

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 28, 2013

PROJECT ANALYST: Fatimah Wilson
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10059-12 / University Radiation Therapy Center, LLC and The Charlotte-Mecklenburg Hospital Authority / Relocate existing radiation therapy center and replace existing linear accelerator and CT simulator / Mecklenburg 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

University Radiation Therapy Center, LLC (URTC) proposes to relocate its existing freestanding radiation therapy center, including a linear accelerator and CT simulator, which will be replaced as part of the project, to space to be constructed adjoining the Carolina Medical Center's University's (CMC-University) campus. The applicants, URTC and The Charlotte Mecklenburg Hospital Authority (CMHA), propose to construct a new 10,745 square foot radiation therapy center to accommodate the relocation of radiation therapy services and the proposed replacement equipment. The applicants do not propose to develop beds or services or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP).

However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 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 50-51, the applicants state:

“URTC and CHS are committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. The project’s plan to assure improved energy and water conservation in accordance with Policy Gen-4 requirements is discussed below.

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. System 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.

URTC and CHS 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 project. 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 North Carolina Building Code in effect when construction drawings are submitted for review to the DHSR Construction Section.*
- Use a Commissioning Agent to verify facility operates as designed.*
- Use Environmental Protection Agency Energy Star for Hospitals rating system to compare performance following 12 months of continuous operation.*
- Refer to United States Green Building Council (USGBC) LEED guidelines and GGHC to identify opportunities to improve the efficiency and performance.*
- Design for maximum efficiency and life cycle benefits within each impacted mechanical system: heating, cooling, water and sewer.*

CHS utilizes and enforces engineering standards that mandate use of state-of-the-art components and systems. The proposed project will be designed in full compliance with applicable local, state, and federal requirements for energy efficiency and consumption.”

The applicants included a written statement describing the project’s plan to assure improved energy efficiency sustainability and water conservation. Therefore, 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.

University Radiation Therapy Center, LLC (URTC) is wholly owned by Pineville Radiation Therapy Center, LLC (PRTC), which is wholly owned by The Charlotte-Mecklenburg Hospital Authority (CMHA). This membership composition was approved by way of a Declaratory Ruling issued January, 2012, in which the Department ruled that PRTC could acquire, without a CON, the entire membership interest of URTC, including the two pieces of equipment (linear accelerator and CT simulator) identified in this review.

University Radiation Therapy Center, LLC (URTC) and The Charlotte-Mecklenburg Hospital Authority (CMHA) propose to construct a new single-story, 10,745 square foot radiation therapy center to accommodate the relocation of radiation therapy services from its existing freestanding facility and the proposed replacement of the linear accelerator and the CT simulator. CMHA d/b/a CMC-University will own the proposed physical space where URTC proposes to relocate the proposed replacement equipment. CMC-University will collect monthly rent from URTC. CMC-University will not own or operate the proposed radiation therapy equipment. In Section II.1, pages 24-28, the applicants discuss the components of the proposed project, briefly described below:

- URTC proposes to relocate its existing freestanding radiation therapy center to newly constructed space adjoining the CMC-University hospital campus;
- The newly constructed space will be developed adjacent to CMC-University's Radiology Department and will include a connector corridor to the medical center, providing access to and from the hospital for patients, physicians and staff;
- URTC proposes to replace its existing Varian 2100C linear accelerator and General Electric Highspeed Advantage 1-slice CT simulator, as part of the proposed project; and
- In addition to the replacement linear accelerator and CT simulator, URTC will purchase other hardware and software that will support the replacement radiation therapy equipment.

Population to be Served

In Section III.5(a), page 54, the applicants state:

“URTC’s primary service area is Mecklenburg County given that the majority of its patients originate from Mecklenburg County.”

The following table illustrates historical and projected patient origin for linear accelerator services for the first two operating years of the project, as reported by the applicants in Section III.4(b), page 54, and Section III.5(c), pages 57.

