

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 29, 2013

PROJECT ANALYST: Fatimah Wilson

SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: F-10155-13 / The Charlotte-Mecklenburg Hospital Authority  
d/b/a Carolinas Medical Center-NorthEast / Replace an existing  
linear accelerator / Cabarrus County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

### C

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center-NorthEast (CMC-NE) proposes to replace an existing linear accelerator to be located in the same vault as the existing equipment. The proposed project will include 3,922 square feet of basic renovations in the current radiation therapy department. The equipment is currently located in the Batte Cancer Center on the hospital campus and provides radiation therapy services to both inpatients and outpatients. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP).

However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 43 of the 2013 SMFP, is applicable to the review of this proposal. Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*”

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

In Section III.2, pages 41-42, the applicant state:

*“CMC-NE has designed the proposed equipment replacement project to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including Policy GEN-4. The building codes apply to systems and equipment for electrical power, lighting, heating, ventilating, air condition service, energy management, water heating and water conservation. Water conservation design standards include the use of low-flow fixtures and low-flow toilets throughout the facility. The hospital facility was constructed to ensure energy efficiency and cost effective utilities. CMC-NE will closely monitor its utility usage and costs in order to maintain efficient and environmentally responsible energy operations. CMC-NE will also follow the status of deregulation in the utility industry in an effort to obtain the most cost effective utilities available.*

*More generally, all CHS facilities, including CMC-NE, are committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities served. In this regard, CHS has several guiding principles:.*

- 1. Implement environmental sustainability to improve and reduce our environmental impact.*
- 2. Integrate sustainable operation and facility best practices into existing and new facilities.*
- 3. Encourage partners to engage in environmentally responsible practices.*
- 4. Promote environmental sustainability in work, home and community.*
- 5. Deliver improved performance to provide a long term return on investment that supports our mission and values.*

*CHS employs a Facility Management Group with experienced, highly trained and qualified architects, engineers, project managers, tradesmen and technicians, who design, construct, operate and maintain CHS facilities. Hospital equipment is maintained on a computerized preventive maintenance schedule and monitored using integrated building control systems. CHS's multi-disciplinary team participates during planning and design to ensure that new systems and components incorporate demonstrated best practices as well as to recommend new and improved practices.*

*CMC-NE will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project, to the degree appropriate with the proposed renovations. The design team for the proposed project has Energy Star Leadership in Energy and Environmental Design (LEED) and Hospitals for a Healthy Environment Green Guide for Healthcare (GGHC) experience. Together the team seeks to deliver the following:*

- Meet or exceed the requirements of the NC Building Code in effect when construction drawings are submitted for review to the DHSR Construction Section.*
- Use EPA Energy Star for Hospitals rating system to compare performance across CHS, North Carolina, and the United States following 12 months of continuous operation.*
- Refer to USGBC LEED guidelines and Hospitals for a Healthy Environment Green Guide for Healthcare (GGHC) to identify opportunities to improve efficiency and performance.*
- Design for maximum efficiency and life cycle benefits within each impacted mechanical system: heating, cooling, water and sewer.”*

The application is consistent with Policy GEN-4 and conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center-NorthEast (CMC-NE) proposes to replace an existing linear accelerator to be located in the same vault as the existing equipment. The proposed project will include 3,922 square feet of basic renovations in the current radiation oncology department. The equipment is currently located in the Batte Cancer Center on the hospital campus

and provides radiation therapy services to both inpatients and outpatients. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP). In Section II.1, pages 15-16, the applicant discusses the components of the proposed project, briefly described below:

- CMC-NE proposes to replace an existing linear accelerator, which was purchased in 1999, with a new system;
- CMC-NE proposes 3,922 square feet of basic renovations in the current radiation therapy department; and
- CMC-NE will upgrade the finishes within the vault and control area.

Population to be Served

In Section III.5(a), page 47, the applicant states:

*“The primary service area for CMC-NE’s radiation therapy services is Cabarrus County. The secondary service area includes Rowan and Stanly counties. The rationale for establishing this service area is based on the historical patient origin for CMC-NE radiation therapy patients, as provided in Section III.4(b). Historically, the counties in the primary and secondary service areas account for over 90 percent of CMC-NE’s linear accelerator patient origin.”*

The following table illustrates historical and projected patient origin for linear accelerator services at CMC-NE for the first two operating years of the project, as reported by the applicant in Section III.4(b), page 46, and Section III.5(c), page 48.

