

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2016

Findings Date: January 29, 2016

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: Q-11114-15

Facility: Vidant Roanoke-Chowan Hospital Radiation Oncology Center

FID #: 150507

County: Hertford

Applicant: East Carolina Health

Radiation Services of North Carolina, LLC

Project: Replace existing linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center (VROA-ROC) and Radiation Services of North Carolina, LLC (RSNC), propose to replace the existing linear accelerator located at VROA-ROC at 310 S. Academy Street in Ahoskie. RSNC currently owns the existing linear accelerator and the radiation oncology center building where the services are provided.

University Health Systems of Eastern Carolina, Inc. d/b/a Vidant Health (VH) is the parent company for East Carolina Health. East Carolina Health operates Vidant Roanoke-Chowan. In 2012, VROA purchased 100% membership interest of RSNC from Alliance Oncology, LLC (Alliance). Since that time VROA has leased the building and equipment from RSNC

and is operating the facility for the provision of radiation oncology services under the d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center. In Section II.1, page 11, the applicants state that throughout the application, they refer to the VROA, RSNC, VROA-ROC relationship collectively as VROA-ROC; therefore, throughout the findings, the three entities are collectively referred to as VROA-ROC or “the applicant”.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES.

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.”

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.2, pages 30-31, the applicant addresses Policy GEN-4 and the center’s plan for energy efficiency and water conservation. The applicant states:

“VROA-ROC will conform to the energy efficiency and water conservation rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation and required by the North Carolina State Building Code. During the design of this project the VH office of Facilities and Properties, in conjunction with the VROA Plant Operations Department, will work with the project Architects and Engineers to assure that the latest technologies for enhanced building energy and water conservation are evaluated for the project and incorporated in to the facility where most appropriate. The goal of this effort will be to maximize energy efficiency and water conservation while creating the best possible care and healing environments for our patients.”

The applicant adequately demonstrates the proposal includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4. Therefore, the application 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.

C

The applicant proposes to replace the existing linear accelerator located at VROA-ROC at 310 S. Academy Street in Ahoskie.

Population to be Served

On page 125, the 2015 SMFP defines a linear accelerator’s service area as *“the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I.”* Table 9I on page 134 of the SMFP shows Hertford County in Linear Accelerator Service Area 27, along with the counties of Beaufort, Bertie, Greene, Hyde, Martin, Pitt and Washington.

Thus, the service area for this facility’s project is Linear Accelerator Service Area 27, consisting of Beaufort, Bertie, Greene, Herford, Hyde, Martin, Pitt and Washington counties. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a and b), page 32, the applicant identifies the historical patient origin for services provided at VROA and VROA-ROC, as shown below.

**VROA Inpatient and Outpatient Visits
Historical Patient Origin by County
FFY2015**

County	Patients	Percent
Hertford	32,129	47.7%
Bertie	16,270	24.2%
Northampton	8,576	12.7%
Gates	3,490	5.2%
Chowan	1,680	2.5%
Washington	699	1.0%
All Other (<1% of Total)	4,445	6.6%
Total	67,289	100.0%

**VROA-ROC Radiation Therapy Services
Historical Patient Origin by County
FFY2015**

County	Patients	Percent
Hertford	42	43.3%
Bertie	31	32.0%
Northampton	9	9.3%
Gates	4	4.1%
Chowan	4	4.1%
All Other	7	7.2%
Total	97	100.0%

The applicant states that historically, Hertford and Bertie counties account for approximately 75 percent of VROA-ROC's total radiation therapy patients as shown in the table on page 32 and above. In clarifying information requested by the Project Analyst in the expedited review of this application, the applicant states that "All Other" in the table above consists of residents from Pitt, Dare, Washington, and Halifax counties in North Carolina and Virginia.

The applicant provides a map on page 33 showing the applicant's proposed primary market of Hertford and Bertie counties, and secondary market of Northampton County.

On page 33, the applicant provides the projected patient origin by county of residence for linear accelerator services for the first two years of operation following completion of the project, as shown below.