URTC Linear Accelerator Services FY 2011		URTC Linear Accelerator Services Project Year 1 and 2			
County	% Patients	Year 1: Projected # Procedures	Year 1: % of Total Procedures	Year 2: Projected # Procedures	Year 2: % of Total Procedures
Mecklenburg	82.1%	6,694	82.1%	6,790	82.1%
Other*	17.9%	1,460	17.9%	1,481	17.9%
TOTAL	100.0%	8,154	100.0%	8,271	100.0%

*Other includes Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties in North Carolina, and other states

In Section II.1, page 25, the applicants state 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 applicants state:

“According to Google Maps, Exhibit 9, URTC’s existing location is approximately 0.7 miles and two minutes travel time from the proposed location on CMC-University’s campus. Given the close proximity of the locations, URTC maintains that the proposed relocation will not have a negative impact on the patients served in terms of access to services and access by medically underserved populations. ”

The applicants adequately identified the population they propose to serve.

Need for the Proposed Project

The applicants state 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 center to provide the best possible care in the most efficient manner. In Section III.1(a), pages 37-44, the applicants discuss the factors contributing to the need to replace the existing equipment, including the age of the existing equipment, advances in linear accelerator technology, and supporting demographic information.

Need to Replace Outdated Equipment

In Section III.1(a), page 37, the applicants state the equipment URTC proposes to replace, the Varian Clinac 2100C, was purchased in 1991 (21 years ago) and is approximately three times the length of its depreciable useful life of seven years as measured by the American Hospital Association’s (AHA) equipment lifetime standards. According to the applicants, the existing linear accelerator is not only the oldest in the CHS System, but also the 42nd oldest Varian linear accelerator nationwide. Moreover, the applicants state that according to Varian, the equipment manufacturer, approximately 84 percent of its linear accelerators are fewer than 12 years old and 76 percent are fewer than 10 years old. On page 38, the applicants state,

“Perhaps the most critical need to replace the outdated equipment is the fact that Varian is phasing out the platform for the 2100C because it is two generations past its prime.”

The applicants state that without a new linear accelerator, URTC will be without a supported linear accelerator when the 2100C platform is no longer available (at which time Varian will stop manufacturing parts for the equipment or providing safety notices relevant to equipment it has deemed at the end of its life).

Advances in Linear Accelerator Technology

In Section III.1(a), pages 38-40, the applicants state:

“While the existing equipment was state-of-the-art when it was installed in 1991, significant advancements in technology have occurred in the intervening time since its installation. Radiation therapy has experienced huge leaps in technology development in the last few decades.

...

Technological advances incorporating new imaging modalities, such as volumetric modulated arc therapy and image guided radiotherapy (IGRT); more powerful computers and software; and new delivery systems have enabled the delivery of radiation therapy in a more effective, safer manner, and often in much less time than in the past.

Given the age of URTC’s existing equipment, it does not provide portal imaging, volumetric modulated arc therapy (RapidArch), or IGRT. Without portal imaging, the existing equipment utilizes film (X-ray images for localization), which is extremely inefficient as it takes approximately four steps to convert into digital images.

...

The proposed replacement equipment will provide integrated portal imaging, volumetric modulated arc therapy (or RapidArc, a form of IMRT), and IGRT, all of which the existing equipment does not offer. With newer linear accelerators, including the replacement Varian High Energy Clinac iX linear accelerator proposed in this application, the treatments are directed by computer-controlled collimators that pinpoint the exact site to be radiated, minimizing collateral exposure and optimizing the delivery to the targeted site. Moreover, newer equipment, such as the proposed Varian High Energy Clinac iX, can perform radiation treatments without interruption to the process to replace manual wedges, as Dynamic wedges are included in the proposed equipment. In addition, physicians and technicians no longer have to enter the vault as often to make changes to patient position as IGRT technology allows for micro adjustments from outside the vault.

...

The replacement equipment will also have RapidArc technology, a breakthrough in radiation therapy that modulates the intensity of the radiation beam (using a full, single arc rotation) with less radiation exposure. This technology will enable the portion of the treatment where the beam is on to be completed in less than two minutes. Overall, the entire treatment will go from approximately 20 to 30 minutes to 10 minutes with the RapidArc technology. Since the beam is on for less than two minutes, the likelihood of patient movement is greatly reduced. Further, by enhancing precision, this modality has substantially decreased urinary and rectal toxicity rates when compared with conventional external beam radiation therapy for prostate patients.

