or in part, for any purpose other than expressly authorized by Armor Mobile Systems. All rights reserved. This proposal is non-binding until signed by all parties and any resulting order is subject to the Terms and Conditions attached hereto.



**Quotation**

**PLEASE REFER TO THIS NUMBER ON ALL CORRESPONDENCES AND ORDERS**

**HOLOGIC**<sup>SM</sup>  
The Women's Health Company

**Quote #: 166610**

**Buying Group: NONE**

**Status : Done**

**TO:** Charlotte Radiology  
1701 East Blvd  
Charlotte, NC

We are pleased to offer you the products listed on the condition that this Quotation and the attached terms comprise the complete and exclusive statement of the contract between us. This Quotation is based on the information known by Hologic regarding your needs as of the date the Quotation is generated. This Quotation and the attached terms supersede all other quotations, agreements, understandings, warranties and representations, whether written or oral, between us, and may be accepted only in accord with their terms. This offer will remain open for 45 days after the quotation date unless otherwise specified, and is subject to change or withdrawal by Hologic prior to acceptance. To accept, please sign below within the time period for acceptance.

**TAX INFO:**

Hologic is required by law to collect all state and local taxes on all sales. If an exemption certificate is not provided by customer at time of order, final invoices will include these amounts. Many states require both specific operator qualifications and/or licensing and registration of x-ray devices. Hologic is not responsible for fulfilling customer's regulatory obligations.

Signed quote and/or purchase order should be forwarded by mail, via e-mail or by fax to:  
Skeletal Health (DXA & Mini-C):  
HOLOGIC, INC.  
35 Crosby Drive  
Bedford, MA 01730  
ATTN: Sales Administration  
Fax: (781) 280-0668  
Bed-SalesAdmin@hologic.com  
Breast Health:  
HOLOGIC, INC.  
36 Apple Ridge Road  
Danbury, CT 06810  
ATTN: Sales Administration  
Fax: (203) 731-8463  
Danburyorders@hologic.com  
Interventional Breast Solutions (Suros):  
HOLOGIC, INC.  
6100 Technology Center Drive  
Indianapolis, IN 46278  
ATTN: Sales Administration  
Fax: (317) 344-7690  
allfieldservicecoordinators@hologic.com

**ATTN:** Mark Farmer

**Phone:**

**Fax:**

**Email:**

<mailto:Mark.Farmer@charlotteradiology.com>

Quote Date	Hologic Representative	Payment Terms	FOB	Est. Del. Date	
Dec 06, 2011	Lynn Smith lsmith@hologic.com	0-80-20	FACTORY, PREPAID & ADDED	60-90 Days ARO	
Qty	Product Model Number and Description			Unit Price (US \$/Unit)	Extended Price (US \$)
1	<b>SELENIA S SYSTEM W/CAD - Selenia S System with R2 CAD</b> The Selenia S Digital Mammography System with R2 CAD is designed to be a dedicated screening system (Large Focal Spot Only).  Selenia S with R2 CAD specifications:  Acquisition Gantry Constant Potential High Frequency Generator kV Range - 22 kVp to 39 kVp mAs Range - 3 mAs to 400 mAs 26.5 to 55 inch Vertical C-Arm Travel +195 to -150 Degree C-Arm Rotation 66 cm SID  Dual Compression Mechanism Dual Function Footswitches (1)  Compression Paddles 24 x 30 cm FAST Paddle Smart Paddle System 18 x 24 cm FAST Paddle 7.5 cm Spot Contact Paddle (for calibration only) Small Breast Paddle  Acquisition Station Small Footprint Design UNIX Based Platform, Sun Solaris 10 Operating System 3 GB Memory 250 GB Hard Drive Temporary Storage for 4,000 - 6,000 Images CDRW for Temporary Image Archiving in DICOM Part 10 Format High Brightness 20" 2MP Flat Panel Display Keyboard, Trackball and Bar Code Reader Ethernet 10/100/1000 Base T Connection  DICOM Services (Worklist, Print, Storage, Storage Commitment, Query/Retrieve, Modality Performed Procedure Step)  IHE Profiles (Scheduled Workflow, Patient Information Reconciliation and Mammography Image)  Image Acquisition Software  Operator and Service Package: Operator Manual Service Manual QC Manual Quick Reference Guide  M.I.C. "Digital Mammography Essentials" Textbook & Test provides CEUs for technologists and training hours for radiologists in digital mammography (1 copy - additional copies available for purchase).			\$0.00	\$0.00

**EXHIBIT**  
**5**



	<p>"Finding a New Groove: Positioning for Digital Mammography" video (developed by Hologic and the American Society of Radiologic Technologists (ASRT) reviews digital differences, basic positioning, as well as advanced positioning for mammography in a full-field digital mammography imaging environment (1 copy - additional courses available for purchase through ASRT)</p> <p>Installation included</p> <p>Warranty - Standard 12 Months all Parts and Labor &amp; Glassware; after the Warranty Period, mammography x-ray tubes are warranted on a straight-line prorated basis during months 13-24.. Warranty available Monday through Friday - 8 am to 5 pm local time except Hologic recognized holidays</p> <p>The Selenia S system can be upgraded to perform diagnostic imaging. The Selenia S Upgrade kit, purchased separately, enables the Selenia to utilize both small and large focal spots to perform full screening and diagnostic views (ASY-01583 - diagnostic paddles included).</p>		
1	<p><b>Digital Image Receptor (Part # ASY-00834) - Digital Image Receptor</b></p> <p>Digital Image Receptor Amorphous Selenium TFT Detector LORAD HTC Anti-scatter Grid Grid Auto-Retractor Mechanism for Geometric Mag Views 24 x 29cm Effective Imaging Area 2560 X 3328 and 3328 x 4096 Image Matrix Sizes 70µm Pixel Size &gt;7 lp/mm Limiting Spatial Resolution MTF @ Nyquist Frequency &gt;0.40 DQE at 0 cycles/mm &gt; 50% 20° - 30° Ambient Operating Temperature</p>	Included	Included
1	<p><b>Selenia S CAD System - Cenova with ImageChecker CAD Port 1 &amp; Citra</b></p> <p>Cenova Digital Mammography Processing System hosts R2 software applications. System includes ImageChecker CAD computer-aided detection for digital mammograms received from a variety of FFDM systems. One ImageChecker CAD port license is included, and optional port licenses can be added to a total of four. R2's patented ImageChecker CAD algorithm analyzes the digitally acquired images. Citra Core software, including RightOn, Male, PeerView Digital, EmphaSize and LesionMetrics, provides additional information about why R2 CAD marked specific regions. R2's digital mammography CAD results are sent to any DICOM PACS or workstations.</p> <p>Includes:</p> <ul style="list-style-type: none"> <li>• Hologic's latest R2 Cenova Processing Unit Server</li> <li>• Windows XP operating system</li> <li>• Dynamic resource management and case control</li> <li>• Output transmission re-try mechanism</li> <li>• Flexible output routing to multiple output destinations</li> <li>• Computer Server (6U)</li> <li>• Compact footprint</li> <li>• License dongle</li> <li>• ImageChecker CAD algorithm, the most trusted name in CAD: <ul style="list-style-type: none"> <li>• Detection of Calcification Clusters and Densities (Mass)</li> <li>• Advanced geometric analysis (CC/MLO correlation and R/L asymmetry)</li> <li>• Nine operating point combinations for tailored CAD performance</li> </ul> </li> <li>• R2 ImageChecker Digital CAD Port 1 Software License, supports: <ul style="list-style-type: none"> <li>• Hologic, GE and Siemens FFDM systems</li> </ul> </li> <li>• Citra* Core Software License: <ul style="list-style-type: none"> <li>• RightOn CAD marks placed right on the region-of-interest to unambiguously flag the location</li> <li>• Male CAD marks where the algorithm sees signs both of density and calcifications</li> <li>• PeerView Digital to show exactly the tissue that caused CAD to mark the region</li> <li>• EmphaSize to differentiate CAD marks that have more prominent features</li> <li>• LesionMetrics to display additional information about the finding</li> </ul> </li> <li>• Hologic Connect remote system diagnostic software for post-installation service and applications support; conforms with Verisign security</li> </ul> <p>Requires:</p> <ul style="list-style-type: none"> <li>• An equal number of Cenova CAD and Quantra Port licenses (if both are present)</li> <li>• Specify manufacturer, and model of FFDM system at time of order</li> </ul> <p>*Restrictions:</p> <ul style="list-style-type: none"> <li>• Advanced R2 CAD features such as the Male Mark, PeerView Digital, EmphaSize and LesionMetrics require workstations that conform to proper display of those features. They can be disabled for use with other non-conformant workstations. Customer needs to check with their workstation vendor</li> </ul>	Included	Included
1	<p><b>Initial Applications - Selenia - Initial Applications per site - Selenia</b></p> <p>Three (3) days of Applications Training for up to 5 technologists per site.</p> <p>Applications must be completed within 12 months of equipment shipment.</p> <p>Please note: Cancellations must be made 48 hours prior to the end of the business week before your scheduled applications to avoid cancellation fees.</p> <p>Initial Applications Added Value: \$5,100.00</p>	Included	Included
1	<b>SELENIA MOBILE CONFIG - Selenia Mobile Configuration</b>	Included	Included