<b>CMC-NE Linear Accelerator Historical Patient Origin, FY 2012</b>		<b>CMC-NE Linear Accelerator Projected Patient Origin, FY 2015-2016</b>
<b>County</b>	<b>% of Total</b>	<b>% of Total</b>
Cabarrus	65.8%	69.5%
Rowan	15.8%	18.1%
Stanly	9.3%	5.1%
Mecklenburg	5.8%	4.2%
Other*	3.2%	3.2%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>

Source: CMC-NorthEast

Totals may not foot due to rounding

\*Other includes <0.1% patient origin from each of Anson, Catawba, Davie, Gaston, Iredell, Lincoln, Montgomery, Scotland, Union, Watauga, and Wilson counties in North Carolina and other states.

The applicant states that the projected patient origin is consistent with CMC-NE’s historical experience. Projected patient origin for the initial three project years is

slightly different compared to FY2012 patient origin because FY2-12 patient origin was impacted by SRMC's replacement linear accelerator project. SRMC's linear accelerator replacement project was completed in fall 2012. The applicant states that the patient origin patterns at CMC-NE have resumed to those similar to FY2010 (68.0%) and FY2011 (70.9%). Thus, for the purposes of projecting linear accelerator patient origin for the proposed project, CMC-NE utilized the average FY2010-FY2011 linear accelerator patient origin by county.

### Access

In Section VI, pages 64-74, the applicant describes how residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicant states:

*“CMC-NE will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

The applicant adequately identified the population they propose to serve.

### Need for the Proposed Project

The applicant states the unmet need that necessitates the proposed project is primarily qualitative, involving the need of patients and physicians for updated equipment, which directly impacts the ability of the hospital to provide the best possible care in the most efficient manner. In Section III.1, pages 27-40, the applicant states the factors contributing to the need to replace the existing equipment, including:

- The existing equipment is technologically obsolete;
- The existing equipment is not longer the clinical standard of care;
- The proposed population growth of the service area;
- The proposed growth of cancer incidence rates for the service area; and
- The proposed growth of future radiation therapy utilization.

### Existing Linear Accelerator

The proposed project seeks to replace one CMC-NE's existing linear accelerators currently located in Treatment Room A of the hospital's radiation oncology department. The existing Varian 23EX linear accelerator was purchased in 1999. The applicant states that the unit has far exceeded its depreciable useful life of five years according to the American Hospital Association. On page 38, the applicant states,

*“Furthermore, the need for the proposed project is primarily qualitative in nature based on the age and limitations of the existing equipment.”* While the equipment was considered state-of-the-art at the time of purchase, the applicant states that there have been numerous advancements in radiation therapy technology during the past 14 years. The applicant states that the age and specifications of the existing linear accelerator are such that it is not possible to upgrade the equipment to be compatible with new radiation therapy innovations.

On page 28, the applicant states,

*“In addition to technologic limitations, the age of the existing linear accelerator limits CMC-NE’s ability to provide an efficient radiation therapy service because treatment times are significantly longer compared to current technology.”*

The applicant states that in addition to the length of treatment times, CMC-NE is also limited by the downtime associated with the aged linear accelerator. This can result in an interruption of service which is not ideal from a clinical or patient perspective. The applicant states that CMC-NE’s Batte Cancer Center is the only comprehensive community cancer center approved by the American College of Surgeons in the North Charlotte Region. Thus, the applicant states that it is imperative that CMC-NE invest in current, state-of-the-art technology that will efficiently and most effectively meet the radiation therapy needs of its cancer patients.

#### Proposed Replacement Linear Accelerator

In Section III.1(a), page 29, the applicant states that the proposed acquisition of a TrueBeam platform linear accelerator from Varian Medical Systems will significantly upgrade the clinical treatment capabilities available to patients treated at CMC-NE and helps achieve the goals of increased accuracy, increased throughput, enhanced patient safety, an improved patient experience and greater physician and patient satisfaction. In addition, on pages 29-32, the applicant states:

