

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 28, 2013

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: N-10080-13 / Southeastern Regional Medical Center, Inc. / Replace existing linear accelerator with a Varian TrueBeam linear accelerator / Robeson

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

Southeastern Regional Medical Center, Inc. (“**SRMC**”) proposes to replace its existing 2004 Siemens Primus linear accelerator, located in the Gibson Cancer Center which is licensed as part of the hospital. SRMC proposes to acquire and install a Varian TrueBeam linear accelerator in renovated space in the Cancer Center. The applicant does not propose to increase the number of licensed beds in any category, add new services, or acquire any equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP).

Since this application is not being submitted pursuant to a need determination identified in the 2013 SMFP, Policy GEN-3 is not applicable to this review.

However, there is one policy in the 2013 SMFP applicable to the review of this application:

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

“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 for 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 47 – 49, and Section XI.7, pages 102 – 103, the applicant states:

“SRMC is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. ...

Plumbing System

The plumbing systems will be designed to meet or exceed the North Carolina Building Code, Plumbing Code, NFPA Codes, and applicable state and local codes.

The water closets will be floor mounted with vitreous china elongated bowls and 1.6 gallon per flush (gpf) flush valves. The lavatories will be wall mounted and will have faucets with wrist blade handles with 0.5 gpm aerators in patient use areas and laminar flow outlets in staff use areas. Sinks in exam rooms will be stainless steel with chrome-plated brass faucets with wrist blade handles and laminar flow outlets. The sink in the break room will also be stainless steel with a faucet having a 1.5 gpm aerator. Handicap accessibility will be provided in all the toilets, for lavatories and for sinks in each room.

...

Mechanical System

The HVAC system will consist of high efficiency split system heat pumps with auxiliary electric heat. The units will be selected to have an EER above 15. Programmable thermostats will be used to increase energy conservation.

Electrical System

The existing building presently is served by a 1600A 120/208V three-phase service. An additional distribution panel will be added to accommodate new loads (i.e. HVAC, plumbing, lighting, receptacles, etc.). Power for new equipment will be fed from the main distribution panel.

All areas being renovated shall have general power receptacles and any power requirements for equipment per owner.

The existing accessible fire alarm system is acceptable for the existing building. New devices shall be added in compliance with NFPA 72 and the latest Office of the State Fire Marshal's requirements.

The new lighting system will include occupancy sensors in required areas, energy saving electronic ballasts and T8 energy saving lamps. In addition, emergency lighting shall be added in accordance with NFPA 101 and the latest North Carolina Building Code.

All existing lighting in renovated areas shall be re-used where applicable. New lighting will be provided in renovated areas where existing lighting cannot be re-used."

The applicant adequately describes its plan to assure improved energy efficiency and water conservation following project completion. Therefore, the application is conforming to Policy GEN-4, and is 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.

Southeastern Regional Medical Center, Inc., located in Lumberton, is currently licensed for 292 acute care beds and is the only hospital in Robeson County. SRMC's license also includes WoodHaven (a long term care facility), Hospice House, a 12-bed hospice inpatient facility, and the Gibson Cancer Center, a comprehensive outpatient center which provides radiation oncology, chemotherapy and hematology services to cancer patients. SRMC also owns Southeastern Home Medical Equipment, Southeastern Home Health, Hospice of Robeson, and several medical facilities throughout Robeson County. In this application, SRMC proposes to replace its existing 2004 Siemens Primus linear accelerator, located in the Gibson Cancer Center at the hospital, and install a Varian TrueBeam linear accelerator. The applicant proposes to add 5,327 square feet of new space, and to renovate 1,640 square feet of existing space in two phases of renovation and construction in the radiation oncology suite to accommodate the replacement equipment. In Section II, page 16, the applicant describes the two phases proposed for the renovation and construction. The applicant states:

“Phase I involves the renovation of 1,338 square feet of existing administrative space to provide two exam rooms, offices for a social worker and dietician, a file room and a break room. Phase I also involves the construction of 1,488 square feet. The new construction will include four new exam rooms, a nurse’s station, physician work area, EMS bay, patient toilet, and HVAC space. ...