The proposed replacement equipment will not only address the age concerns associated with the existing equipment, but will also enable URTC to provide state-of-the-art radiation therapy. The advanced technology of the proposed replacement equipment will enable radiation oncologists to target tumors within millimeter accuracy, escalate radiation dose, and minimize exposure to health tissue and organs. The precise delivery of radiation, made possible by advances in technology, improves recovery time and reduces side effects and complications associated with conventional radiation therapy treatments. This decrease in site effects can result in an improvement in patients' quality of life and may result in lower costs of radiotherapy patient management."

Other Project Components

Replacement CT Simulator

The applicants state that URTC also proposes to replace its existing General Electric Highspeed Advantage 1-slice CT simulator with a General Electric Optima CT580 RT 16-slice CT simulator. The existing CT simulator is a 1995 model that was purchased used in 2002. The applicants state that while the CT simulator has been well maintained, it is outdated, inefficient and at the end of its useful life. Moreover, the applicants also state that the existing CT simulator cannot accommodate the bariatric patient population. In Section III.1, page 41, the applicants state, "*The proposed CT simulator will address the limitations of the existing equipment.*"

Relocation to Space on CMC-University's Campus

As previously stated, the proposed project involves the relocation of URTC's freestanding radiation therapy center from University Executive Park to space to be constructed on CMC-University's campus. According to Google Maps, the proposed location is approximately 0.7 miles and two minutes travel time from the current site. The existing facility is currently operating in 5,961 square feet of leased space. The proposed facility will be operating in 10,745 square feet of leased space. The applicants state that the existing space is inadequate and drives the need to relocate services.

According to the applicants, privacy is the most pressing concern in the existing space in that treatment control areas are not walled off and are essentially out in the hallway that serves as a right of way to offices and dosimetry services and is also located across from the rear entrance of the center used by staff, handicapped patients, and EMS for patients arriving by way of ambulance. Without walls, the video monitors in the control area are visible to all who walk through this high traffic area, which presents a major privacy concern since patients may be in various stages of dress during treatments that are displayed on the video monitors in the control area.

The existing dressing rooms are approximately 20 square feet each. The applicants state that these spaces are too small to accommodate wheelchairs or multiple persons (in the even a patient needs assistance changing). The existing patient waiting area occupies 62 square feet of space, which can only accommodate five chairs, to include both men and women patients. The applicants state given that the patients are waiting in dressing gowns, the lack of separation between male and female patients is less than ideal. It is noted that the patient waiting area is also too small for wheelchairs.

Storage is an issue in the existing space. The applicants state that equipment and supplies are piled up in any available space and there is no separation between clean and soiled utility. There is currently no area in the existing space for patient education, thus, exam rooms are utilized to provide this service as available. According to the applicants, the existing vault is too small and restricts URTC's ability to implement best practices and cannot accommodate the replacement equipment.

The applicants state that the proposed location will include adequate space for offices, storage, and patient changing and education, and will also promote patient privacy, comfort and satisfaction. The project analyst also notes that a larger facility with state-of-the-art equipment will also enhance employee satisfaction. Therefore, the applicants adequately demonstrate that the proposed relocation of the facility is needed.

Mecklenburg County Population

In Section III.1(a), page 43, the applicants state that URTC'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 43, the applicants state:

“Mecklenburg County and its surrounding communities are among the fastest growing regions in the country. According to data from the North Carolina Office of State Budget and Management (NC OSBM), Mecklenburg County is the second fastest growing county in North Carolina based on numerical growth and the seventh fastest behind Hoke, Onslow, Harnett, Wake, Cumberland, and Brunswick counties based on percentage growth. Further, Mecklenburg County's high growth is projected to continue.

...