**VROA-ROC Radiation Therapy Services
Projected Patient Origin by County**

County	OY1/FFY2018		OY2/FFY2019	
	Patients	Percent	Patients	Percent
Hertford	45	43.3%	46	43.3%
Bertie	33	32.0%	34	32.0%
Northampton	10	9.3%	10	9.3%
Gates	4	4.1%	4	4.1%
Chowan	4	4.1%	4	4.1%
All Other	8	7.2%	8	7.2%
Total	104	100.0%	106	100.0%

Note: the analyst's calculation of percent of patients differs from the applicants' by 0.1% to 0.5%, which could be due to rounding and is an insignificant amount and therefore irrelevant to the review.

The applicant states that VROA-ROC does not expect any changes in patient origin as a result of the proposed project. Therefore, the applicant projects patient origin to approximate historical distribution for FFY2015.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to replace the existing Siemens Oncor Impression linear accelerator with a new Varian Clinac iX linear accelerator. In Section III.1, pages 24-28, the applicant discusses the need for the proposed project and states that the need is based on numerous factors, including:

- cancer as a leading health concern for the communities the applicant serves and the disparity in the proposed patient population's cancer incidence and mortality rates,
- radiation therapy is an important component of the cancer treatment process,
- the existing linear accelerator is technologically obsolete and has performance limitations,
- the proposed replacement represents the current clinical standard of care, and
- the economic demographics of the service area population makes travel for state-of-the-art radiation therapy difficult.

Cancer Incidence and Mortality Rates

In Section III, the applicant states that cancer is the second leading cause of death and a leading health concern for the patient population from Hertford, Bertie and Northampton counties. The chart provided by the applicant on page 24 and summarized below, shows that these three counties have lower incidence rates of cancer as compared to the State average, but have some of the highest rates of cancer mortality in the State, with Hertford County having the 11th highest mortality rate in the State.

County	Cancer Incidence			Cancer Mortality		
	Rate	% Under Average	State Rank	Rate	% Over Average	State Rank
Hertford	471.3	-3.6%	68	202.2	14.6%	11
Bertie	470.0	-3.9%	70	187.4	6.2%	37
Northampton	485.2	-0.8%	47	195.0	10.5%	22
North Carolina	488.9			176.5		

The applicant attributes the disparity between incidence and mortality rates to the fact that these counties have some of the highest percentages of cancer cases diagnosed at Stage 3 and 4 in the country.

In Section III, page 25, the applicant states that radiation therapy is one of the most important components of the cancer treatment process with nearly two-thirds (67%) of all cancer patients expected to receive radiation therapy during their course of treatment.

“Therefore, as the only local providers of cancer care in the service area, it is imperative VROA and VROA-ROC maintain the latest state-of-the-art technology and services for the diagnosis and treatment of cancer, including radiation therapy.”

Existing Equipment

The applicant’s existing linear accelerator was manufactured in 2003 and allows VROC-ROC to offer only electron beam radiation therapy, 2D conventional radiation therapy, 3D conformal radiation therapy, and intensity-modulated radiation therapy (IMRT). The applicant states that the existing unit does not have the technological capabilities to allow VROA-ROC to provide image-guided radiation therapy (IGRT) or volumetric arc therapy (VMAT) radiation therapy services, which have become the standards of treatment for certain types of cancer like breast cancer and prostate cancer. Because VROA-ROC’s unit cannot provide these services, the applicant states that approximately 40% of the applicant’s proposed patient population have to leave the area for treatment at another facility that has IGRT and /or VMAT technology.

In Section III, pages 25-26, the applicant states that most of the 40% of the patient population leaving the area for radiation therapy treatment travel to Greenville, Virginia, UNC or Duke for care, requiring travel time from one hour to more than two hours five days a week for five to eight weeks.

In addition to technology limitations, the applicant states that the existing linear accelerator also has performance limitations as well. The existing accelerator is almost 13 years old and is rapidly approaching the end of its useful life. As a result, the amount of time the existing unit is not operating due to maintenance or performance issues has been increasing and the time it takes to get the equipment back on line is also increasing. The applicant states that

Siemens, the manufacturer, is no longer building or servicing linear accelerators which makes it hard to find spare parts, qualified service techs or ongoing technical training.

Proposed Replacement Equipment

VROC-ROC is proposing to replace the existing unit with a new linear accelerator with the latest technology, a Varian Clinac iX. The new unit will allow VROA-ROC to provide all the services it has historically been providing along with the added ability to provide the newest radiation therapy options available via IGRT and VMAT technology. The applicant states that the proposed new linear accelerator will not be used to perform stereotactic radiosurgery.