#### *“Image-Guided Radiotherapy*

*IGRT gives the necessary assurance to allow treatment planners the freedom to create tighter treatment portal margins that conform to tumor margins, increasing the potential to deliver increased radiation doses with less damage to healthy tissues. With IGRT, radiation oncology clinicians possess tools that can better account for the uncertainties involved in setting up patients for fractionated radiation delivery. Additionally, IGRT allows for the monitoring of changes in tumor position due to the normal physiological motion of the body’s organs.*

#### *Rapid Arc*

*The RapidArc VMAT delivery mode available on the True Beam enables clinicians to program the linear accelerator to deliver radiation to the tumor as the machine moves*

*around the patient in a single, continuous 360 degree rotation. This advanced technology allows three factors to be adjusted simultaneously during therapy: 1) the rotation speed of the equipment (gantry speed), 2) the shape of the radiation beam (aperture shape), and 3) the rate at which the dose is delivered. Such capability enables the linear accelerator to provide IMRT quality dose distributions in a single optimized arc delivery around the patient in less than two minutes.*

...

*Overall, the entire treatment time will significantly decrease, from approximately 20 to 30 minutes to 10 minutes with the RapidArc.”*

### Improved Accuracy

In Section III.1 page 31, the applicant states that the proposed equipment was developed to deliver powerful cancer treatments with pinpoint accuracy and precision. On pages 31-32, the applicant describes how the new system addresses the technical challenges of four common cancer types: head and neck, breast, lung, and prostate. The applicant states:

#### *“Head and Neck*

- *Multiple arcs, partial arcs or a combination can be planned and seamlessly delivered using RapidArc radiotherapy technology*
- *A range of diagnostic imaging studies can be introduced in treatment planning to assist in accurate contouring of the target*
- *The real-time control system synchronizes and choreographs all elements of delivery 10 times per second*
- *Imaging hardware and software allow capture of high-quality cone-beam CT images with lower concomitant dose*
- *Integration of SmartAdapt<sup>TM</sup> deformable registration algorithms provide convenient means for clinicians to account for anatomical changes during the course of treatment*

#### *Breast*

- *IMRT tools such as field-in-field help create treatment plans designed to minimize radiation exposure of the heart and healthy lung tissue*
- *Noninvasive high tech surveillance synchronized to patient breathing to spare critical structures*
- *Treat patients in the prone position using the Pivotal<sup>TM</sup> treatment solution for prone breast care to help minimize dose to critical structures such as the heart and lung*
- *Transponder for real-time deep inspiration breath hold to help ensure accuracy*
- *Integration of technologies such as real-time beam gating on a respiratory trigger can allow the reduction of treatment when compared to a full ITV-based treatment*

*Lung*

- *To reduce discrepancies between planned dose and delivered dose, Varian’s Acuros® algorithm provides Monte Carlo equivalent dose calculations*
- *Contour propagation, intermediate dose calculation and a fine calculation grid all contribute to create an efficient and desired treatment plan*
- *Respiratory gating allows the reduction of irradiated volumes when compared with large ITV-based approaches*
- *Fluoroscopic, KV, MV and CBCT, along with the capability to mix and match from the menu of imaging possibilities, allow clinicians to tailor treatment delivery*
- *2400 MU/minute, the highest dose rate in the industry, allows rapid delivery of large fractions*

*Prostate*

- *Using SmartSegmentation™ knowledge-based contouring, physicians can take advantage of built-in expert cases, or create their own expert cases to standardize treatment across the institution*
- *Deliver treatment with speed and accuracy using RapidArc® radiotherapy technology and Eclipse™ treatment planning system*
- *Deliver fast hypofractionated prostate SBRT treatments using High Intensity Mode at 1400 MU/minute or 2400 MU/minute*
- *Track and correct, in real time, prostate drift and sporadic motion with Varian Calypso® technology for prostate”*

Cabarrus County Population

In Section III.1(a), pages 33-35, the applicant states that CMC-NE’s need to replace its existing outdated equipment is also supported by population growth and aging which drives increased utilization of healthcare services. On page 33, the applicant states:

*“According to the North Carolina Office of State Budget & Management (NCOSBM), Cabarrus County experienced the seventh highest rate of growth in North Carolina during 2000 to 2010. During the first decade of 2000, the local population grew over 35 percent. ...*

*Cabarrus County is projected to continue to grow at a faster rate compared to the State overall. Please refer to the following table.*