Based on NC OSBM projections, of the counties in North Carolina, Mecklenburg County will have the second largest number of residents over the age of 65 in 2020. Further, within this decade, Mecklenburg County’s 65+ population is projected to grow by 57.8 percent. These data are significant because as the population ages, the incidence of cancer rises. Moreover, data from a study published in the Journal of Clinical Oncology approximates that the number of adults ages 65 and older needing radiation therapy will increase by 38 percent between 2010 and 2020.¹ For the residents age 65 and older in particular, the improvement in throughput as a direct result of the proposed new radiation therapy technology will support the expected higher utilization of this population group.”

The applicants state that as a result of the population growth and aging in Mecklenburg County, the demand for healthcare services is expected to increase, thus, URTC must prepare for this projected population growth and aging, particularly as it relates to the provision of radiation therapy.

In Section III.1(b), pages 46-48, the applicants describe the assumptions and the methodology used to project future linear accelerator volume as described below.

- The applicants begin with the historical volume of URTC’s existing linear accelerator;

Year	Treatments
2008	7,434
2009	6,918
2010	7,279
2011	7,758
2012*	8,151
08-11 CAGR	1.4%

*Source: URTC internal data annualized from January-July 2012 data

- Base volume begins with 2011 treatment volume (7,758) as this is the last full calendar year of data, projected to grow at 1.4 percent per year through the third project year, based on the CAGR for 2008-2011 (1.4%);
- ESTVs projections will use a base volume including simple, intermediate, complex and IMRT procedures; and

Year	Procedures	ESTVs
2012 (CY)	7,869*	7,259
2013 (CY)	7,982	7,363
2014 (CY)	8,096	7,468
2015 (CY)	8,212	7,575

¹ The Journal of Clinical Oncology, *The Future of Radiation Oncology in the United States from 2010 to 2020: Will Supply Keep Pace with Demand?* (October 18, 2010), available at <http://jco.ascopubs.org/content/early/2010/10/27/JCO.2010.31.2520.full.pdf+html>, Exhibit 19.

2016 (CY)	8,330	7,684
2017 (CY)	8,449	7,794

*Note that this methodology results in a lower projection of linear accelerator procedures in 2012 than the annualized data provided above suggests is actually likely to be realized

- Convert calendar year to project year

Year	Procedures	ESTV's
7/1/2014 – 6/30/2015 (PY1)	8,154	7,522
7/1/2015 – 6/30/2016 (PY2)	8,271	7,630
7/1/2016 – 6/30/2017 (PY3)	8,389	7,739

The project analyst notes a slight decline in historical volume in 2009; however, treatments performed on URTC's existing linear accelerator have increased significantly since then. Projected increases are based on growth in the service area population and the aging population in Mecklenburg County. The applicants adequately demonstrate projected linear accelerator volumes are based on reasonable, credible and supported assumptions.

Projected Utilization

In Section IV.1, page 61, the applicants provide the historical and projected utilization for URTC's linear accelerator prior to completion of the project, as illustrated in the table below.

Historical and Projected Linear Accelerator Utilization 1/1/10 – 12/31/2017

Linear Accelerators	Prior Full FY 1/1/10-12/31/10	Last Full FY 1/1/11-12/31/11	Interim Full FY 1/1/12-12/31/12	Interim Full FY 1/1/13-12/31/13	Interim Full FY 1/1/14-12/31/14	First Full FY 1/1/15-12/31/15	Second Full FY 1/1/16-12/31/16	Third Full FY 1/1/17-12/31/17
# of Units	1	1	1	1	1	1	1	1
# of Treatments	7,279	7,758	7,869	7,982	8,096	8,212	8,330	8,449
# of ESTVs	6,750	7,157	7,259	7,363	7,468	7,575	7,684	7,794

The applicants historical and projected utilization exceeds the 6,750 equivalent simple treatment visits (ESTVs) required by 10A NCAC 14C.1903(a) for an applicant proposing to acquire an additional linear accelerator which URTC is not proposing. Upon completion of this project, URTC would continue to own and operate one linear accelerator. The applicants adequately demonstrated the need to relocate the existing freestanding radiation therapy center and to replace the existing linear accelerator and CT simulator to accommodate current utilization and to accommodate projected growth and the increasing age of the population to be served.

In summary, the applicants 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.