Demographics

The applicant provides selected demographic and socioeconomic data in Appendix I, comparing Hertford, Bertie and Northampton counties with 29 eastern North Carolina counties (ENC). The applicant states that the data shows:

- Hertford County has the lowest average household income, almost \$10 thousand less than the ENC average. Hertford County also has the highest percent of households below the poverty level at 41.3% of households (ENC =30.3%).
- Bertie County has the 9th lowest average household income and the 3rd highest percent of households below the poverty level at 37.7% of households.
- Northampton County has the 7th lowest average household income, and the 4th highest percent of households below the poverty level at 36.5% of households.

As discussed above, the proposed patient population must currently leave the Hertford County area for state-of-the-art radiation therapy. The applicant states that with the poor, rural nature of the communities VROA-ROC serves, for many of these patients, the financial and logistical burden of traveling to other facilities is too great. Some of these patients may elect not to receive treatment or choose other treatment modalities like higher doses of chemotherapy and/or radically invasive surgical procedures. On page 27, the applicant provides data from the North Carolina State Center for Health Statistics that indicates that as many as one in three patients from the proposed market that need radiation therapy are not getting the treatment.

The applicant states that because of this, it is imperative that the only provider of radiation therapy services in its proposed market, VROA-ROC must maintain the most up-to-date and generally accepted radiation therapy treatment options locally for the treatment of cancer.

Projected Utilization

In Section IV.1, page 37, the applicant provides the historical and projected radiation therapy utilization at VROA-ROC.

	Historical Years			Interim Years		First Three Full Fiscal Years		
	FFY2013	FFY2014	FFY2015	FFY2016	FFY2017	FFY2018	FFY2019	FFY2020
Simple	9	-	-	-	-	-	-	-
Intermediate	-	-	-	-	-	-	-	-
Complex	1,491	1,555	1,455	1,455	1,455	1,455	1,455	1,455
Subtotal	1,500	1,555	1,455	1,455	1,455	1,455	1,455	1,455
Percent Change		3.7%	-6.4%	0.0%	0.0%	0.0%	0.0%	0.0%
Other (IMRT/IGRT/VMAT)	845	866	968	992	1,042	1,146	1,203	1,233
Percent Change		2.5%	11.8%	2.5%	5.0%	10.0%	5.0%	2.5%
Total Treatments	2,345	2,421	2,423	2,447	2,497	2,601	2,658	2,688
Percent Change		3.2%	0.1%	1.0%	2.0%	4.2%	2.2%	1.1%
Unique Patients	95	99	97	98	100	104	106	108
Treatments per Patient	24.7	24.5	25.0	25.0	25.0	25.0	25.0	25.0
Number of Units	1	1	1	1	1	1	1	1
Number of ESTVs	2,345	2,421	2,423	2,447	2,497	2,601	2,658	2,688

Assumptions:

- FFY2013 through FFY2015 is actual data from VROA-ROC's internal databases.
- Growth of traditional radiation therapy will remain flat which approximates the weighted average of the projected population of Hertford, Bertie and Northampton counties (no growth) with the distribution level approximating FFY2015.
- Growth for Other (IMRT/IGRT/VMAT) in FFY2016 will be 2.5% above FFY2015 utilization, a growth rate approximating FFY2014 growth.
- Other therapy treatments FFY2017-FFY2020 result in more patients, with the initial impact of the pent up demand affecting FFY2017 (5.0% increase) at project completion mid-year and FFY2018 (10.0% increase). FFY2019 and FFY2020 increases will begin to decline back to the 2.5% level of increase for FFY2014 and FFY2016.
- Resulting growth is only a net gain of 10 radiation therapy patients by FFY2020.
- ESTVs are calculated based on the accepted definition of simple, intermediate, complex and IMRT radiation procedures being equal to 1.0 ESTVs.

The applicant states the projection is reasonable and even conservative, given the number of patients previously traveling outside the service area for treatment or foregoing treatment combined with the significant disparity in cancer incidence and mortality rates.

The applicant adequately demonstrates the projected utilization is based on reasonable and supported assumptions. Thus, the applicant adequately demonstrates the need the identified population has for the proposed services.

Access

In Section VI.2, page 44, the applicant states:

“As a not-for-profit hospital, VROA has an obligation to accept any patient requiring medically necessary treatment. As part of VROA’s compliment of services, no patient is denied access to non-elective care at VRAO-ROC based on race, color [sic] creed, age, sex, national origin, religion, disability status, sexual preference, source of payment for care or lack of medical insurance.