Phase II involves the renovation of 302 square feet of existing radiation oncology space currently utilized as a gowned waiting area to provide an area for dosimetry/physics. Phase II also involves the construction of 3,839 square feet to include a replacement linear accelerator vault and control area, waiting area, toilets, and a reception/work room.”

The applicant projects that both phases will be complete in April 2014. In addition, according to the applicant, the vault that currently houses the existing linear accelerator will be used for general storage in the hospital following the installation of the replacement equipment and new vault.

Population to be Served

In Sections III.4 and III.5, pages 52 - 53, the applicant provides the current patient origin for acute care inpatient services and for radiation therapy services provided at SRMC. See the following table, which illustrates patient origin for radiation therapy services at SRMC for FY 2012:

SRMC Radiation Therapy Services Patient Origin FY 2012

COUNTY	% PATIENTS
Robeson	69.4%
Columbus	15.5%
Bladen	12.6%
Other*	2.5%
Total	100.0%

*Other includes Cumberland, Hoke, Sampson Counties and other states, as reported by the applicant on page 52.

In Section III.5, page 55, the applicant projects patient origin for the first two years of operation following project completion, as shown in the table below:

COUNTY	FY 2015	FY 2016
Robeson	69.4%	69.4%
Columbus	15.5%	15.5%
Bladen	12.6%	12.6%
Other*	2.5%	2.5%
Total	100.0%	100.0%

*Other includes Cumberland, Hoke, Sampson Counties and other states.

Furthermore, nearly 75% of the patients treated at SRMC are Medicare/Medicaid recipients. The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.1, pages 28 – 45, the applicant describes the need SRMC has for the replacement linear accelerator, including an internal need at SRMC to replace outdated imaging equipment, a need for updated linear accelerator technology at Gibson Cancer Center, a need to reconfigure and renovate existing space, and a projected increase in the service area population that most commonly utilizes oncology imaging services. Additionally, the applicant states that the first phase of the project will be to renovate existing space; the second phase will involve acquisition and installation of the linear accelerator, and construction of a new vault to house the proposed equipment. Each of the factors is discussed below.

Need Internal to SRMC

In Section III.1, page 28, the applicant states the existing linear accelerator is nine years old, and thus past its “seven year useful life as measured by the American Hospital Association’s equipment lifetime standards.” In Section III.1, page 29, the applicant states:

“Not only does the existing equipment operate slowly and have antiquated capabilities when compared to newer technology available today, but also ..., the existing equipment has begun to show signs of catastrophic failure that could potentially put it out of service for as long as a month. This poses a significant risk to SRMC’s patients and their cancer treatment as the medical center has no back up

machine for its patients in the event its existing machine fails. Within the past seven months, SRMC has experienced issues with its injector and has had to replace its multileaf collimator (MLC) pad with parts ordered from Germany. In addition, SRMC's waveguide has shown signs of malfunction and the couch drive and hand controls are failing. As a result, SRMC has experienced a lot of downtime. In 2012 alone, there were a total of 256 missed treatments as a result of the linear accelerator being down for repair.

Perhaps the most critical need to replace the outdated equipment is the fact that Siemens, vendor of the existing linear accelerator, no longer sells new linear accelerators."

In Section III.1, page 30, the applicant states:

"Without a new linear accelerator, SRMC will be left with a machine which has begun to show signs of catastrophic failure...."

It also bears mention that SRMC is the only provider of radiation therapy services in Robeson County. As such, the proposed project is needed to improve access to state-of-the-art radiation therapy services for the residents of Robeson County and surrounding communities. SRMC believes that traveling for treatments is an undue burden. In particular, given that two of the major side effects associated with radiation therapy are extreme fatigue and bowel problems, it is important that patients are able to stay as near home as possible for the treatment sessions."