The Selenia Mobile Configuration allows the Selenia Base system to be installed and operated in a mobile environment.			
<b>System Specifications:</b> Selenia Mobile configuration shares the same system specifications with Selenia Base configuration except the following: a) the Selenia Mobile system does not come with a radiation shield for the operator. It is the responsibility of the customer or the coach manufacturer to obtain and install proper shielding for the system operator, b) a gantry C-arm switch is provided on the Selenia Mobile to allow for easy system reset in the event that a C-arm travel limit safety switch is tripped during system transport.			
<b>Power Requirements:</b> Selenia Mobile configuration requires clean power equivalent to shore power when powered by an external generator. Hologic recommends the use of a UPS/power conditioner in conjunction to the external power generator to assure shore power quality. The selection of the appropriate power generator and UPS/power conditioner is the responsibility of the customer and the coach manufacturer. Hologic will provide Selenia Mobile power requirements and specifications upon request.			
1	<b>MIME-00147 - ACCESSORY CABINET</b> This Accessory Cabinet is the perfect complement for your Lorad M-IV or Selenia System. Multiple slots and hooks for hanging compression paddles help to prevent scratching or damage. Storage space is provided for the Buckys, paddles, magnification and localization assemblies.  For use with the M-IV or Selenia systems.	\$0.00	\$0.00
<b>Total Package Price - Total Package Price</b>		\$220,100.00	\$220,100.00
		<b>Equipment Total:</b>	\$220,100.00
		<b>Final Quote Price:</b>	\$220,100.00

**Notes:**

Freight charges are prepaid and added to the invoice.

The buyer is responsible for any additional cost that may accrue as a result of special delivery requirements and handling costs incurred at time of delivery.

Payment for Product: If you are being quoted "split payments" (0-80-20, or 20-60-20 for example) the first payment percentage is due with your order, the second payment percentage is due upon delivery, and the final payment percentage is due upon Hologic notification of installation, or delivery if Products are designated as buyer installed. Otherwise, payments are due in full as noted.

You may be eligible to lease 100% of the proposed equipment subject to current rates and credit approval. Contact your local account manager for details or call Patrick Dawkins, Lease/Financing Manager for Hologic at 781-761-7149.

**Hologic may request new customers and established customers to complete our credit application to create or update current credit files. This requirement will be contingent on order amount and prior history with Hologic.**

This Quote is not entered into, pursuant to, or in connection with any group purchasing arrangement of which Customer or Hologic is a party, and is not intended to result in the reporting of sales or the payment of administrative fees to any group purchasing organization. In no event will Hologic be obligated to pay administrative fees to a group purchasing organization, integrated delivery network, or other entity with respect to any single purchase order by Customer under this Quote.

The customer agrees to treat all quoted and sales information as confidential and not to disclose it to any third party other than required by law.

**Buyer Acceptance:**

Charlotte Radiology

By: \_\_\_\_\_ (signature)

Name and Title: \_\_\_\_\_ (print/type)

Date: \_\_\_\_\_

**Additional Buyer Acceptance (if applicable):**

By: \_\_\_\_\_ (signature)

Name and Title: \_\_\_\_\_ (print/type)

Date: \_\_\_\_\_

**Please provide the Shipping and Billing address here if different from the quote address above  
(If this section is left blank, the product will ship and bill to the address printed at the top)**

Shipping Address: \_\_\_\_\_ Billing Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Hologic Approval: *John Pekarney*

Date: Dec 07, 2011

HOLOGIC, INC. 35 CROSBY DRIVE BEDFORD, MA 01730 TEL: 781-999-7300



696 S.E.2d 163  
Court of Appeals of North Carolina.  
MISSION HOSPITALS, INC., Petitioner,  
and  
North Carolina Radiation Therapy  
Management Services, Inc., d/b/a 21st  
Century Oncology, Petitioner-Intervenor,  
v.  
NORTH CAROLINA DEPARTMENT OF  
HEALTH AND HUMAN SERVICES, DIVISION  
OF HEALTH SERVICE REGULATION  
(Formerly Division of Facility Services[.])  
Certificate of Need Section, Respondent,  
and  
Asheville Hematology and Oncology  
Associates, P.A., Respondent-Intervenor.

No. COA08-1478. | July 6, 2010.

#### Synopsis

**Background:** Oncology treatment center sought a no-review determination from the Certificate of Need (CON) Section of the Department of Health and Human Services, Division of Facility Services (Agency), for relocation of offices and acquisition of radiation treatment equipment. After no-review determinations were issued, hospital filed a petition for a contested case hearing. Competing treatment center intervened. The ALJ issued a recommended decision affirming the no-review determinations, and petitioners filed joint exceptions. After a hearing the Agency reversed, and treatment center appealed. The Court of Appeals, 189 N.C.App. 263, 658 S.E.2d 277, vacated and remanded. On remand, the Agency determined that acquisition and expansion did not require a CON, and petitioners appealed.

**Holdings:** The Court of Appeals, Stephens, J., held that:

- 1 lease created a vested right in applying prior CON law;
- 2 costs associated with the record and verify system were properly excluded from the total cost of linear accelerator (LINAC);
- 3 CT scanner was exempt from CON requirements;
- 4 Agency could use fair market value of used diagnostic contrast equipment rather than full cost when allocating portion to cost of CT scanner;

5 expanded and relocated physician office building was exempt from CON review;  
6 lease of building to house center was an "operating lease";  
and  
7 center did not incur any additional staff costs pertinent to CON review.

Affirmed.

\*166 Appeal by Petitioners from the final agency decision signed 30 May 2008 by Jeff Horton, Acting Director for the North Carolina Department of Health and Human Services, Division of Health Service Regulation. Heard in the Court of Appeals 8 June 2009.

#### Attorneys and Law Firms

Smith Moore Leatherwood LLP, Greensboro, by Maureen Demarest Murray and Allyson Jones Labban, for Petitioner.

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., Raleigh, by Susan H. Hargrove, Sean A. Timmons, and Courtney H. Mischen, for Petitioner-Intervenor.

Attorney General Roy Cooper, by Assistant Attorney General June S. Ferrell, for Respondent.

Bode, Call & Stroupe, L.L.P., Raleigh, by Robert V. Bode, S. Todd Hemphill, Diana Evans Ricketts, and Matthew A. Fisher, for Respondent-Intervenor.

#### Opinion

STEPHENS, Judge.

The present matter was before this Court on a prior appeal from a Final Agency Decision ("the first FAD") entered 7 August 2006 by the North Carolina Department of Health and Human Services ("DHHS" or "the Agency"). The pertinent factual background of this matter up to the time of that appeal is set out in our opinion in *Mission Hospitals, Inc. v. N.C. Dep't of Health and Human Services*, 189 N.C.App. 263, 658 S.E.2d 277 (2008) ("*Mission I*").<sup>1</sup> However, to aid understanding of the current appeal, we find it useful to set forth the factual background and procedural history which brought this matter to our Court.

#### Factual Background and Procedural History

On 1 February 2005, Asheville Hematology ("AHO" or appellant), an oncology treatment center, sought a "no-review" determination from the Certificate of Need ("CON") Section of the North Carolina Department of

Health and Human Services, Division of Facility Services ("Agency"), for a proposed relocation of its offices and acquisition of medical equipment that would allow AHO to provide radiation therapy. AHO presented four proposals: acquisition of a linear accelerator ("LINAC"), acquisition of a CT scanner, acquisition of treatment planning equipment, and relocation of their oncology treatment center. AHO sought a ruling that its proposals "do not require certificate of need review and are not new institutional health services, within the meaning of the CON law."