**Cabarrus County  
 Projected Population**

	2013	2014	2015	2016	2017	4-Yr CAGR
<b>Cabarrus Co.</b>	186,531	189,499	192,468	195,435	198,404	<b>1.6%</b>
<b>North Carolina</b>	9,873,948	9,980,919	10,087,832	10,196,150	10,303,787	<b>1.1%</b>

Source: NCOSBM



*Cabarrus County projects to remain in the top 20 fastest growing counties in North Carolina during the next four years. According to NCOSBM projections, Cabarrus County will continue to grow at a compound annual growth rate of 1.6 percent per year, or 11,873 additional residents, from 2013 to 2017. Thus, the need for the proposed project is supported by the steady projected growth of the service area.*

*As described previously, cancer incidence increases with age. The Cabarrus County population age 65 and older is also projected to grow each year as seen in the following table.*

**Cabarrus County  
 Population Age 65+**

	<b>2013</b>	<b>2017</b>	<b>4-Yr CAGR</b>
<b>Total Population</b>	186,531	198,404	1.6%
<b>Population Age 65+</b>	22,716	26,136	3.3%

Source: NCOSBM

*The service area population age 65 and older is projected to increase over two times faster compared to the overall service area population. Thus, as the aging population continues to rapidly increase, the demand for radiation therapy services will continue to increase. ...”*

The applicant states that as a result of population growth and aging in Cabarrus County, the demand for healthcare services is expected to increase, thus, CMC-NE must prepare for this projected population growth and aging, particularly as it relates to the provision of radiation therapy.

Cancer Incidence Rates

On page 35, the applicant states that according to the Centers for Disease Control and Prevention (CDC), cancer was the second leading cause of death in the United States and the leading cause of death in North Carolina in 2011.<sup>1</sup> According to the 2009 North Carolina Central Cancer Registry, cancer was the leading cause of death in North Carolina. The cancer incidence rate in Cabarrus County was also higher overall compared to North Carolina. The applicant states that CMC-NE’s prestigious status as a leading cancer provider is driven by its mission to provide much needed cancer treatment services to a population of patients in need of such services.

**Cabarrus County  
 2006-2010 Cancer Incidence Rates per 100,000**

	<b>Colon</b>	<b>Lung</b>	<b>Breast</b>	<b>Prostate</b>	<b>All Cancers</b>
Cabarrus County	43.6	82.9	161	186.6	558.7

<sup>1</sup> Center for Disease Control and Prevention website: [www.cdc.gov/nchs/fastats/deaths.htm](http://www.cdc.gov/nchs/fastats/deaths.htm).

North Carolina	43.4	74.8	155.9	153.7	498.1
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Source: NC Central Cancer Registry

The applicant states that as a result of the aging population in Cabarrus County, the incidence of cancer is also expected to increase, thus, CMC-NE must prepare for this projected population growth and aging, by increasing demand for radiation therapy services at CMC-NE.

Methodology and Assumptions

In Section III.1(b), pages 38-40, the applicant describes the assumptions and methodology used to project future linear accelerator volume as described below.

- The applicants begin with the historical utilization of CMC-NE’s two existing linear accelerators;

**CMC-NorthEast  
 Historical Linear Accelerator Utilization**

	FY2009	FY2010	FY2011	FY2012	FY2013*
Linear Accelerator Procedures	12,317	12,109	12,900	14,666	13,859
Linear Accelerator ESTVs	11,348	11,195	11,899	13,532	12,887

\*Annualized based on eight months data (Oct 12-May 13)

Source: CMC-NorthEast, 2011-2013 SMFP

- Base volume begins with 2013 annualized linear accelerator procedure volume (13,859) based on eight months data (Oct 12-May13);
- Volume growth is projected at 0.8% percent (one half the projected population 4-Yr CAGR for Cabarrus County) for interim project year (FY2014) and 1.6% (projected population 4-Yr CAGR for Cabarrus County) for the first three full project years (FY2015-FY2017);
- Base volume for ESTV projections begins with 2013 annualized ESTV volume (12,887) based on eight months of data (Oct 12-May 13);
- Volume growth is projected at 0.8% percent (one half the projected population 4-Yr CAGR for Cabarrus County) for interim project year (FY2014) and 1.6% (projected population 4-Yr CAGR for Cabarrus County) for the first three full project years (FY2015-FY2017);

**CMC-NorthEast  
 Projected Linear Accelerator Utilization**

	FY2014	FY2015	FY2016	FY2017
Linear Accelerator Procedures	13,966	14,183	14,404	14,628
Linear Accelerator ESTVs	12,987	13,189	13,394	13,602

Totals may not foot due to rounding.