C

The applicants state that the relocated radiation therapy services would be located approximately 0.7 miles and two minutes travel time from the current location. URTC does not expect any change in patient origin or any negative impact on patient access as a result of the relocation. Therefore, the applicants adequately demonstrate the needs of the patients presently served will continue to be met in the new location. Consequently, the application is conforming to this criterion.

- (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 52-53, the applicants describe the alternatives considered which include the following:

- 1) Status Quo – the applicants decided doing nothing would not be in the best interest of the radiation therapy center’s 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 the existing system in its current location – the applicants concluded that this option would not be viable as the existing vault is too small and is located internally to the existing radiation therapy center. That is, the existing vault is not located on an external wall, thus, there is no where to expand the existing vault without infringing upon the already inadequate facility space in the existing location. The existing vault would not accommodate the proposed replacement equipment.

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

- 1. University Radiation Therapy Center, LLC and The Charlotte Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**
 - 2. University Radiation Therapy Center, LLC and The Charlotte Mecklenburg Hospital Authority shall acquire no more than one linear accelerator and one CT simulator to replace the existing linear accelerator and CT simulator for a total of no more than one linear accelerator and one CT simulator upon project completion.**
 - 3. University Radiation Therapy Center, LLC and The Charlotte Mecklenburg Hospital Authority 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. University Radiation Therapy Center, LLC and The Charlotte Mecklenburg Hospital Authority 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, University Radiation Therapy Center, LLC and The Charlotte Mecklenburg Hospital Authority 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, pages 90-91, the applicants state that the total capital cost of the project will be \$9,755,255, including \$600,000 for site costs, \$3,710,000 for construction costs, \$3,758,175 for equipment purchase/lease, \$200,000 for furniture, \$50,000 for landscaping, \$525,000 for architect/engineering fees, \$65,000 for legal and

CON fees, \$110,000 for testing and permits and \$737,080 for contingency. On page 89, the applicants state,

“CMHA d/b/a CMC-University will fund the site work and development of the proposed space where the radiation therapy service will be located. CMHA d/b/a CHS will fund the upfit of the proposed space as well as the replacement equipment.”

On pages 90-91, the applicants allocate the capital cost of the proposed project as follows:

Project Capital Cost	CMC-University	CHS	Total
Site Costs	\$600,000		\$600,000
Construction Contract(s)	\$1,845,000	\$1,865,000	\$3,710,000
Miscellaneous Project Costs	\$735,000	\$4,710,255	\$5,445,255
Total Capital Cost of the Project	\$3,180,000	\$6,575,255	\$9,755,255

*Miscellaneous Project Costs including: equipment, furniture, landscaping, consultant fees Architect/engineering fees, testing and permits, legal and CON fees and contingency.

In Section IX, page 97, the applicants project there will be no start-up expenses or initial operating expenses associated with the proposed project. In Section VIII.3, page 92, the applicants state that the project will be funded by means of CMHA’s accumulated reserves. Exhibit 27 contains a October 15, 2012 letter signed by the Chief Financial Officer for CMHA, which states:

“As Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System, I am responsible for the financial operations of Carolinas Medical Center-University. As such, I am very familiar with the organization’s financial position. The total capital expenditure for this portion [sic] project is estimated to be \$3,180,000. There are no start-up costs related to this project.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University will fund this portion of the capital cost from existing accumulated cash reserves.”

Exhibit 27 contains a second letter dated October 15, 2012 signed by the Chief Financial Officer for CMHA, which states:

“As Chief Financial Officer for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System, I am responsible for the financial operations of the System. As such, I am very familiar with the organization’s financial position. The total capital expenditure for this portion [sic] project is estimated to be \$6,575,255. There are no start-up costs related to this project.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System will fund this portion of the capital cost from existing accumulated cash reserves.”

Exhibit 28 of the application contains the audited financial statements for The Charlotte Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, CHS had \$97,506,000 in cash and cash equivalents, total assets of \$6,155,124,000 and \$3,517,048,000 in total net assets (total assets less total liabilities). The applicants adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicants provided pro forma financial statements for the first three years of the project for CMC-University and URTC. The applicants project URTC's revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below.