In determining the allocable costs for the CT scanner and LINAC projects, AHO applied upfitting costs to accommodate the CT scanner and LINAC and did not allocate general office construction costs, which were instead attributed to the base costs of the developer. AHO clearly specified in its letter which costs were attributed to each project and which costs were attributed to the developer's base costs. \*167 The submitted costs for the four projects, and associated thresholds against which AHO analyzed each of the proposals as a new institutional health service under the statute, were as follows:

<u>Project</u>	<u>AHO's Cost Projection</u>	<u>Statutory Threshold for "No Review"</u>
CT Scanner	\$ 488,547	\$ 500,000 <sup>2</sup>
LINAC	\$ 746,416	\$ 750,000 <sup>3</sup>
Treatment Planning	\$ 381,135	\$ 750,000 <sup>4</sup>
Relocation	\$1,985,278	\$2,000,000 <sup>5</sup>

On 2 August 2005, the CON Section issued four "no-review" letters, reviewing each proposal separately and confirming that none required a Certificate of Need. Each letter stated that "this determination is binding only for the facts represented by you." Shortly thereafter, the General Assembly amended N.C. Gen.Stat. § 131E-176(16) to require a CON for the acquisition of linear accelerators, regardless of cost, as a new institutional health service. (2005 Sess. Laws ch. 325, § 1). The relevant portion of the amendment became effective on 26 August 2005.

that the relocation of the existing oncology treatment center and the acquisition of equipment as proposed by AHO and addressed in the August 2005 No-Review determinations did not require Certificates of Need. The ALJ recommended that no CON was necessary because neither the relocation nor the acquisition projects "constitute[d] a 'new institutional health service' as defined by N.C. Gen.Stat. § 131E-176 at the time that [AHO] acquired vested rights to develop these services."

*Mission I*, 189 N.C.App. at 265-67, 658 S.E.2d at 278-79.

On 1 September 2005, Mission Hospitals, Inc. ("Mission" or "petitioner"), a nonprofit hospital in Asheville, North Carolina, filed a petition for a contested case hearing in the Office of Administrative Hearings ("OAH"), challenging each of the No-Review Determinations. North Carolina Radiation Therapy Management Services, Inc. d/b/a 21st Century Oncology ("21st Century" and, with Mission, "petitioners"), an oncology treatment center in Asheville, North Carolina, intervened in the proceeding, also contesting the No-Review Determinations. AHO intervened in support of the CON Section's No-Review Determinations.

On 7 August 2006, DHHS entered the first FAD reversing the ALJ's recommended decision. AHO appealed from the first FAD to the Court of Appeals. *See id.* This Court vacated the first FAD upon holding that the Division of Facility Services of DHHS erred by engaging in *ex parte* communications with one party without notice to the other parties or affording an opportunity to all parties to be heard, and that these *ex parte* communications were prejudicial. *Id.* at 276, 658 S.E.2d at 285.

On 26 May 2006, the ALJ entered a 65-page Recommended Decision affirming the No-Review Determinations. The ALJ agreed with the CON Section

On remand from this Court, Jeff Horton, Acting Director of the Division of Health Service Regulation of DHHS, entered a second FAD ("FAD") on 30 May 2008. In its FAD, DHHS adopted Administrative Law Judge ("ALJ") Beecher R. Gray's Recommended Decision that AHO's acquisition of a LINAC and a CT scanner and expansion of the oncology

treatment center did not require a CON. From the FAD adopting the recommendations of the ALJ, Petitioners appeal.

### Standard of Review

1 Pursuant to N.C. Gen.Stat. § 150B-34(c),

in cases arising under Article 9 of Chapter 131E of the General Statutes, the administrative law judge shall make a recommended decision or order that contains findings of fact and conclusions of law. A final decision shall be made by the agency in writing after review of the official record as defined in G.S. 150B-37(a) and shall \*168 include findings of fact and conclusions of law. The final agency decision shall recite and address all of the facts set forth in the recommended decision. For each finding of fact in the recommended decision not adopted by the agency, the agency shall state the specific reason, based on the evidence, for not adopting the findings of fact and the agency's findings shall be supported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31. The provisions of G.S. 150B-36 (b), (b1), (b2), (b3), and (d), and G.S. 150B-51 do not apply to cases decided under this subsection.

N.C. Gen.Stat. § 150B-34(c) (2007).

It is well settled that in cases appealed from administrative tribunals, “[q]uestions of law receive *de novo* review,” whereas fact-intensive issues “such as sufficiency of the evidence to support [an agency’s] decision are reviewed under the whole-record test.” *In re Greens of Pine Glen Ltd. Part.*, 356 N.C. 642, 647, 576 S.E.2d 316, 319 (2003). Thus, where the gravamen of an assigned error is that the agency violated subsections 150B-51(b)(1), (2), (3), or (4) of the APA, a court engages in *de novo* review. Where the substance of the alleged error implicates subsection 150B-51(b)(5) or (6), on the other hand, the reviewing court applies the “whole record test.”

*N.C. Dep’t of Env’t & Natural Res. v. Carroll*, 358 N.C. 649, 659, 599 S.E.2d 888, 894-95 (2004) (internal citations omitted). Under whole record review, the Agency’s decision should be reversed only if it is not supported by substantial evidence. *Total Renal Care of N.C. v. N.C. Dep’t of Health & Human Servs.*, 171 N.C.App. 734, 739, 615 S.E.2d 81, 84 (2005).

2 North Carolina law gives great weight to the Agency’s interpretation of a law it administers. *Frye Reg’l Med. Ctr. v. Hunt*, 350 N.C. 39, 45, 510 S.E.2d 159, 163 (1999); *see*

*also Carpenter v. N.C. Dep’t of Human Res.*, 107 N.C.App. 278, 279, 419 S.E.2d 582, 584 (1992) (When a court reviews an agency’s interpretation of a statute it administers, so long as the agency’s interpretation is reasonable and based on a permissible construction of the statute, the court should defer to the agency’s interpretation of the statute.); *High Rock Lake Ass’n. v. N.C. Envtl. Mgmt. Comm’n*, 51 N.C.App. 275, 279, 276 S.E.2d 472, 475 (1981) (The interpretation of a statute given by the agency charged with carrying it out is entitled to great weight.).

### Discussion

#### I. Amendment to the CON Law

A CON is “a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project.” N.C. Gen.Stat. § 131E-176(3) (2007). The CON Law, *inter alia*, regulates the acquisition of certain types of equipment. *See Total Renal Care v. Dep’t of Health & Human Servs.*, 195 N.C.App. 378, 379-82, 673 S.E.2d 137, 139-40 (2009) (setting forth the history and purpose of the CON Law and the procedure involved in obtaining a CON in North Carolina).

AHO submitted a request for a CON determination to the Agency on 1 February 2005. This submission was made in good faith reliance on the CON Law then in existence, N.C. Gen.Stat. § 131E-175, *et. seq.* (2003) (the “prior CON Law”). The CON Law was amended effective 26 August 2005 (“the amended CON Law”), more than six months after AHO’s initial submission to the Agency. The amended CON Law changed certain definitions regarding oncology treatment centers and the acquisition and operation of new LINACs. As a result of the amendment, the statutory definition for oncology treatment center was stricken from the text of N.C. Gen.Stat. § 131E-176(18a), and a new definition was added to section 131E-176 defining LINACs.

Petitioners argue that the amended CON Law applies to AHO’s acquisition of medical equipment and expansion of its oncology center. Specifically, Petitioners argue that AHO did not have a vested right in the prior CON Law and that AHO acquired the LINAC and CT scanner for purposes of the CON Law after the amendment became effective. \*169 We are not persuaded by Petitioners’ contentions, as addressed below.

#### A. Building Lease

3 On 6 June 2005, AOR Management, as managing agent for AHO, entered into a lease with CC Asheville MOB for the building to which AHO would relocate. AOR Management and CC Asheville MOB modified this lease by amendment twice after the CON Law was amended on 26 August 2005. In its FAD, the Agency found that “the only reasonable reading of the Lease and its subsequent amendments is to view all three writings as one contract memorialized by multiple writings, as contemplated by the Statute of Frauds in North Carolina.” Furthermore, the Agency found that “for the purposes of determining the vesting of rights in the Lease of the Building, as set forth above, [AHO] had vested rights in such Lease as of June 6, 200[5].”

4 5 6 A vested right is a common law right that is based upon the constitutional right prohibiting Congress or the State from enacting laws which would impair a party's right to contract. U.S. Const. amends. V, XIV; N.C. Const. Art. 1, § 19; see *Lester Bros., Inc. v. Pope Realty & Ins. Co.*, 250 N.C. 565, 567-68, 109 S.E.2d 263, 265-66 (1959) (Plaintiff had a vested right in the individual liability of defendant, a stockholder of a corporation, stemming from purchases made from the corporation in 1955, when a 1957 amendment to the law would have relieved defendant of individual liability.). The common law of North Carolina has addressed the issue of vested rights within the context of amendments to statutory law impacting government-issued permits. See generally *Booker v. Duke Med. Ctr.*, 297 N.C. 458, 256 S.E.2d 189 (1979); *Lester Bros.*, 250 N.C. 565, 109 S.E.2d 263. “The proper question for consideration is whether the act as applied will interfere with rights which had vested or liabilities which had accrued at the time it took effect.” *Booker*, 297 N.C. at 467, 256 S.E.2d at 195. Furthermore, the good faith reliance of the concerned parties upon the then-existing state of the law is a consideration in determining whether such rights have vested. See *Michael Weinman Assocs. Gen. P'ship v. Town of Huntersville*, 147 N.C.App. 231, 234, 555 S.E.2d 342, 345 (2001) (“[W]here property owners have reasonably made a substantial expenditure of money, time, labor or energy in a good faith reliance of a government approved land-use, they have a vested right.”).