Thus, a component of the applicant's need to replace its existing linear accelerator is internal to SRMC, since the existing equipment is outdated.

Need for Advanced Linear Accelerator Technology

In Section III.1, pages 30 – 34, the applicant discusses the technological advances in radiation oncology that have occurred since SRMC acquired its existing linear accelerator in 2004. On page 31 the applicant states that technological advances which incorporate new imaging modalities provide for more focused radiation, thereby reducing the patient's overall radiation exposure while more effectively delivering radiation therapy. On page 31, the applicant states:

"Given the age of SRMC's existing equipment, it does not provide kilovoltage (KV) imaging, cone beam capabilities, on board imaging (OBI), or volumetric modulated arc therapy (RapidArc). The existing equipment has megavoltage (MV) imaging capabilities as opposed to newer equipment that features the more advanced KV imaging capabilities. The difference in image detail between MV imaging and KV imaging is dramatic. For matching on head and neck cases, which can be some of the most difficult cases, KV imaging capabilities are crucial."

On page 32, the applicant states:

“While the existing equipment does have IGRT [image guided radiation therapy] capability, it is a cumbersome process that takes approximately 25 to 30 minutes per patient. Newer machines, such as the proposed replacement equipment, have OBI/KV imaging capabilities that reduce this time up to 15 to 20 minutes per patient....

...

The existing equipment is also more labor and time intensive than newer equipment. ... Currently, films are taken, scrutinized and the therapist must go back into the treatment room to make any changes as they are done by hand. Depending on the amount of change needed, patients may be re-filmed. Newer equipment, such as the proposed replacement equipment, has the capability to allow the therapist to film the patient at a more rapid pace and make small changes by programming at the console outside the treatment room. On newer equipment the therapist simply extends the portal arm, takes the film, examines the film, programs changes on the console, moves the table, and retracts the arm - all from outside the treatment room.”

Furthermore, on page 33, the applicant states:

“SRMC proposes to replace its existing outdated linear accelerator with a Varian TrueBeam linear accelerator. The proposed replacement equipment will provide TrueBeam technology and volumetric modulated arc therapy (or RapidArc, a form of IMRT [Intensity Modulated Radiotherapy), which the existing equipment does not offer.”

In addition, in Section III.1, page 34, the applicant states:

“In addition, physicians and technicians no longer have to enter the treatment room as often to make changes as advanced IGRT technology allows for micro adjustments from outside the treatment room. Since organs move (due to breathing, bladder volume, swallowing, etc.), IGRT acts like a GPS that enables precise targeting and repositioning to correct motion and ensure accuracy. 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. Since the beam is on for less than two minutes, the likelihood of patient movement is greatly reduced. ...

The proposed replacement equipment will not only address the age concerns associated with the existing equipment, but will also enable SRMC 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 healthy tissue and

organs....”

Therefore, the proposed replacement linear accelerator will allow the applicant to treat its oncology patients more effectively and efficiently.

Robeson County Population Projections

In Section III.1, page 41, the applicant discusses the projected population growth within Robeson County, the county from which the applicant projects to serve a majority of its patients. The applicant states:

“SRMC’s need to replace its existing outdated equipment is also supported by population aging which drives increased utilization of healthcare services. Of note, by 2020, 13.7 percent of the total population in Robeson County will be over the age of 65 (more than 18,600 people). Further, within this decade, Robeson County’s 65+ population is projected to grow by 21.8 percent. ... These data are significant because, as the population ages, the incidence of cancer rises. ... 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.”

In addition, citing the North Carolina State Office of Budget and Management (NCOSBM), the applicant states that, by 2020, 13.7% of the Robeson County population will be over the age of 65. The applicant states:

“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.”

Thus, the number of persons age 65 and over as a percent of total population in Robeson County is projected to grow faster than younger population groups. Furthermore, the cancer incidence statistics presented by the applicant show that the incidence of cancer and thus the use of the proposed equipment are projected to increase as well in Robeson County and the other counties which comprise the applicant’s service area.