URTC			
Gross Patient Revenue	\$11,968,921	\$12,504,547	\$13,064,143
Deductions from Gross Patient Revenue	\$7,738,577	\$8,084,889	\$8,446,699
Total Revenue	\$4,230,345	\$4,419,658	\$4,617,444
Total Expenses	\$4,138,744	\$4,274,851	\$4,416,564
Net Income	\$91,601	\$144,808	\$200,880

The assumptions used by the applicants 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 applicants 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 applicants propose to relocate an existing freestanding radiation therapy center, including a linear accelerator and CT simulator, which will be replaced as part of the project, to space to be constructed adjoining the Carolina Medical Center's University's (CMC-University) campus. The applicants stated throughout the application that maintaining the status quo would not be in the best interest of the radiation therapy center's patients as it would not provide current standards in radiation therapy technology. The applicants also stated that the existing vault is too small and is currently located on internal walls, thus, there is no where to expand the existing vault without infringing upon the already inadequate facility

space in the existing location. The existing vault simply would not accommodate the proposed replacement equipment.

The applicants do not anticipate any change in projected patient origin from what has historically been seen at the facility. No new services will be offered. The applicants adequately demonstrate that it is more cost effective to relocate the existing radiation therapy center and 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 applicants adequately demonstrate the need to relocate radiation therapy services and replace existing equipment. The applicants historical and projected utilization exceeds the 6,750 equivalent simple treatment visits (ESTVs) required by 10A NCAC 14C.1903(a). 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 45-48. A summary can be found in Criterion (3) which is incorporated hereby as if fully set forth herein.

In Section III.1, pages 36-48, the applicants adequately demonstrate the demand for state-of-the-art enhanced radiation therapy services in the service area, which is based on current utilization. In Section IV, page 61, the applicants project that the linear accelerator will perform 7,794 ESTVs in the third project year (FFY 2017). Additionally, in Section III.6, page 57, the applicants state that URTC is among six radiation oncology providers in Linear Accelerator Service Area 7 (Mecklenburg and Union counties) as designated by the 2012 SMFP, as shown in the table below.

Facility	SMFP Service Area	FFY 2011 # of Linear Accelerators	FFY 2011 Average ESTVs per unit	FFY 2011 Total ESTVs	% of Capacity*
Presbyterian Hospital	7	4	3,155	12,622	46.7%
Matthews Radiation Oncology	7	1	10,723	10,723	158.9%
University Radiation Oncology	7	1	7,118	7,118	105.5%
Carolinas Medical Center	7	3	6,537	19,612	96.8%
Pineville Radiation Therapy Center	7	1	9,128	9,128	135.2%
Carolinas Medical Center-Union	7	1	7,438	7,438	110.2%

* The percent of capacity is calculated by dividing the Average ESTVs per unit by the 6,750 ESTVs capacity defined on page 133 of the 2012 SMFP.

As shown in the table above, URTC’s existing linear accelerator operated at 105.5 percent of capacity. The only provider operating at less than 96.8 percent of capacity is Presbyterian Hospital. The units under the control of CMHA (the last four in the table above) are well utilized based on FFY 2011 data from license renewal applications and registration and inventory documents. The applicants state the other providers would be unable to meet the identified need based on their current capacity.

The applicants adequately demonstrate 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 83-84, the applicants provide the current and proposed staffing for the radiation therapy center 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.

Position	Existing FTE Positions	Proposed FTE Positions	Total # of Contract Hours
Radiation Therapist	3.75	3.75	
Registered Nurse	1.00	1.00	
Director	0.50	0.50	
Assistant Director	1.00	1.00	
Patient Registration/Billing	1.00	1.00	
Registrar	2.00	2.00	
Physicist			1,248
Dosimetrist			2,080
Total	9.25	9.25	

In Section II.1, page 23, the applicants state,

“Radiation therapy staff includes the radiation oncologist, the radiation physicist, a dosimetrist, radiation therapists, a registered nurse, registrars, a patient registration/billing supervisor, director, and assistant director. Radiation oncology, medical physicist, and dosimetrist services are currently provided pursuant to professional services agreements with Southeast Radiation Oncology Group, PA (SERO) and Landauer Medical Physics (LMP). These agreements will continue to govern the provision of professional services upon completion of the proposed project. ...All remaining radiation therapy staff are employees of URTC.”