7 8 9 A lease of real estate is the type of contract which creates a vested right. *Carolina Mineral Co. v. Young*, 220 N.C. 287, 290-91, 17 S.E.2d 119, 121-22 (1941) (right to partition land may be lost or suspended where contractual obligations between tenants are “manifestly inconsistent with partition, especially by sale of the land, and where such a sale would destroy a property right growing out of the lease

and guaranteed by it”). Furthermore, the terms of leases “are interpreted according to general principles of contract law.” *Wal-Mart Stores, Inc. v. Ingles Markets, Inc.*, 158 N.C.App. 414, 418, 581 S.E.2d 111, 115 (2003). Under contract law, a modification to a lease does not necessarily create a new contract, and rather, the intention of the parties governs. *Id.* at 419, 581 S.E.2d at 115 (“[T]he heart of a contract is the intention of the parties as determined from its language, purposes, and subject matter and the situation of the parties at the time of execution.” (internal citation and quotation marks omitted)).

In accordance with our case law, we agree with the Agency's interpretation of AOR Management's lease and conclude that the parties' lease created a vested right in applying the prior CON Law. Accordingly, we analyze the additional issues regarding AHO's building lease under the prior CON Law. The Agency also found that AHO had a vested right in the purchase contracts for the LINAC and CT scanner. We address the applicability of the appropriate CON Law to these purchase contracts below.

#### B. Acquisition of Equipment

An acquisition of equipment can occur “by donation, lease, transfer or comparable arrangement[.]” N.C. Gen.Stat. § 131E-178 (b) (2003). The prior CON Law tied its requirement of a CON for the acquisition of a LINAC or CT scanner to the total cost of the equipment. N.C. Gen.Stat. § 131E-176(7a) and (14f) (2003). The amended CON \*170 Law, however, requires a CON prior to acquiring a LINAC or CT scanner, regardless of cost. N.C. Gen.Stat. § 131E-176(16)f1.5a. and f1.9. (2007). The amended CON Law requires a CON prior to making an acquisition of a “new institutional health service” by donation, lease or transfer, or comparable arrangement “if the acquisition would have been a new institutional health service if it had been made by purchase.” N.C. Gen.Stat. § 131E-178(b) (2007). The definition of “[n]ew institutional health services” includes “[t]he acquisition by purchase, donation, lease, transfer, or comparable arrangement of ... [a] [l]inear accelerator[, or a] [s]imulator [by or on behalf of any person.]” N.C. Gen.Stat. § 131E-176(16)f1.5a and f1.9.

In its FAD, the Agency made the following pertinent findings of fact:

241. Pursuant to the Management Agreement between AOR Management and Asheville Hematology, US Oncology, through its subsidiary AOR Management, will



own the equipment located at Asheville Hematology's relocated oncology treatment center....

....

243. *Whether the equipment is owned by Asheville Hematology or its manager would not impact the CON Section's Determination. Whether a provider acquires medical equipment for purposes of the CON Law by purchase, lease, or other comparable arrangement, the CON Section's treatment of that acquisition is the same under the CON law. Such a comparable arrangement could be through a management agreement.... Through its Management Agreement with US Oncology, Asheville Hematology will acquire the equipment to be located in the facility.*

....

248. On June 3, 2005, US Oncology issued a purchase order to Varian for the linear accelerator described in Quotation No. EHD20050511-002....

249. Once US Oncology has issued a purchase order, that binds it to purchase the equipment described in the purchase order....

....

261. On June 8, 2005, US Oncology issued a purchase order to GE for the CT scanner....

(emphasis added).

Thus, DHHS concluded that AHO acquired the LINAC and CT scanner on 3 June and 8 June 2005, respectively, when the purchase agreements were issued. The Agency further concluded that AHO had vested rights in this equipment as of the date each piece of equipment was acquired.

Our Court's opinion in *Koltis v. N.C. Dep't of Human Res.*, 125 N.C.App. 268, 480 S.E.2d 702 (1997), defined the scope of inquiry with regard to a determination as to whether binding contracts predated a change in the laws of this State continue to be vested. In *Koltis*, the petitioners

proposed to develop and operate a new oncology treatment center in Pitt County, North Carolina. To that end, petitioners notified the North Carolina Department of Human Resources, Division of Facility Services, Certificate of Need Section (DHR) of their ongoing efforts to develop the center and requested DHR's confirmation

that the project was exempt from obtaining the certificate of need required for a "new institutional health service" under N.C. Gen.Stat. § 131E-178. DHR responded that no certificate of need was required since the project did not meet the current statutory definition of a "new institutional health service" under N.C. Gen.Stat. § 131E-176(16) but warned that pending legislation would significantly change that definition and if enacted, the project would have to be reevaluated in light of the statutory amendment.

*Id.* at 269, 480 S.E.2d at 703. Section 131E-176 was amended effective 18 March 1993 "so that an oncology treatment center fell within the definition of a 'new institutional health service' requiring a certificate of need under N.C.G.S. § 131E-178." *Id.* at 270, 480 S.E.2d at 703. The General Assembly included a "grandfather" provision, however, "which excepted from application of the amended statute 'any person ... [or] corporation ... who has lawfully entered into a binding legal contract to develop and offer any service that was not a new institutional \*171 health service requiring a certificate of need prior to the ratification of this act.'" *Id.* (quoting 1993 N.C. Sess. Laws ch. 7, sec. 12.). On appeal, our Court held that a mere binding contract for "consulting services related to development of the proposed oncology treatment center" which was entered into prior to the amendment to the CON Law was sufficient to create vested rights on the part of the petitioners. *Id.* at 272, 480 S.E.2d at 705.

10 In the present case, the Agency found that AHO's purchase contracts for the LINAC and the CT scanner met the definition set forth in *Koltis* of valid, binding contracts, and thus, these contracts gave AHO vested rights in the equipment as of June 2005 under the prior CON Law. Petitioners argue, however, that AHO acquired the equipment after the amended CON Law went into effect, and thus, that AHO did not have any vested rights in the prior CON Law. Petitioners contend that the *purchase* of equipment by US Oncology and the *transfer* of that equipment to AHO were two separate events. Thus, Petitioners argue that although US Oncology acquired the LINAC and CT scanner in June 2005, AHO acquired the equipment when it was transferred to AHO for installation and use at AHO's oncology treatment center after 26 August 2005.

In support of their position, Petitioners argue further that the FAD in the present case contradicts the Agency's decision in 2006 in which DHHS concluded that an acquisition of a LINAC at Thomasville Medical Center ("Thomasville") occurred after the effective date of the CON Law amendment.

In that case, although Forsyth Medical Center ("Forsyth") purchased a LINAC with the intended purpose of installing and using the LINAC at Thomasville, DHHS concluded that Thomasville did not acquire the LINAC until it was actually installed. Thus, although Forsyth purchased the LINAC before the amendment went into effect, DHHS concluded that the amended CON Law applied to Thomasville since the LINAC was installed at Thomasville after the new law went into effect.

In a letter titled "Review Determination & Notice to Cease and Desist" from DHHS to Thomasville, DHHS stated that

[t]he Certificate of Need Section received a December 19, 2005 letter from Forsyth Medical Center ... stating that Forsyth Medical Center had purchased a linear accelerator which it intends to install at Thomasville Medical Center. However, the proposal is a new institutional health service within the meaning of N.C. Gen.Stat. § [ ]131E-176(16)f1.5a because it results in the acquisition of a linear accelerator by Thomasville Medical Center by donation, lease, transfer or comparable arrangement.

The record before us does not reveal any relationship between Forsyth and Thomasville beyond Forsyth's intent to donate a LINAC to Thomasville, nor does the record include any written agreement between the two.

We conclude that Petitioners' reliance on the 2006 Agency decision is misplaced. Unlike Thomasville and Forsyth, AHO and US Oncology share a symbiotic relationship in which US Oncology serves as AHO's "Business Manager." Under the "Management Services Agreement" ("MSA"), US Oncology "provide[s] all Management Services as are necessary and appropriate for the day-to-day administration of the business aspects of AHO's operations[.]" US Oncology's responsibilities as AHO's business manager include: (1) ordering and purchasing medical supplies for AHO; (2) repairing and maintaining AHO's office; and (3) exercising special power of attorney for various purposes including billing AHO's patients. US Oncology purchased the LINAC and CT Scanner on behalf of AHO. Unlike Thomasville's relationship with Forsyth, AHO and US Oncology enjoyed a reciprocal relationship that extended far beyond the donation of a LINAC.