Additionally, the applicant cites *The Journal of Clinical Oncology* to state that, between 2010 and 2020, the number of adults age 65 and older who will need radiation therapy will increase by 38%.

In Section III.1, pages 35 – 40, the applicant discusses specific aspects of the proposed project and the impact those aspects will have on SRMC. On page 35, the applicant states the existing space in the Gibson Cancer Center is too small and risks breach of patient confidentiality because the space limitations restrict patient and physician flow. Specifically, the applicant states:

- *“Patients walk unescorted from the front desk to the sub-waiting area through the center;*
- *The therapists’ work console is located in a corridor with no privacy (please note that the console area is located outside of the linear accelerator vault in the corridor ...);*
- *The sub-waiting area often becomes crowded and family is asked to wait in the central lobby;*
- *The treatment monitoring by therapists is in clear view of the patients waiting;*
- *Therapists are frequently interrupted by patients/family members at the console during treatment;*
- *The corridor serves as the main thoroughfare for patients, staff, and ambulance personnel;*
- *The ambulance bay serves the entire facility (radiation oncology and medical oncology) ... The entrance to simulation is through the main corridor running through the center;*
- *Simulation patients walk by the treatment console when treatment is in progress; and,*
- *The button for the simulation room, which is located next to the exit button, may accidentally be pressed for egress, potentially exposing patients to radiation.”*

On pages 36 – 38 of the application and in Exhibits 4 and 5, the applicant provides illustrations of current patient and physician flow in relation to the existing linear accelerator, and the location of the nurses’ station. Currently, the radiation oncology patients must walk through other medical units and past other exam rooms. With the proposed design, patient waiting will be located adjacent to the treatment bays, and the nurses’ station will be located centrally to allow the nurses visual access to the patients.

On page 40, the applicant states:

“The redesign of the space as well as the proposed replacement equipment will drastically improve work flow as well as patient flow, privacy, comfort, and satisfaction. As detailed in the proposed line drawing included in Exhibit 4, the proposed new construction and redesign promotes patient flow and privacy.”

In Section III.1, pages 40 – 42, the applicant discusses the second phase of the project, which involves acquisition of the replacement equipment and construction of a new vault to house the linear accelerator. On page 40, the applicant states the existing vault, built to accommodate the existing outdated equipment, is too small for the proposed replacement system. In addition, on page 40, the applicant describes why it proposes two phases for the project. Specifically, the applicant states:

“Notwithstanding the size constraints of the existing vault, it bears mention that SRMC only has one linear accelerator and no access to another vault to treat its patients and would need to shut down for six to eight weeks to remove and replace the existing outdated equipment in its current location. Such an undertaking is not

only impractical given the size of new linear accelerator systems, but also would represent an incredible hardship for exiting patients and staff of the Gibson Cancer Center. Further, it bears mention that the development of a new vault area will enable SRMC to reconfigure the radiation oncology department in order to eliminate privacy concerns associated with the existing space....”

Utilization

In Section III.1(b), pages 43 – 45, the applicant provides assumptions that support the projected utilization of the proposed replacement linear accelerator. On page 43 the applicant provides a table that illustrates historical utilization of the existing linear accelerator at SRMC. In addition, according to information submitted by the applicant, SRMC’s experience has been an average of 25 linear accelerator treatments per patient. Therefore, the project analyst divided the number of treatments provided by the applicant by 25, to show the historical number of patients served by the existing linear accelerator at SRMC. See the following table:

YEAR	NUMBER OF TREATMENTS	NUMBER OF PATIENTS
FY 2009	7,489	300
FY 2010	6,532	261
FY 2011	8,610	344
FY 2012	8,885	355
CAGR	5.9%	5.8%

The number of linear accelerator treatments provided by SRMC has increased, except for a decline in the number of treatments in FY 2010. Furthermore, even with the decline in the number of treatments provided in FY 2010, the overall compound annual growth rate (CAGR) for those years is 5.9%. In fact, for three of the past four years, the number of treatments provided by SRMC exceeded the planning standard of 6,750 annual treatments for linear accelerators. In addition, the need to replace the linear accelerator is one that is internal and thus unique to SRMC, because the existing equipment has reached the end of its useful life. According to the applicant in Section III.1, on pages 29 – 30, the existing equipment is in danger of catastrophic failure, which would adversely impact SRMC’s radiation oncology patients.