The applicant states that the increase in volume for FY2012 was high due to the redirection of Stanly Regional Medical Center (SRMC) patients to CMC-NE while their linear accelerator was being replaced (Project I.D.#F-8770-12). Therefore, the decrease in linear accelerator volume at CMC-NE for FY2013 does not reflect a decrease in demand, but stabilization upon completion of the replacement linear accelerator at SRMC. The applicant also states that annualized FY2013 linear accelerator procedures are 7.4% higher compared to FY2011 procedures (13,859 – 12,900 = 959 / 12,900 = 0.074 or 7.4%). The applicant states that the projected growth rate is much lower compared to the most recent four-year, three-year and two-year compound annual growth rates (FY09-FY13 CAGR: 3.0%; FY10-FY13 CAGR 4.6%; FY11-FY13 CAGR 3.6%%). Projected increases are based on growth in the service area population and the aging population in Cabarrus County. The applicant adequately demonstrates projected linear accelerator volumes are based on reasonable, credible and supported assumptions.

Projected Utilization

In Section IV.1, pages 54-55, the applicant provides the historical and projected utilization for CMC-NE’s linear accelerators prior to completion of the project, as illustrated in the table below.

**CMC-NorthEast  
 Historical and Projected Accelerator Procedures & ESTVs,  
 FY2011-FY2017**

<b>Linear Accelerators</b>	<b>FY2011</b>	<b>FY2012</b>	<b>FY2013</b>	<b>FY2014</b>	<b>FY2015</b>	<b>FY2016</b>	<b>FY2017</b>
# of Units	2	2	2	2	2	2	2
# of Treatments	12,900	14,666	13,859	13,966	14,183	14,404	14,628
# of ESTVs	11,899	13,532	12,887	12,987	13,189	13,394	13,602

The applicant is not proposing to acquire a new linear accelerator, therefore, the performance standards required by 10A NCAC 14C.1903(a) is not applicable to this review. However, the linear accelerators at CMC-NE are projected to be performing at or above the performance standard by the third year of operation (FY2017). Upon completion of this project, CMC-NE would continue to own and operate two linear accelerators. The applicant adequately demonstrates the need to replace an existing linear accelerator in order to accommodate current utilization, projected growth and the increasing age of the population to be served.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for the project. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

In Section III.3, pages 42-44, the applicant describes the alternatives considered which include the following:

- 1) Status Quo – the applicant decided doing nothing would not be in the best interest of radiation therapy patients as it would not provide current standards in radiation therapy technology, thus maintaining the status quo was not considered to be a viable option.
- 2) Replace and Update Components of the Existing Linear Accelerator – the applicant decided replacing and updating components of the existing linear accelerator would not represent a permanent solution. Because of the aged equipment, eventually, the vendor would cease to develop new software for the aged equipment, as such; this alternative would only serve as a temporary solution, therefore, not a viable option.

The applicant concluded that developing the project as proposed was its most effective and least costly alternative because it results in the “*best patient care.*”

Furthermore, the application is conforming to all other applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need to replace the existing linear accelerator. The application is conforming to this criterion and approved subject to the following conditions.

- 1. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-NorthEast shall materially comply with all representations made in the certificate of need application.**
- 2. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-NorthEast shall acquire no more than one linear accelerator to replace an existing linear accelerator for a total of no more than two linear accelerators upon project completion.**
- 3. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-NorthEast 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 and which would otherwise require a certificate of need.**

- 4. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-NorthEast shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicants' representations in the written statement as described in paragraph one of Policy GEN-4.**
  - 5. Prior to issuance of the certificate of need, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-NorthEast shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 85, the applicant states that the total capital cost of the project will be \$6,251,400, including \$530,000 for construction costs, \$4,706,754 for fixed equipment purchase/lease, \$256,646 for movable equipment purchase/lease, \$32,000 for furniture, \$128,000 for consultant fees and \$598,000 for contingency. On page 89, the applicant states,

*“CMC-NE will not use a loan to fund this project, but will fund the project using accumulated reserves.”*