Thus, we conclude that AHO acquired the LINAC and CT scanner by a "comparable arrangement" (*i.e.*, its management agreement with US Oncology) when US Oncology acquired the LINAC and CT scanner, on 3 June and 8 June 2005, respectively. Accordingly, AHO had vested rights in the

equipment as of June 2005 under the prior CON \*172 Law. Furthermore, the Agency rendered its no-review decision on 2 August 2005 determining that AHO's project did not require a CON, prior to the 26 August 2005 effective date of the amendment to the CON Law. Accordingly, we hold that the prior CON Law applies to the determination of whether AHO's project requires a CON.

## II. AHO's Acquisition of the LINAC

The Agency found the costs "essential to acquiring and making operational" the LINAC to total \$746,416.62. N.C. Gen.Stat. § 131E-176(14f) (2003). Because the total cost of the LINAC was found to be less than the \$750,000 statutory threshold, the Agency determined that AHO's acquisition of the LINAC did not require a CON. Petitioners argue that the Agency erroneously excluded the record and verify system and the construction costs from this total and that the inclusion of either of these omitted costs would have caused the cost of the LINAC to exceed the statutory threshold and require a CON. We are not persuaded by Petitioners' contention.

### A. Record and Verify System

11 The record and verify system's primary role is to assure that the patient is treated within the proper parameters as described in the treatment plan. The Agency describes the record and verify system as a single system consisting of a data processing computer and software that processes raw data, including numerical values generated from the views of a tumor and tissues taken by the CT simulator and the data making up the different numerical parameters of the treatment plan, verifying dosage, rate and time of delivery, and creating a record in the computer memory of what transpired during a patient's treatment.

N.C. Gen.Stat. § 131E-178 requires that a CON be obtained before any person acquires "a new institutional health service[.]" N.C. Gen.Stat. § 131E-178 (2003). An "acquisition by purchase, donation, lease, transfer, or comparable arrangement ... of major medical equipment" constitutes a "new institutional health service[.]" N.C. Gen.Stat. § 131E-176(16)p. (2003).

"Major medical equipment" means a *single unit or single system of components with related functions* which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical

equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities *essential to acquiring and making operational the major medical equipment shall be included*. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C. Gen.Stat. § 131E-176(14f) (2003) (now subsection (14o), effective 26 August 2005) (emphasis added).

In its brief on appeal, the Agency contends that in applying the statutory phrase, "activities essential to acquiring and making operational the major medical equipment[.]" the Agency applied the customary meaning of "essential" which is "those items which are indispensable, the absence of which renders the equipment useless." N.C. Admin. Code tit. 10A, r. 14C.3102(1) (January 1994). This definition tracks the ordinary meaning of the word, "essential," which is customarily defined to mean "necessary," "indispensable," "inherent," and constituting the "intrinsic character" of a thing. *Webster's Third New International Dictionary* 777 (2002).

The Agency concluded that the record and verify system was not "essential to acquiring and making operational" the LINAC, and thus the costs associated with the record and verify system were excluded from the total cost of the LINAC. *See* N.C. Gen.Stat. § 131E-176(14f). The Agency instead allocated the costs of the record and verify system to the treatment planning equipment.

Petitioners argue that the record and verify system is not separate from the LINAC, and that "[l]ike four-wheel drive in a vehicle, [the record and verify system] has no independent purpose or function, and record and verify services cannot be separated or occur \*173 apart from the delivery of radiation by the LINAC." Petitioners contend that the following features of the record and verify system make it essential to the operation of the LINAC: (1) where the parameters of a patient's radiation plan differ from the parameters set on the LINAC, the record and verify system will not allow the LINAC to operate unless manually overridden or disengaged by the radiation therapist; (2) the record and verify system is physically connected or hard-wired to the LINAC; (3) the record and verify system communicates with the LINAC and not with the treatment planning system; and (4) and the only

use for a record and verify system is for use with a LINAC in providing radiation therapy.

12 Petitioners' argument is inconsistent with this Court's interpretation of the CON Law, however. "[T]he overriding legislative intent behind the CON process [is the] regulation of major capital expenditures which may adversely impact the cost of health care services to the patient." *Cape Fear Mem. Hosp. v. N.C. Dep't of Human Res.*, 121 N.C.App. 492, 494, 466 S.E.2d 299, 301 (1996). In *Cape Fear*, our Court reversed the Agency's determination that Cape Fear Memorial Hospital ("Cape Fear") was required to obtain a CON prior to purchasing an image intensifier and cine camera in an effort to upgrade and expand the capabilities of its existing Angiostar cardiac catheterization equipment ("Angiostar"). *Id.* at 492-93, 466 S.E.2d at 300. This Court held that the Agency's decision would have the effect of allowing micro-management over relatively minor capital expenditures,<sup>6</sup> and that "the legislature clearly did not intend to impose unreasonable limitations on maintaining ... *or* expanding ... presently offered health services." *Id.* at 494, 466 S.E.2d at 301 (citing N.C. Gen.Stat. § 131E-176(14f) (1994) (CON not required for purchase of unit or system to provide new health service which costs less than \$750,000)). Accordingly, we construed N.C. Gen.Stat. § 131E-175, *et. seq.*, as a whole to mean "that the legislature intended 'cardiac catheterization equipment' to include only the actual unit capable of performing cardiac catheterization procedures, not the component parts used to maintain, upgrade, or expand a unit." *Id.*

Although the present case involves the purchase of a new LINAC and not an existing piece of equipment, our holding in *Cape Fear* is nevertheless instructive to our decision in the case *sub judice*. The Agency's determination that N.C. Gen.Stat. § 131E-176(14f) was intended to include only the LINAC and not the component parts used to maintain, upgrade, or expand the unit is consistent with our interpretation in *Cape Fear*. In determining that the record and verify system was a separate unit and not an essential part of the LINAC, the Agency made the following pertinent findings of fact:

34. ... The Agency has interpreted [N.C. Gen.Stat. § 131E-176(14f)] to mean that if an equipment component is not required for the operation of the proposed item of major medical equipment and it is operated separately from such equipment, then the two items of equipment are not a single system of components, and the equipment

component is not essential to making operational the major medical equipment....

....

41. In correspondence to the Agency prior to the Determination, Asheville Hematology described the record and verify system as follows:

*When treating patients with radiation on a linear accelerator, the use of a record and verify system serves as an optional component of a quality control system for the radiation therapists. The record and verify system provides electronic validation of the daily treatment parameters but is not necessary in administration of radiation therapy. As such, it is an optional part of the treatment planning system, which is a separate piece of medical equipment....*

....

\*174 43. Asheville Hematology also notified the CON Section that it can operate the treatment planning system without this record and verify system....

44. Only 74 of the 94 radiation sites US Oncology manages have chosen to install a record and verify system....

45. The record and verify system is a separate piece of equipment from and is not attached to the linear accelerator. It is manufactured by a company other than Varian, the manufacturer of Asheville Hematology's proposed linear accelerator....

46. The record and verify system's primary role is to assure that the patient is treated with the proper parameters as described in the treatment plan....

47. The record and verify system does not turn the linear accelerator "on" for the purpose of delivering radiation. Rather, it sets up the linear accelerator so that it is ready to deliver radiation, by ensuring that treatment parameters contained in the treatment plan are accurate. In that regard, the record and verify system is an extension of the treatment planning system, because it manages the data contained in the treatment plan and provides it to the linear accelerator for delivery....

....

51. [Lee Hoffman, Chief of the CON Section,] saw the record and verify system as a communication link or a

bridge between the treatment plan and the delivery of the treatment. As a result, she determined that it was part of the treatment planning [equipment] because it was to assure that the treatment delivered was consistent with the treatment plan....

The Agency's findings are supported by the testimony of AHO witnesses, Mission's expert witnesses, and by the testimony of Lee Hoffman ("Hoffman"), the Chief of the CON Section. Prior to making the no-review determination, Hoffman visited Duke Health Raleigh Hospital's radiation oncology program. Hoffman met with Duke Health Raleigh staff, viewed the LINAC, and reviewed the documentation for their record and verify system. Duke Health Raleigh treated the record and verify system consistently with the way that AHO had represented to the Agency: that is, as a separate treatment planning system apart from the LINAC.

Accordingly, the Agency's determination that the record and verify system was not "essential to acquiring and making operational" the LINAC is supported by substantial evidence in the record and is consistent with the CON Law. Petitioners' argument regarding the record and verify system is overruled.

#### **B. Construction Costs**

13 Petitioners also argue that the Agency erroneously excluded two categories of construction costs when calculating the total costs for the LINAC: (1) the "general conditions" costs, and (2) the costs associated with construction of the space to house the mechanical room or the mold room. Timothy Knapp, an architect and witness for 21st Century, testified that general conditions are the general contractor's costs related to the overall construction of a project which are not specifically related to any one particular aspect of the construction project. Bryan Royal ("Royal"), a project manager for one of the contractors involved with the AHO Project and a witness for AHO, testified that general conditions costs include costs such as contractor employee salaries, construction trailer, office supplies, porta-johns, storage trailers, temporary utilities, waste receptacles, and clean-up.