In Section VII.8(a), page 87, the applicants state that Dr. Mark Liang, MD, will continue to serve as the Chief of Staff/Medical Director for URTC. See Exhibit 24 for a letter dated October 5, 2012 from Dr. Liang expressing his willingness to continue to serve as the Medical Director for the radiation therapy center, respectively. Exhibit 31 includes letters of support from area physicians for the proposed project.

The applicants 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

URTC is an existing radiation therapy center and the necessary ancillary and support services are currently available. In Section II.2(a), page 29, the applicants state that no additional ancillary and support services will be required.

See Exhibit 7, for a letter dated October 5, 2012, from the President of Southeastern Radiation Oncology Group (SERO) and a letter dated August 20, 2012 from the Vice President of Landauer Medical Physics (LMP) documenting that URTC currently offers radiation oncology, medical physicist and dosimetrist services. See Exhibit 31 for letters of support from physicians who support the proposed project and indicate a willingness to continue to refer to URTC's radiation therapy center.

The applicants adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would 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.

NA

- (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.

C

In Section I.7, page 8 and Section XI.2, page 102, the applicants identify the site for the proposed single-story project. The radiation therapy equipment and services will be located in a facility addition constructed by CMC-University and leased to URTC. Exhibit 1 contains a proposed lease agreement.

In Section XI.2(a), page 158, the applicants state that the primary site is located at 8800 North Tryon Street, Charlotte. See Exhibit 8 for a copy of the proposed site map and line drawing. In Section XI.4, page 104, the applicants provide the proposed square footage for the radiation therapy center, as illustrated in the table below:

URTC	Estimated Square Feet	Construction Cost Per Sq. Ft	Total Cost Per Sq. Ft
Radiation Therapy Suite	9,295		
Radiation Therapy Vault	1,450		

Total	10,745	\$345.28*	\$907.89**
--------------	---------------	------------------	-------------------

*The construction cost per square foot amount was calculated as follows: $\$3,710,000 / 10,745 = \345.28

**The total cost per square foot amount was calculated as follows: $\$9,755,255 / 10,745 = \907.89

Exhibit 30 contains a September 19, 2012 letter from the Managing Principal of Wright McGraw Beyer Architects, which states:

“Having worked with Carolinas Healthcare Systems to develop the design for the referenced project, Wright McGraw Beyer Architects, p.a. is pleased to provide the cost certification letter. The probable cost is based on the drawings included with the CON submittal. The estimated cost construction reflects our experienced with similar healthcare projects. Wright McGraw Beyer Architects, p.a. certifies to the best of their knowledge the site improvement and shell building costs of \$2,445,000.”

The project analyst notes that the \$2,445,000 cost estimate accurately reflects the cost estimate provided by the applicants in Section VIII.1, page 91, for CMC-University (\$600,000 site cost and \$1,845,000 construction cost = \$2,445,000).

Exhibit 30 also contains an August 30, 2012 letter from the Managing Principal of Wright McGraw Beyer Architects, which states:

“Having worked with Carolinas Healthcare Systems to develop the design for the referenced project, Wright McGraw Beyer Architects, p.a. is pleased to provide the cost certification letter. The probable cost is based on the drawings included with the CON submittal. The estimated cost construction reflects our experienced with similar healthcare projects. Wright McGraw Beyer Architects, p.a. certifies to the best of their knowledge the building upfit cost of \$1,865,000.”

The project analyst notes that the \$1,865,000 cost estimate accurately reflects the cost estimate provided by the applicants in Section VIII.1, page 91, for CHS (i.e., URTC).

Section III.2, pages 50-51 and Section XI.7, pages 106-108 contains the applicants' energy efficiency and sustainability plan and water conservation plan. See Criterion (1) for additional discussion regarding energy conservation which is incorporated hereby as if set forth fully herein.

The applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative for the proposed hospital expansion and renovation project. See Criterion (5) for discussion of costs and charges which is incorporated hereby by reference as if fully set forth herein. Therefore, the application is conforming to this criterion.

- (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 30, the applicants discuss URTC’s history of providing radiation therapy services to the underserved populations of North Carolina. The applicants state:

“URTC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay. As with all CHS facilities, URTC does not discriminate based on age, race, national or ethnic origin, disability, sex, income, or ability to pay. Services are rendered in compliance with:

1. Title VI of Civil Rights Act of 1963.
2. Section 504 of Rehabilitation Act of 1973.
3. The Age Discrimination Act of 1975.

URTC utilizes CHS’s System-wide Non-Discrimination Policy, Exhibit 25.”

In Section V.12, page 80, the applicants state that historically, 49.4% of patients at URTC have some or all of their services paid for by Medicare or Medicaid and an additional 28.4% are covered by Managed Care. Thus, 77.8% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

URTC	
1/1/12 - 7/31/12	
Current Procedures As Percent of Total Utilization	
Self-Pay/Indigent/Charity	4.5%
Medicare/Medicare Managed Care	45.8%
Medicaid	3.6%
Commercial	13.8%
Managed Care	28.4%
Other (Specify)*	3.9%
Total	100.0%

*Other includes Workers Comp. and other governmental plans

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 Mecklenburg County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15.0%	5.1%	20.1%
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 applicants demonstrated that medically underserved populations currently have adequate access to the services offered at University Radiation Therapy Center. 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 80, the applicants state:

“URTC has had no obligation to provide uncompensated care during the last three years. As noted above, URTC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.”

In Section VI.10(a), page 79, the applicants state:

“No complaints have filed against any affiliated entity of CHS regarding civil rights equal access in the past 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 81, the applicants provide the projected payor mix for the second full fiscal year (2016) of operations for the proposal, as illustrated in the table below.

URTC 1/1/16 - 12/31/16 Projected Procedures As Percent of Total Utilization	
Self-Pay/Indigent/Charity	4.5%
Medicare/Medicare Managed Care	45.8%
Medicaid	3.6%
Commercial	13.8%
Managed Care	28.4%
Other (Specify)*	3.9%
Total	100.0%

*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 75, the applicants state, “Radiation therapy services at URTC are available to all persons with a clinical need who present themselves for radiation therapy services, regardless of ability to pay. As noted previously, URTC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.” [emphasis in original]

In Section VI.3, page 73, the applicants state that the proposed new construction will maintain compliance with all access requirements under the Americans with Disabilities Act (ADA) and be appropriately designed for use by patients.

The applicants 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 78, the applicants state:

“Persons needing radiation therapy services are typically receiving treatment for cancer related illnesses and, as such, are referred by their physicians.”

Please see Exhibit 31 for letters of support from physicians who support the proposed project and indicate a willingness to continue to refer to URTC’s radiation therapy center.

The applicants adequately demonstrated URTC 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 63, the applicants state that as a part of CHS, URTC has access to established clinical relationships and training programs supported by all CHS facilities and that URTC 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

See Exhibit 23 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

University Radiation Therapy Center currently owns and operates one linear accelerator and CT simulator located on University Executive Park. The applicants propose to replace the existing Varian Clinac 2100C linear accelerator with a new Varian High Energy Clinac iX linear accelerator and the existing General Electric Highspeed Advantage 1-slice CT simulator with a General Electric Optima CT580 RT 16-slice CT simulator. The applicants are not proposing to add beds, equipment or new services in Mecklenburg County.

In Section V.7, pages 68-70, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicants state *“The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area. ...”* See also Sections II, III, V, VI, and VII. The information provided by the applicants 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 Mecklenburg County.

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

- The applicants adequately demonstrate the need to replace an existing linear accelerator and CT simulator at URTC with a Varian High Energy Clinac iX linear accelerator and a General Electric Optima CT580 RT 16-slice CT simulator;
- The applicants adequately demonstrate that the proposal is a cost-effective alternative to meet the need (see Section III of the application);
- The applicants will continue to provide quality services (see Section II and VII of the application);
- The applicants 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.

NA

- (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.