In Section III.1, page 43, the applicant projects future growth in linear accelerator treatments based on the North Carolina OSBM’s Robeson County population projections. On pages 43 – 44, the applicant states:

“Using the last full fiscal year’s (FY 2012) treatments as base volume, radiation therapy treatments are projected to grow at 0.14 percent per year through the third full fiscal year (FY 2017) following the project’s completion. Again, SRMC believes this growth rate is very conservative because the compound annual growth rate in linear accelerator procedures from FY 2009 to FY 2012 of 5.9 percent as shown in the above table, is significantly greater than the 0.14 percent utilized in the projections.

Furthermore, the application of Surveillance Epidemiology and End Results (SEER) cancer incidence rates to the Robeson County population suggests that new cancer cases in Robeson County will grow at a CAGR of 0.86 percent, which is approximately six (6) times the 0.14 percent growth rate utilized for the projections.

...

SRMC then assumed that the FY 2012 mix of its radiation therapy treatments by type will remain constant throughout the project years. Although the mix of treatments changes over time as a result of advancements in technology and treatment protocols, the use of the most recent year's data most accurately reflects the current standards of cancer treatment.

For SRMC's projection of ESTVs [Equivalent Simple Treatment Visit], it assumed that the base volume, excluding Additional Field Check Radiographs (ARCR), would include simple, intermediate, complex, and intensity modulated radiation treatments, all of which have an ESTV weighting of 1.0....”

On page 45, the applicant provides a table that illustrates growth projections, again assuming an average of 25 linear accelerator treatments per patient:

YEAR	NUMBER OF TREATMENTS	NUMBER OF PATIENTS*	ESTVS
FY 2013	8,898	356	8,566
FY 2014	8,910	356	8,578
FY 2015	8,923	357	8,590
FY 2016	8,935	357	8,602
FY 2017	8,948	358	8,614

*These are averages and may not exactly foot due to computer rounding.

The projections of the number of treatments to be performed on the replacement linear accelerator are based on reasonable and credible assumptions. The applicant projects future utilization based on the Robeson County population growth projections, rather than on the equipment's historical utilization. The population growth projections for Robeson County are less than one-third of the historical utilization of the equipment. It would likewise have been reasonable for the applicant to project future linear accelerator growth based on the historical utilization of the existing unit. In addition, the existing equipment is outdated and is not capable of providing the radiotherapy technology that more effectively treats radiation oncology patients.

In summary, the applicant adequately identifies the population it proposes to serve and adequately demonstrates the need the population has for the proposed linear accelerator replacement. Consequently, 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.

CA

The applicant proposes replace an existing nine-year old linear accelerator with a new linear accelerator system that will enable faster treatment times, increased radiation accuracy with less damage to surrounding tissue, increased privacy for patients, and more efficient throughput. The project will consist of two phases: phase I will involve renovation to the existing radiation area in the Gibson Cancer Center and acquisition of the replacement equipment. Phase II will involve construction of a new vault to accommodate the new linear accelerator. The applicant states in Section III.3, pages 49 - 51, that it considered several alternatives before proposing this project, which include maintaining the status quo, replacing the existing linear accelerator in its current location, and replacing the existing equipment for less than \$2 million. The applicant states the proposed alternative is the most effective alternative to meet SRMC's need to provide quality diagnostic and treatment radiotherapy to its patients at the Gibson Cancer Center.