The Agency found that the projected cost for the LINAC was \$746,416.62. Royal testified that the general conditions costs attributable to the LINAC vault totaled \$23,418.00. Thus, had the Agency included these costs in calculating the cost of the LINAC, the total would have exceeded the \$750,000 statutory threshold and required a CON.

Petitioners' argument is flawed, however, as the general conditions costs attributable to the LINAC vault did not increase the cost of general conditions related to the cost of construction for the medical office building. In its FAD, the Agency found that "[h]ad the vault not been constructed, total general conditions would have been the same. Consequently, there [were] no additional general condition cost[s] incurred to build the [LINAC] vault." In addition, a new medical \*175 office building is not "essential" to acquiring and making operational a LINAC. See N.C. Gen.Stat. § 131E-176(14f). Accordingly, the general conditions costs of the LINAC vault were properly excluded from the projected cost of the LINAC.

Petitioners also contend that the costs associated with constructing the space to house the mechanical room and mold room were erroneously excluded from the total cost of the LINAC. The Agency classified these costs as "developer's base costs" which Hoffman testified are not included in the cost of health service. The Agency made the following findings of fact with regard to the developer's base costs:

61. Ms. Hoffman explained her reasoning during the contested case hearing as to why developer's base costs are not included in the cost of the health service. She explained that the development of an office building, including a medical office building, is not a capital expenditure falling within the statutory definition of "new institutional health service" under the CON Law....

62. If the builder is unrelated to the entity which will be providing the health service, and is only leasing space to the health service, then the CON Section only will look at what costs are going to be incurred to make that office building a health service facility. That is consistent with the way exemptions are handled in G.S. § [ ]131E-184(a), so the CON Section looks at no review requests the same way....

63. If the builder is a party which is related to the provider of the health service, the CON Section considers the builder to be developing the health service facility, and therefore, the entire cost of the facility would be considered....

....

70. Neither Asheville Hematology nor US Oncology owns the Building or the land on which it is being constructed. Both are owned by CC Asheville MOB....

Based on the record before us, the Agency's findings are supported by the evidence and support the Agency's conclusion that the developer's base costs were not attributable to the LINAC. Petitioners' argument is overruled.

### III. AHO's Acquisition of the CT Scanner

14 Next, Petitioners contend the Agency erroneously concluded that AHO's acquisition of the CT scanner was exempt from the CON requirements. We disagree.

15 Under the CON Law, a CON must be obtained before establishing a diagnostic center, which is defined as

a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C. Gen.Stat. § 131E-176(7a) (2003).

Because a CT scanner is considered medical diagnostic equipment, the Agency found that

the utilization of any medical diagnostic equipment, including a diagnostic CT scanner, which cost in excess of \$500,000, would cause Asheville Hematology to be a diagnostic center, which is a new institutional health service. Because Asheville Hematology is not currently a diagnostic center, it would not be able to acquire a diagnostic CT scanner without a CON, if the cost to acquire and make operational the CT scanner and the cost of any other medical diagnostic equipment currently utilized or proposed to be utilized at the facility would exceed \$500,000....

\*176 The Agency determined the total cost to acquire and make operational the CT scanner to be \$488,547.62. Because

the total cost was less than \$500,000, the Agency concluded that the acquisition of the CT scanner did not require a CON. The Agency made the following findings of fact with regard to the costs associated with the CT scanner:

310. ... [T]he final purchase price for the diagnostic CT scanner of \$308,500 is reasonable and supported by the preponderance of the evidence.

311. Mr. Royal's and Mr. Kury's<sup>7</sup> estimates and allocations of total construction costs related to the CT scanner as presented at the hearing properly included the construction of all space essential to the installation and operation of the CT scanner. Petitioners were given a thorough opportunity to cross examine Mr. Royal and Mr. Kury on the bases for those estimates, and the witnesses were able to demonstrate that all of the essential construction costs were included and supported by back-up documentation.

312. Further, ... equipment used for simulation which is not essential to the performance of diagnostic CT scans should not be included in the \$500,000 diagnostic center cost threshold, because such equipment is not medical diagnostic equipment within the meaning of the CON Law.

313. Asheville Hematology's estimate of equipment and other costs essential to the operation of the CT scanner as presented at the hearing properly identified all such essential equipment, and the cost attributed to that equipment was reasonable.

314. The preponderance of the evidence demonstrates that the actual cost to acquire and make operational the Asheville Hematology diagnostic CT scanner will not exceed \$500,000.

The above findings of fact support the Agency's conclusion that AHO's acquisition of the CT scanner did not require a CON. Petitioners, however, argue that several necessary costs were excluded from the Agency's determination, and that had any of these costs been included, the cost of the CT scanner would have exceeded the \$500,000 threshold. Among these excluded costs are: (1) the entire cost of CT diagnostic contrast equipment valued at \$21,000; (2) presently owned diagnostic equipment totaling \$20,598; (3) the cost of constructing the CT room and control room totaling \$118,745 or alternatively \$104,716; and (4) the portion of the capital lease attributable to the CT scanner valued at \$165,156. We address each of these contested items below.

#### *A. Total Cost of CT Diagnostic Contrast Equipment*

16 Included in the cost of the CT scanner was certain used diagnostic contrast equipment. This equipment was to be transferred from another US Oncology facility to AHO's new facility. The Agency found that

this equipment is fully depreciated and has no market value, because there is not a secondary market where it could be sold. Asheville Hematology's estimate of 40% [of the original cost of the equipment] was a conservative estimate of the equipment's value. In reality, if it could not be relocated to another US Oncology facility, it would be thrown away.

Thus, the Agency allocated \$8,400, or 40% of the original price of \$21,000, to the CT scanner for this diagnostic contrast equipment.

Petitioners argue that the entire \$21,000 should have been allocated to the CT scanner. This would add \$12,600 to the total cost of the CT scanner, bringing the total cost of the CT scanner to \$501,147.62, which is in excess of the \$500,000 CON threshold.

N.C. Gen.Stat. § 131E-176(7a) provides that "[t]he capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater." N.C. Gen.Stat. § 131E-176(7a). Petitioners contend that for purposes of the statute, "the cost" of the diagnostic contrast equipment was the cost of the equipment when it was originally purchased, \$21,000, which was greater than the fair market value of the equipment, \*177 \$8,400. Thus, Petitioners argue that the Agency erroneously excluded \$12,600 from its calculation of the total cost of the CT scanner. We are not persuaded by Petitioners' argument.

The diagnostic contrast equipment to be used with the CT scanner was estimated to be three to four years old and had fully depreciated by the time it was acquired by AHO. The equipment was estimated to be worth 40% of the cost of purchasing new equipment, and the Agency found that the equipment had no market value because there was no secondary market in which it could be sold. Thus, "the greater" of the cost or fair market value of the used diagnostic contrast equipment was properly determined to be \$8,400, which was properly allocated to the cost of the CT scanner.

### *B. Presently Owned Diagnostic Equipment*

17 At AHO's existing facility, AHO housed a type of diagnostic equipment called a "Coulter counter," which AHO purchased in 2003 for \$20,598. Petitioners argue that the Agency erroneously excluded this amount from the total cost of the CT scanner. Petitioners, however, have identified no evidence, nor have they argued, that this piece of equipment was essential to acquiring and making operational the CT scanner. Thus, we cannot conclude that the Agency erred in excluding the presently owned diagnostic equipment from the cost of the CT scanner.

### *C. Construction Costs for the CT Room*

18 The Agency found that "Mr. Royal's and Mr. Kury's estimates and allocations of total construction costs related to the CT scanner as presented at the hearing properly included the construction of all space essential to the installation and operation of the CT scanner." The Agency further found that "Petitioners were given a thorough opportunity to cross examine Mr. Royal and Mr. Kury on the bases for those estimates, and the witnesses were able to demonstrate that all of the essential construction costs were included and supported by back-up documentation." Petitioners now contend that construction costs for the CT room and control room were erroneously omitted from the total cost of the CT scanner. Petitioners fail to demonstrate, however, that the Agency's findings were in error, and argue only that "[n]one of these spaces would be necessary except for the CT [scanner]." Petitioners have not shown that either the CT room or the control room was essential to the installation and operation of the CT scanner. Accordingly, the construction costs for these spaces were properly omitted from the determination of the total cost of the CT scanner.

### *D. Portion of Building Lease Attributable to CT Scanner*

19 Petitioners also argue that a portion of AHO's lease of its new facility should be allocated to the CT scanner. Petitioners' argument is based on their incorrect assumption that AHO's lease was a capital lease. As we discuss *infra*, AHO's building lease is an *operating* lease, not a *capital* lease, which is not subject to CON review. Thus, no part of AHO's lease was attributable to the CT scanner and this was properly excluded.