In Section IX, page 92, the applicant projects there will be no start-up expenses or initial operating expenses associated with the proposed project. In Section VIII.3, page 88, the applicant states that the project will be funded by means of Carolina's HealthCare System (CHS) accumulated reserves. Exhibit 7 contains a July 15, 2013 letter signed by the Executive Vice President and Chief Financial Officer for CHS, which states:

*“As the Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (CHS), I am responsible for the financial operations of CMC-NE. As such, I am very familiar with the organization's financial position. The total capital expenditure for this project is estimated to be \$6,251,400. There is no start-up costs related to this project.*

*CHS will fund the capital cost from existing accumulated cash reserves. ...”*

Exhibit 8 of the application contains the audited financial statements for CMHA d/b/a CHS for the years ending December 31, 2012 and December 31, 2011. As of December 31, 2012, CHS had \$85,603,000 in cash and cash equivalents and \$3,313,001,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project for CMC-NE. The applicant projects CMC-NE revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below.

<b>CMC-NE Radiation Therapy Services</b>			
	<b>FY2015</b>	<b>FY2016</b>	<b>FY2017</b>
<b>Gross Patient Revenue</b>	<b>\$1,934,013</b>	<b>\$2,127,087</b>	<b>\$2,327,609</b>
Deductions from Gross Patient Revenue	\$1,345,473	\$1,509,668	\$1,682,786
<b>Net Patient Revenue</b>	<b>\$588,540</b>	<b>\$617,419</b>	<b>\$644,823</b>
Other Operating Revenue	\$18,081	\$18,614	\$19,166
<b>Total Operating Revenue</b>	<b>\$606,621</b>	<b>\$636,033</b>	<b>\$663,989</b>
Total Operating Expenses	\$565,196	\$593,860	\$620,763
<b>Net Income</b>	<b>\$41,425</b>	<b>\$42,173</b>	<b>\$43,880</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center-NorthEast (CMC-NE) proposes to replace a Varian 23EX with a Varian High Energy True Beam linear accelerator to be located in the same vault (Treatment Room A) as the existing equipment. The equipment is currently located in the Batte Cancer Center on the hospital campus and provides radiation therapy services to both inpatients and outpatients. The total capital cost for the equipment and renovation of existing space (3,922 square feet) is \$6,251,400. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2013 SMFP. This project will not result in the addition of a linear accelerator in Linear Accelerator Service Area 9 (Cabarrus and Stanly County).

The 2013 SMFP need methodology (based on 2012 Licensure Renewal Application data) for linear accelerators uses 6,750 ESTVs (equivalent simple treatment visits) as a

benchmark utilization standard. In Section III.6(a), page 50, the applicant provides an inventory of operational linear accelerators in the service area as shown in the table below.

Health Service Facility	Linear Accelerator Inventory	FY2012 ESTVs	FY Average ESTVs per Unit	% of Benchmark Standard
CMN-NorthEast	2	13,352	6,676	98.9%
Stanly Regional Medical Center	1	3,625	3,625	53.7%
Novant Health Rowan Medical Center	1	6,131	6,131	90.8%

Source: CMC-NorthEast, 2013 Hospital License Renewal Applications

The 2013 SMFP linear accelerator need methodology requires an applicant to demonstrate that the existing linear accelerators located in the service area performed at least 6,750 ESTV treatments per accelerator per year based on the most recent LRA data. However, the applicant’s proposal is not pursuant to a need determination in the SMFP. The need for this project is internal to CMC-NE, in that it involves replacement of an existing linear accelerator. The project analyst notes that the Criteria and Standard required by 10A NCAC 14C.1903(a), which requires the applicant to demonstrate that the existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine in the twelve months prior to the date the application was submitted is not applicable to this review. The applicant is not proposing to acquire a linear accelerator but to replace an existing one. As shown above, CMC-NE provided a total of 13,352 procedures (6,676 / unit), approximately 98.9% of the SMFP benchmark standard (6,676 / 6,750 = 0.989, or 98.9%), the highest number of ESTVs per linear accelerator in the applicant’s service area.