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

The applicant adequately demonstrates that the proposed project is the least costly or most effective alternative to meet the need for a replacement linear accelerator at SRMC. Therefore, the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Southeastern Regional Medical Center, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Southeastern Regional Medical Center, Inc. shall acquire no more than one replacement linear accelerator.**
- 3. Southeastern Regional Medical Center, Inc. shall dispose of the existing linear accelerator no more than 30 days after the operation of the replacement linear accelerator.**
- 4. Southeastern Regional Medical Center, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards in the latest**

edition of the North Carolina Building Codes. The plan must be consistent with the applicant’s representation written in the statement as described in paragraph one of Policy GEN-4.

- 5. Southeastern Regional Medical Center, Inc. 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 that would otherwise require a certificate of need.**
 - 6. Southeastern Regional Medical Center, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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.2, pages 86 - 89, the applicant projects the total capital cost for the project will be \$7,482,681, as shown in the table below that illustrates costs to be incurred in each phase of the proposed project.

CATEGORY	PHASE I	PHASE II	TOTAL
Site Costs	\$200,000	\$0	\$ 200,000
Material / Construction Contract	\$901,492	\$1,911,030	\$2,812,522
Fixed Equipment Purchase / Lease	\$0	\$3,723,520	\$3,723,520
Moveable Equipment Purchase / Lease	\$0	\$ 183,200	\$ 183,200
Furniture	\$ 30,000	\$0	\$ 30,000
Architect and Engineering Fees	\$233,439	\$0	\$ 233,439
Other (Contingency)	\$150,000	\$ 150,000	\$ 300,000
Total Project Cost	\$1,514,931	\$5,967,750	\$7,482,681

*Source: Application pages 87 – 88.

In Section IX, page 103, the applicant states that there are no start-up or initial operating expenses, as this is not a new facility or service.

In Section VIII.8, page 90, the applicant states that the project will be financed with the accumulated reserves of Southeastern Regional Medical Center, Inc. In Exhibit 21, the applicant provides an February 15, 2013 letter signed by the Chief Financial Officer for Southeastern Regional Medical Center, which states:

“As the Chief Financial Officer for Southeastern Regional Medical Center, I am responsible for the financial operations of the hospital. As such, I am very familiar with the organization’s financial position. The total capital expenditure

for this project is estimated to be \$7,482,681. There are no start-up costs related to this project. Southeastern Regional Medical Center will fund the capital cost of the project with hospital reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time.”

Exhibit 22 contains the audited financial statements for the Southeastern Regional Medical Center, Inc. and related organizations for the years ending September 30, 2012 and 2011. The balance sheet shows total assets in the amount of \$374,383,858, including cash and cash equivalents in the amount of \$1,645,078 as of December 31, 2012. The financial statements also show Southeastern Regional Medical Center, Inc. and related organizations had current net assets (total current assets less total current liabilities) in the amount of \$5,225,888. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In the financial section of the application, the applicant provides pro forma financial statements for the first three years of the project, which are fiscal years 2015, 2016, and 2017. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

LINEAR ACCELERATOR	PROJECT YEAR 1 (FY 2015)	PROJECT YEAR 2 (FY 2016)	PROJECT YEAR 3 (FY 2017)
Number of Treatments	8,923	8,935	8,948
Gross Patient Revenue	\$16,974,246	\$17,678,130	\$18,411,203
Deductions from Gross Patient Revenue	\$11,781,504	\$12,270,057	\$12,778,869
Net Patient Revenue	\$ 5,192,742	\$ 5,408,073	\$ 5,632,334
Total Expenses	\$ 3,316,457	\$ 3,547,750	\$ 3,740,693
Net Income	\$ 1,876,285	\$ 1,860,323	\$ 1,891,641

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See pages 112 - 114 of the application following the “*financials*” tab for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates 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.