Based on the foregoing, we conclude that the Agency correctly determined that AHO's acquisition of a CT scanner

for its new facility did not require a CON. Petitioners' argument is overruled.

### *IV. Expansion of Oncology Treatment Center*

Petitioners also argue that the Agency erroneously concluded that AHO's expansion of its existing oncology treatment center was exempt. We disagree.

#### *A. Physician Office Building*

20 AHO was formed in 1982 to engage in the practice of medical oncology. Thus, AHO was in existence as a physician practice specializing in oncology 11 years prior to the 1993 enactment of the CON requirements for new oncology treatment centers, diagnostic centers, and acquisition of major medical equipment. In 1984, the physician owners of AHO formed a partnership<sup>8</sup> in order to purchase \*178 real estate in Asheville, North Carolina, construct a building for a medical oncology practice ("the Facility"), and lease the Facility to AHO. In its 1 February 2005 letter, AHO informed the Agency that AHO had entered into a tentative lease agreement with CC Asheville MOB<sup>9</sup> to relocate the Facility to a new building which was constructed by CC Asheville MOB. CC Asheville MOB incurred all construction costs and would maintain ownership of the new building while AHO leased its space pursuant to an operating lease.

It is undisputed that AHO is an oncology treatment center within the meaning of N.C. Gen.Stat. § 131E-176(18a). The Agency found that because of this, AHO is an existing health service facility. The Agency further found that

[u]nder the law applicable to the CON Section's Determination, an existing oncology treatment center may relocate its oncology treatment center and acquire certain items of medical equipment without obtaining a certificate of need, so long as the cost to acquire and make operational each unit of equipment does not exceed \$750,000, and so long as the combination of the costs to acquire and make operational all such equipment and all other costs related to relocating the oncology treatment center, do not exceed \$2,000,000.

Thus, the Agency treated AHO's expansion and relocation of its office building as a "physician office building" which does not require a CON so long as the total cost of expansion and relocation of said office building does not exceed \$2,000,000. See N.C. Gen.Stat. § 131E-176(16)b. and 184(a)(9) (2003).

21 Petitioners, however, argue that because AHO was an existing oncology treatment center, AHO's expanded and relocated office building must be treated as a "health service facility," defined by N.C. Gen.Stat. § 131E-176(9b), rather than an unregulated "physician office building." If AHO's new office building was deemed a "health service facility," the entire cost of the land and building for the relocated AHO office would be included as a "capital expenditure" which would count toward the expansion of an oncology treatment center. Thus, no part of AHO's project would be exempt under the "physician office building" exemption. Petitioners' argument is contrary to the CON Law, however. The CON Law provides that an exempt physician office building may include certain non-exempt portions, such as an oncology treatment center, which is the case here.

N.C. Gen.Stat. § 131E-184(a)(9) provides in pertinent part that

the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required.... [t]o develop or acquire a physician office building regardless of cost, unless a new institutional health service other than defined in G.S. 131E-176(16)b. is offered or developed in the building.

N.C. Gen.Stat. § 131E-184(a)(9) (2003). If another type of "new institutional health service" is developed in the building, N.C. Gen.Stat. § 131E-184(b) nonetheless preserves the exemption for the physician office building while allowing regulation of the nonexempt portions.

Those portions of a proposed project which are not proposed for one or more of the purposes under subsection (a) of this section are subject to certificate of need review, if these non-exempt portions of the project are new institutional health services under G.S. 131E-176(16).

\$ 381,135.62	Costs of the treatment planning equipment
\$ 488,547.62	Costs of the CT simulator equipment
\$ 746,416.62	Costs of the linear accelerator equipment
\$ 364,301.00	Costs of the construction/relocation (in letter dated 2/01/05)
\$ 1,500.00	Costs of the view boxes (in letter dated 6/16/05)
\$ 4,277.62	Costs for 1/4 of staff effort (in letter dated 7/11/05)
(\$ 900.00)	Less 1/4 of legal fees for no review prep (in letter dated 7/26/05)
<hr/>	
\$1,985,278.49	Total costs

N.C. Gen.Stat. § 131E-184(b) (2003).

The physician office building exemption applies to (1) developing or acquiring a physician office building regardless of cost, and (2) offering or developing "in the building" a new institutional health service as defined by \*179 N.C. Gen.Stat. § 131E-176(16)b. Thus, the following projects in a physician office building are exempt:

[t]he obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

N.C. Gen.Stat. § 131E-176(16)b. (2003).

22 Reading N.C. Gen.Stat. §§ 131E-176(16)b., 184(a)(9), and 184(b) together, the CON Law therefore exempts "a capital expenditure ... to develop or expand a health service or a health service facility, or which relates to the provision of a health service[.]" N.C. Gen.Stat. § 131E-176(16)b., if it is "in the [physician office] building." N.C. Gen.Stat. § 131E-184(a)(9). Accordingly, the Agency here considered the equipment which would expand the services of the oncology treatment center—the LINAC, the CT scanner, and the treatment planning equipment. The Agency found that

[t]he CON Section's "no review" determination for relocation of the existing oncology treatment center, including the acquisition of the radiation oncology treatment equipment, attributed the following activities for purpose of determining the applicability of CON review:



Thus, the Agency properly focused on whether the costs *essential* to acquiring this equipment and making it operational exceeded the \$2,000,000 threshold, and excluded the part of the project that was exempt as a physician office building. The Agency defines "essential" to mean "those items which are indispensable, the absence of which renders the equipment useless." N.C. Admin. Code tit. 10A, r. 14C.3102(1) (January 1994). The Agency's definition of "essential" as applied to major medical equipment has been in effect since 1993 and has not been modified by the General Assembly which suggests agreement with the Agency's interpretation. Further, the Agency's interpretation is consistent with the General Assembly's intention because Agency

micro-management over relatively minor capital expenditures ... does not effectuate the overriding legislative intent behind the CON process, *i.e.*, regulation of major capital expenditures which may adversely impact the cost of health care services to the patient.... Nevertheless, the legislature clearly did not intend to impose unreasonable limitations on maintaining ... or expanding ... presently offered health services.

*Cape Fear Mem. Hosp.*, 121 N.C.App. at 494, 466 S.E.2d at 301. Accordingly, Petitioners' argument is overruled.

### B. Building Lease

23 Petitioners also argue that AHO's lease of the building which was to house AHO's relocated oncology treatment center was a capital lease, and thus it was a capital expenditure which should be counted toward the \$2,000,000 threshold pursuant to N.C. Gen.Stat. § 131E-176(16)b. We disagree.

In its FAD, the Agency explained that under generally accepted accounting principles ("GAAP"), a building lease may be classified as an operating lease or a capital lease, depending upon certain circumstances. A capital lease is treated differently on a company's books than an operating lease. A capital lease is considered a financing arrangement under GAAP, such that it is an asset in the balance sheet of the lessee, with an off-setting debt in the balance sheet liabilities.

\*180 An operating lease, however, would not be shown in the balance sheet. Rather, the expense of an operating lease would be shown in the company's income statement.

On 6 June 2005, AOR Management, a subsidiary of US Oncology and managing agent for AHO, entered into a

lease with CC Asheville MOB, for a building and the land on which it was located to be used for its oncology treatment center. On 2 September 2005, AOR Management and CC Asheville MOB entered into a "First Amendment to Lease Agreement[.]" In its FAD, the Agency found that at the time the lease and the first amendment were executed, US Oncology believed the lease to be an operating lease. However, Kevin Krenzke ("Krenzke"), a certified public accountant and Vice President and Controller of US Oncology, later concluded that under GAAP, the lease and first amendment constituted a capital lease.

On 31 March 2006, AOR Management and CC Asheville MOB entered into a "Second Amendment to Lease Agreement[.]" in which the parties renegotiated the lease in a manner that changed the minimum lease payments. Krenzke applied GAAP, and concluded that the second amendment was an operating lease.

The Agency's findings in the FAD establish that AHO's lease is an operating lease and not a capital lease. Specifically, the Agency made the following pertinent findings:

281. Under FASB 13, a lease would be a capital lease if (a) the lease transfers ownership of the property at the end of the term; (b) the lease contains a bargain purchase option; (c) the lease term is equal to 75% or more of the estimated life of the leased property; or (d) the present value at the beginning of the lease term of the minimum lease payments equals or exceeds 90% of the fair market value of the leased property....

....

283. Centex-Concord, the parent company of CC Asheville MOB, is a development company engaged in the primary business of constructing, owning, leasing, and selling real estate development properties. As such, it meets the definition of a manufacturer for determining the fair market value of the property. For the same reason, the value defined in an appraisal would be the proper basis for determining whether a lease for property developed by Centex-Concord is a capital lease or an operating lease under the 90% test....