In Section III.1, pages 27-40, the applicant adequately demonstrates the need for state-of-the-art enhanced radiation therapy services in the service area, which is based on projected utilization, projected population growth, the increasing age of the population to be served and increased cancer incidence rates. In Section III.1, page 39, the applicant projects that the linear accelerators will perform 13,602 ESTVs (6,801 / unit) in the third project year (FY2017), exceeding the benchmark standard of 6,750 ESTV procedures used in the 2013 SMFP linear accelerator need methodology. Projected utilization is based on reasonable, credible and supported assumptions. A description of the assumptions and methodology used to project utilization is provided in Section III.1(b), pages 38-40. A summary can be found in Criterion (3) which is incorporated hereby as if fully set forth herein.

No new services will be offered. The applicant adequately demonstrates that it is more cost effective to replace existing equipment in order to meet the needs of patients who are presently being served at the facility. The proposed project will improve quality of care, improve patient satisfaction, improve employee satisfaction and improve efficiency and effectiveness of staff. The applicant

adequately demonstrates the need to replace existing equipment. The criteria and standard required by 10A NCAC 14C.1903(a) is not applicable to the review as the linear accelerator inventory in the service area will not change as a result of the proposed project.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1(a), pages 75-76, the applicant provides the current staffing and the proposed staffing for linear accelerator services during the second full fiscal year, as illustrated in the table below. No new FTE positions are being projected as a result of the proposed project.

<b>Position</b>	<b>Existing FTE Positions</b>	<b>Proposed FTE Positions PY2</b>
Administrative Director	1.0	1.0
Assistant Technical Director	1.0	1.0
Radiation Therapist	5.5	5.5
Registered Nurse	2.0	2.0
Social Worker	1.0	1.0
Receptionist/Patient Registration	2.0	2.0
Dosimetrist	2.0	2.0
Physicist	2.0	2.0
<b>Total</b>	<b>16.5</b>	<b>16.5</b>

In Section II.1, page 23, the applicant states:

*“This project involves linear accelerator equipment replacement and thus does not involve any new FTE positions. The existing radiation oncology staff is sufficient.”*



In Section VII.8(a), page 81, the applicant states that Dr. Brian Moore, MD, is the Chief of Staff/Medical Director for the existing medical staff. See Exhibit 18 for a letter dated July 15, 2013 from Dr. Scott Lankford expressing his willingness to continue to serve as the Medical Director for radiation therapy services, respectively. Exhibit 19 includes letters of support from area physicians for the proposed project.

The applicant adequately demonstrated the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

CMC-NE is an existing provider of radiation therapy services. In Section II.2(a), pages 17-18, the applicant states that the necessary ancillary and support services are already in place. In Section II.2, page 18, the applicant states:

*“CMC-NE provides the following services to support radiation therapy services:*

- *Reception, Medical Records, and associated support services provided by the CMC-NE Health Information Services and Business Office Personnel*
- *Medical Supplies – ordered from vendors by CMC-NE Materials Management Department*
- *Administration – provided by Scott Gollinger, VP Clinical Services*
- *Laundry, Maintenance, and Housekeeping provided by the proforma statements under 1) Other Overhead/G&A and, 2) Plant Operations and Maintenance.”*

Exhibit 11 includes copies of patient referral, transfer, and follow-up polices and procedures. Exhibit 13 includes copies of transfer agreements with existing health care facilities. Exhibit 19 includes physician letters of support. The applicant adequately demonstrates the availability of necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.2(a), page 64, the applicant discusses CMC-NE's history of providing radiation therapy services to the underserved populations of North Carolina. The applicant states:

*“CMC-NE will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Specific to this project, radiation therapy services at CMC-NE will continue to be available to and accessible by any patient having a clinical need for those services. ...*

*CMC-NE has historically provided substantial care and services to all of the above categories of medically underserved persons. ...”*

On page 71, the applicant states that historically, 60.2% of linear accelerator patients at CMC-NE have some or all of their services paid for by Medicare or Medicaid and an additional 32.6% are covered by Managed Care. Thus, 92.8% of the revenue for linear accelerator services is derived from government payors. The table below illustrates the current historical payor mix for the facility.

<b>CMC-NorthEast CY2012 (January – December 2012) Linear Accelerator Services Current Procedures As Percent of Total Utilization</b>	
Self-Pay	1.8%
Medicare	53.5%
Medicaid	6.7%
Managed Care	32.6%
Commercial	4.7%
Other	0.6%
<b>Total</b>	<b>100.0%</b>

Totals may not exactly add due to rounding

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Cabarrus County and statewide.