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Southeastern Regional Medical Center is the only hospital in Robeson County, and operates the only cancer center in the county. Southeastern Regional Medical Center proposes to replace its existing, outdated 2004 Siemens Primus linear accelerator with a new Varian TruBeam linear accelerator. In addition, the applicant proposes to renovate existing space to improve patient privacy, throughput, and physician workflow, and to construct a new vault to accommodate the replacement equipment. The proposal will not result in an increase in the inventory of linear

accelerators located in Robeson County. The historical and projected utilization of the equipment is consistent with the planning standard for radiotherapy equipment in the 2013 SMFP. The applicant adequately demonstrates the need to replace the outdated equipment. Therefore, the applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved linear accelerators located in Robeson County. Consequently, 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, page 80, the applicant provides the current and projected staffing for radiation services at SRMC. In Section VII.3, on page 82, the applicant states that no new positions will result from this project. See the following table, which represents a combination of present and projected staffing, from application pages 80 and 81:

POSITIONS	TOTAL NO. FTE POSITIONS 2012 AND 2016
Radiation Therapists	4.0
Staff Registered Nurse	1.0
Radiation Oncology Technician	1.0
Manager, Radiation Oncology	1.0
Total FTE Positions	7.0

In Section V.3(c), page 64, the applicant states there will be no change in leadership positions in the radiation oncology department following replacement of the linear accelerator. Therefore, Dr. Thomas Walden currently serves as Medical Director for the radiation oncology program; and Dr. Joseph Roberts serves as the Chief Medical Officer. Both physicians will continue in that capacity following project completion. In Exhibit 26, the applicant provides a February 1, 2013 letter signed by Dr. Walden in which he confirms his support of the project. In addition, in the same exhibit, the applicant provides 6 letters from area physicians, each indicating his or her support for the proposed replacement linear accelerator. The applicant demonstrates 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

In Section II.2, page 21, the applicant states that since radiation therapy is an existing service at SRMC's Gibson Cancer Center, and no new equipment or services are proposed, all necessary ancillary and support services are currently in place, and will continue to be available following the linear accelerator replacement. In Exhibit 6, the applicant provides a February 15, 2013 letter from President of Southeastern Regional Medical Center, which documents that these services will continue to be provided following replacement of the linear accelerator. Furthermore, in Section V.2, page 62, the applicant states existing transfer agreements between SRMC and area healthcare providers are currently in place, and will continue following project completion. In Exhibit 18, the applicant provides a list of area healthcare providers with which it currently has transfer agreements, including:

- Raleigh Community Hospital
- University of North Carolina Hospitals
- Beverly Healthcare – Lumberton
- Pitt County Memorial Hospital, Inc.
- NC Baptist Hospital
- Duke University health Systems, Inc. (Duke Raleigh Hospital)
- Woodhaven Nursing and Alzheimer's Care Center
- Duke University Health Systems, Inc.

The applicant also provides a copy of an existing transfer agreement in Exhibit 18. The applicant provides letters of support for the proposal from area physicians in Exhibit 26. 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.

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

Southeastern Regional Medical Center proposes to construct 5,327 square feet of new space and to renovate 1,640 square feet of existing space in the radiation oncology department of the Gibson Cancer Center in order to replace its linear accelerator, improve patient and physician workflow, and increase patient privacy. In Exhibit 22, an architect certifies that the total site preparation and construction cost is estimated to be \$3,012,522, which is consistent with the cost reported by the applicant in Section VIII.1, pages 87 - 88. In Section XI.7, pages 102 - 103, the applicant describes the applicable energy savings features that will be incorporated into the plans for the plumbing, mechanical and electrical systems in the renovated area and the new square footage. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project it proposes, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. 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.12, page 77, the applicant provides the current payor mix for all services provided at SRMC during FY 2012, as shown in the table below:

Entire Facility FY 2012 (10/01/11 – 09/30/12)

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	9.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	24.5%
Managed Care/ Commercial Insurance	12.3%
Total	100.0%

*On page 77, the applicant states “Other” includes “workers comp and other government payors.”

In addition, in Section VI.13, page 77, the applicant provides the current payor mix for linear accelerator services provided at SRMC during FY 2012, as shown in the table below:

Linear Accelerator Services FY 2012 (10/01/11 – 09/30/12)

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	6.0%
Medicare/Medicare Managed Care	56.8%
Medicaid	16.8%
Managed Care/ Commercial	20.4%
Total	100.0%

*On page 77, the applicant states “Other” includes “workers comp and other government payors.”