284. An appraisal of the property owned by CC Asheville MOB was conducted by Fred H. Beck and Associates ("Beck") in August 2005. Beck appraised the fair market value of the leased property as \$8,500,000....

....

288. At the time the Lease and the First Amendment were executed, it was US Oncology's understanding that the Lease was an operating lease. After the First Amendment was executed, it and the Lease were submitted by US Oncology's capital planning group to Mr. Krenzke in his financial reporting capacity, to confirm whether or not that conclusion was correct. By the time his analysis was completed, he concluded that the Lease and the First Amendment as structured constituted a capital lease....

....

290. [Because US Oncology prefers all leases to be operating leases,] US Oncology and Centex-Concord renegotiated the Lease so that the minimum lease payments were changed under the Second Amendment. Instead of a 2.5% annual increase in the minimum rental payment, the annual increase would be tied to the Consumer Price Index ("CPI"), with a minimum annual increase of 1% and a maximum annual increase of 4%....

....

296. For purposes of determining whether the Second Amendment is a capital lease, it is appropriate to value the property at \$8,500,000, as per the Beck appraisal. The preponderance of the evidence shows that the terms of the Second Amendment would not cause the appraised value in the Beck appraisal to decrease.

297. Further, under the Second Amendment, the present value at the beginning of the lease term of the minimum lease payments \*181 would be calculated under GAAP based upon a 1% annual increase. Using those assumptions, the present value at the beginning of the lease term of the minimum lease payments would be less than 90% of the fair market value of the leased property.... *Therefore, the Second Amendment is an operating lease.*

(Emphasis added).

Petitioners argue that for purposes of the CON Law, AHO incurred the expense of the lease when it first entered into the lease on 6 June 2005. Thus, Petitioners contend that when deciding whether AHO's lease constituted a capital expenditure, the Agency should have looked at the initial lease—a *capital* lease—which, by its nature, constituted a capital expenditure. We disagree.

N.C. Gen.Stat. § 131E-176(16)b. requires a CON for a capital expenditure exceeding \$2,000,000. The CON Law defines a "capital expenditure" as

an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. *Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase.*

N.C. Gen.Stat. § 131E-176(2d) (2003) (emphasis added). Furthermore, the Agency found that a capital lease would not be "an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment," N.C. Gen.Stat. § 131E-176(2d), and therefore would not be a capital expenditure under N.C. Gen.Stat. § 131E-176(2d), because it is not a lease of equipment. Thus, even assuming *arguendo* that AHO's lease constituted a capital lease, it would not have been a capital expenditure for purposes of the CON Law. Accordingly, Petitioners' argument is overruled.

### C. Staff Costs

24 Petitioners argue that staff costs which were attributable to the relocation and expansion of AHO's oncology treatment center were erroneously excluded in the CON determination. We disagree.

The Agency considered AHO's staff costs irrespective of the relocation and expansion of its oncology treatment center and determined that AHO did not incur any additional staff costs as a result of its project. The Agency made the following findings of fact:

216. In its July 11, 2005 letter, Asheville Hematology provided documentation of \$17,110.49 in internal staff costs as of that date....

....

221. Ultimately, the evidence offered indicated that all actual internal staff costs incurred by Asheville Hematology/US Oncology to date, along with the prospective staff costs reasonably anticipated to be incurred prior to the treatment of the first patient at the new Asheville Hematology facility, total \$30,402.41....

....

227. All the foregoing staff members were salaried employees of Asheville Hematology/US Oncology and that no additional cost was incurred as a result of their efforts in furtherance of the project. Their salaries would have been paid irrespective of the Asheville Hematology Project....

228. Neither G.S. § 131E-176(7a) ("diagnostic centers") nor G.S. § 131E-176(14d) ("major medical equipment") specifically includes staff costs among the costs which are deemed essential to the operation of that equipment. Only G.S. § 131E-176(16)b ("New Institutional Health Service" / \$2 million total capital expenditure) specifically mentions staff costs in the cost threshold determination.

229. [Lee] Hoffman stated, however, that in her opinion these staff costs were nonetheless attributable to the linear accelerator, the CT scanner, the treatment planning equipment, and total capital costs for the Asheville Hematology Project, despite the fact that no additional cost was incurred \*182 by Asheville Hematology/US Oncology as a result of their efforts in furtherance of the project....

230. Furthermore, Ms. Hoffman admitted that, in numerous prior no-review determinations, the Agency had not included the cost of internal staff time in furtherance of a project in the total capital costs essential to making a health service operational....

231. In light of the foregoing, there were no staff costs, above and beyond staff costs which would have otherwise been incurred by Asheville Hematology or US Oncology irrespective of the Asheville Hematology Project, and therefore, there were no additional capital costs attributable to the Asheville Hematology Project, for the efforts of salaried staff in furtherance of the Asheville Hematology Project.

232. Notwithstanding this fact, even if costs related to the efforts of salaried staff in the employ of Asheville Hematology or US Oncology in furtherance of the Asheville Hematology Project are attributable, the allocations of the staff costs associated with the development of the Asheville Hematology Project are reasonable in light of the evidence adduced.

Petitioners contend that the Agency erroneously excluded the \$30,402.41 AHO reported in internal staff costs as of 11 July 2005 from its CON determination. Petitioners do not, however, demonstrate that the Agency's findings were unsupported by substantial evidence or otherwise erroneous, and thus, this argument is overruled.

#### *V. Certified Cost Estimate*

Under the CON Law, if a licensed architect or engineer provides a valid cost estimate and certifies that the costs contained in the estimate are "equal to or less than the expenditure minimum for capital expenditure for new institutional health services, such expenditure shall be deemed not to exceed the amount for new institutional health services regardless of the actual amount expended," provided that the following requirements are met: (1) the licensed architect or engineer must certify the costs; (2) the certified cost estimate must be issued in writing at least 60 days before the obligation for the capital expenditure is incurred; and (3) the proponent must notify the Agency in writing within 30 days of any expenditure that exceeds the expenditure minimum. N.C. Gen.Stat. § 131E-178(d) (2003).

As part of its 1 February 2005 submission to the Agency, AHO provided an architect's estimate of the expected costs and a series of cost breakdowns for the proposed cancer center. AHO provided a letter and supporting materials from the licensed architect responsible for the design and management of the project as a certified estimate of the construction costs with the attached cost breakdowns. AHO's architect estimated the costs for the project to be less than the applicable thresholds in the CON Law.

Petitioners argue that AHO's estimate did not qualify as a certified estimate under section 131E-178(d). The Agency did not ultimately decide whether the estimate provided by AHO's architect qualified as a certified cost estimate under this section, because the Agency found that the evidence established that the actual construction costs for the project would not exceed the relevant cost thresholds in the CON Law. Thus, the Agency found that section 131E-178(d) was not applicable in this instance. In light of the Agency's finding and based on our holding that the Agency properly determined the AHO project did not require a CON, we need not decide whether AHO's cost estimate constituted a certified cost estimate under section 131E-178(d).<sup>10</sup>

*Conclusion*

AFFIRMED.

For the foregoing reasons, we affirm the Final Agency Decision adopting the recommended decision of the Administrative Law Judge.

Chief Judge MARTIN and Judge HUNTER, JR. concur.

Footnotes

- 1 Since the entry of our Court's decision in *Mission I*, the name of Respondent North Carolina Department of Health and Human Services, Division of Facility Services, Certificate of Need Section has been changed to "North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section."
- 2 See N.C. Gen.Stat. § 131E-176(7a) (2003) (governing diagnostic centers).
- 3 See N.C. Gen.Stat. § 131E-176(14f) (2003) (governing acquisition of major medical equipment).
- 4 *Id.*
- 5 See N.C. Gen.Stat. § 131E-176(16) (2003) (governing capital expenditures).
- 6 The cost of acquiring the image intensifier and cine camera was found to be \$232,510. *Id.* at 495, 466 S.E.2d at 301. In the present case, the fair market value of the record and verify system was found to be \$230,000.
- 7 "Mr. Kury" refers to Mark Kury, Vice President of Centex-Concord, the developer of the AHO project.
- 8 The partnership formed by the physician owners of AHO is Paschal, Jackson, Puckett and Davis General Partnership.
- 9 In AHO's 1 February 2005 letter to the Agency, the building developer and owner is referred to as "Centex Development Company." In the Agency's FAD, CC Asheville MOB is referred to as the owner of AHO's new facility. CC Asheville MOB is a subsidiary of Centex-Concord, and while it appears that Centex-Concord is affiliated with Centex Development Company, the record does not confirm this relation.
- 10 Nonetheless, it is obvious from the Agency's findings set out above, which are supported by substantial evidence in the record, that Petitioners' argument lacks merit.

End of Document

© 2011 Thomson Reuters. No claim to original U.S. Government Works.