	<b>Total # of Medicaid Eligibles as % of Total Population June 2010</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010</b>	<b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Cabarrus	14.0%	4.9%	18.5%
Statewide	17.0%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that medically underserved populations currently have adequate access to the services offered at Carolinas Medical Center-NorthEast. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

### C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 70, the applicant states:

*“CMC-NE is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, as previously stated, CMC-NE does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. ...And as previously stated, CMC-NE will*

*continue to be accessible to persons with physical disabilities and handicaps, as required by the Americans with Disabilities Act.”*

In Section VI.10(a), page 70, the applicants state:

*“CMC-NE has not had any civil rights complaints filed during the last five years.”*

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14(a) page 73, the applicant provides the projected payor mix for the second full fiscal year (2016) of operations for the proposal, as illustrated in the table below.

<b>CMC-NorthEast PY2 (October 2015 – September 2016) Linear Accelerator Services Projected Procedures As Percent of Total Utilization</b>	
Self-Pay	1.8%
Medicare	53.5%
Medicaid	6.7%
Managed Care	32.6%
Commercial	4.7%
Other	0.6%
<b>Total</b>	<b>100.0%</b>

\*Other includes Workers Comp. and other governmental plans

As shown in the table above, the applicants do not anticipate any change to the future payor mix upon project completion.

In Section VI.6, page 68, the applicant states, “CMC-NE will continue to provide services to Medicare and Medicaid recipients, the uninsured, and the

*underinsured, without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay.* [emphasis in original]

In Section VI.3, page 66, the applicant states that the facility will continue to be accessible to persons with disabilities, as required by the Americans with Disabilities Act (ADA). The applicant also states that the design of the facility will continue to operate consistent with: Title VI of the Civil Rights Act of 1963, Section 504 of the Rehabilitation Act of 1973 and The Age Discrimination Act of 1975.

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 71, the applicant states:

*“Access to CMC-NE’s radiation oncology services (including linear accelerator) will continue to be by referral from physicians who have admitting privileges at the hospital. Some patients also are admitted for hospital services via the hospital Emergency Department.”*

Please see Exhibit 19 for letters of support from physicians who support the proposed project.

The applicant adequately demonstrated CMC-NE offers a range of means by which patients will have access to the proposed services. Therefore, the application is conforming with this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1(a) page 58 the applicant states that as a part of CHS, CMC-NE has access to established clinical relationships and training programs supported by all CHS facilities and that CMC-NE is committed to accommodating the clinical needs of area professional programs and will provide access to programs requiring clinical training through its radiation therapy program. CHS has established relationships with the following health professional training programs:

- Central Piedmont Community College (CPCC);
- Queens University of Charlotte;
- University of North Carolina at Charlotte (UNCC);
- Gardner-Webb University;
- Presbyterian School of Nursing; and
- Mercy School of Nursing

In addition, the Cabarrus College of Health Sciences is located on the campus of CMC-NE and offers an Associate Degree in Nursing, as well as a Bachelor of Science in Nursing. See Exhibit 14 for a copy of an Education Affiliation Agreement.

The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Carolinas Medical Center NorthEast (CMC-NE) currently owns and operates two linear accelerators on CMC-NE campus. The applicant proposes to replace the Varian 23EX linear accelerator in Treatment Room A with a new Varian High Energy TrueBeam linear accelerator. The applicant is not proposing to add beds, equipment or new services in Cabarrus County.

In Section V.7, pages 62-63, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicant states the existing equipment has limited clinical capabilities and is no longer the standard of care for local patients. See also Sections II, III, V, VI, and VII. The information provided by the applicant in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost effectiveness, quality, and access to linear accelerator services in Cabarrus County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicant adequately demonstrates the need to replace the existing Varian 23EX linear accelerator with a new Varian High Energy TrueBeam linear accelerator;
- The applicant adequately demonstrates that the proposal is a cost-effective alternative to meet the need (see Section III of the application);
- The applicant will continue to provide quality services (see Section II and VII of the application);
- The applicant will continue to provide adequate access to medically underserved populations (see Section III and VI of the application); and
- The proposal will have a positive impact on competition by providing residents with increased access to quality services (see Section II and VI of the application).

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center-NorthEast (CMC-NE) is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center



teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicants propose to replace an existing linear accelerator, not acquire an additional linear accelerator. Therefore the Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C.1900, are not applicable to this review.