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

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Robeson	31.0%	13.2%	23.9%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the

population, particularly the radiotherapy services offered at the Gibson Cancer Center by SRMC.

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 applicant's 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 such as the radiotherapy services offered at SRMC. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that SRMC currently provides adequate access to medically underserved populations. 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.2, pages 69 - 70, the applicant describes SRMC's commitment to providing services to all people, "*regardless of age, race, national or ethnic origin, disability, gender, sexual orientation, income, or immediate ability to pay.*" In Exhibit 19, the applicant provides a copy of SRMC's charity and collection policies, which outline the poverty standards and the applicant's expectations. On page 70, the applicant states SRMC provided more than \$68 Million, which is 8.0% of gross revenue, in uncompensated care (charity care and bad debt) in FY 2012. In Section VI.10, page

85, the applicant states no civil rights equal access complaints were filed against SRMC in 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 Sections VI.14 and VI.15, pages 78 – 79, the applicant projects the following payor mix for all of SRMC’s services and for linear accelerator services for the second project year (FY 2016):

Entire Facility FY 2016 (10/01/15 – 09/30/16)

ENTIRE FACILITY PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION (FY 2016)	PERCENT
Self Pay/Indigent/Charity/Other*	9.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	24.5%
Managed Care/ Commercial	12.3%
Total	100.0%

*On page 78, the applicant states “Other” includes “workers comp and other government payors.”

Linear Accelerator Services FY 2016 (10/01/15 – 09/30/16)

PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	6.0%
Medicare/Medicare Managed Care	56.8%
Medicaid	16.8%
Managed Care/ Commercial	20.4%
Total	100.0%

*On page 79, the applicant states “Other” includes “workers comp and other government payors.”

As shown in the tables above and the tables in Criterion (13a), the applicant assumes no change in payor mix following the linear accelerator replacement.

In Section VI.4, page 70, the applicant states it will provide services to “...all patients regardless of ability to pay.” The applicant demonstrates that SRMC will continue to provide adequate access to medically underserved groups following the linear accelerator replacement. Therefore, the application is conforming to 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, page 75, the applicant states persons currently have and will continue have access to radiotherapy services at SRMC through physician referrals. The applicant states the project is not expected to effect current referral patterns. The application is conforming to 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, page 61, the applicant states the hospital currently has training agreements in place with many area health professional training programs, and will continue those affiliations when the proposed replacement linear accelerator is replaced. In Exhibit 17, the applicant provides a list of those facilities with which it currently has and will have clinical training agreements. Those facilities include, but are not limited to:

- Bladen Community College
- Campbell University
- University of North Carolina at Chapel Hill
- Duke University
- East Carolina University
- Robeson Community College

The applicant adequately demonstrates that the hospital will continue to accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to 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

SRMC currently operates one linear accelerator at its campus in Lumberton. In this application, SRMC proposes to replace its existing 2004 Siemens Primus linear accelerator with a new

Varian TrueBeam linear accelerator, in order to better serve its radiation oncology patients. The current and projected utilization exceeds the planning standard for linear accelerators in the 2013 SMFP.

In Section III.6, pages 55 - 56, 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 to radiotherapy services. The applicant states:

“SRMC is among three radiation therapy providers in Linear Accelerator Service Area 18 as designated by the 2013 SMFP. ...

The identified need is internal to SRMC as it involves the replacement of existing outdated equipment to accommodate the patients it serves. No other provider can meet the internal needs at SRMC.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed radiotherapy services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to replace its 2004 Siemens Primus linear accelerator and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates it will continue to provide quality services; and
- ◆ The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

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

SRMC is certified by the Centers for Medicare and Medicaid for participation in the Medicare and Medicaid programs, and licensed by the NC Division of Health Service Regulation as an acute care hospital. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, 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