VROA and VROA-ROC ensures access to health care services for all patients noted in (a) through (f).”

In Section VI.15, page 50, the applicant projects that 60.8% of projected FFY2019 patients to be served will be Medicare beneficiaries and 13.4% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identifies the population to be served; adequately demonstrates the need the population to be served has for the proposed services; and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.3, page 31, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states that maintaining the status quo would not be in the best interest of cancer patients in the community because the existing equipment is no longer state-of-the-art. Therefore, this option was rejected.

- 2) Eliminate Radiation Therapy Services – The applicant states that this alternative would only serve to increase the socioeconomic burden of the cancer patients in the community and would not address the significant disparity between cancer incidence and mortality in the area. Therefore, this option was rejected.
- 3) Pursue the Project as Proposed – The applicant states that the proposed project, as presented in this application, was seen as the only option to pursue, stating that the socioeconomic and health improvement benefits gained by implementing the project far outweighs the cost of not moving forward with the project.

The applicant adequately demonstrates that the proposed project to replace its existing linear accelerator with state-of-the-art equipment is the most effective alternative to meet VROA-ROC's identified need.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center and Radiation Services of North Carolina, LLC shall materially comply with all representations made in the certificate of need application and the clarifying supplemental information dated January 5, 2016. In those instances where representations conflict, East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center and Radiation Services of North Carolina, LLC shall materially comply with the last-made representation.**
- 2. East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center and Radiation Services of North Carolina, LLC shall acquire no more than one linear accelerator to replace the existing linear accelerator located at Vidant Roanoke-Chowan Hospital Radiation Oncology Center.**
- 3. East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center and Radiation Services of North Carolina, LLC 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.**
- 4. East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital Radiation Oncology Center and Radiation Services of North Carolina, LLC shall acknowledge**

acceptance of and agree to comply with all conditions stated herein to the Agency 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

The applicant proposes to replace its existing linear accelerator. The project involves minor renovations to the vault space at VROA-ROC to house the replacement equipment.

Capital and Working Capital Costs

In Section VIII, page 62, the applicant projects the total capital cost of the proposed project will be \$2,123,129, including:

Costs	Total Costs
Construction Contract	\$ 392,000
Equipment/Furniture	\$ 1,588,299
Landscaping	\$ 1,500
Consultant Fees	\$ 67,080
Other (signage and commissioning)	\$ 74,250
Total Capital Costs	\$ 2,123,129

In Section IX, page 63, the applicant states there are no start-up or initial operating expenses for this project.

Availability of Funds

In Section VIII.3, page 58, the applicant states that the total capital cost will be funded with East Carolina Health accumulated reserves. Appendix R contains a letter from the Chief Financial Officer of Vidant Health which documents East Carolina Health's commitment to fund the proposed project and the availability of funds. Appendix S contains the audited consolidated financial statements for Vidant Health for years ending September 30, 2014 and 2013. According to the financial statements, as of September 30, 2014, Vidant Health had \$15,896,635 in cash and cash equivalents, \$576,853,000 in current assets, \$1,808,781,000 in total assets and \$1,013,618,000 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The application projects a loss in net income for the project in each of the first three operating years of the project, as shown in the table below. In clarifying information requested by the Project Analyst during the expedited review of this application, the applicant provided corrected Forms C, D and E, based on the projected number of patients for FFY2018-FFY2020 (Section IV, page 37) which results in the following revenue and expense statement.

Radiation Therapy Services	PY 1 FFY2018	PY 2 FFY2019	PY 3 FFY2020
Projected # of Patients	104	106	108
Projected # of Procedures	2600	2658	2688
Projected Average Charge per Patient	\$ 35,465	\$ 36,629	\$ 37,448
Projected Average Charge per Procedure	\$ 1,419	\$ 1,461	\$ 1,505
Gross Patient Revenue	\$ 3,688,331	\$ 3,882,672	\$ 4,044,409
Deductions from Gross Patient Revenue	\$ 2,244,714	\$ 2,362,989	\$ 2,461,422
Net Patient Revenue	\$ 1,443,617	\$ 1,519,683	\$ 1,582,987
Total Expenses	\$ 1,589,132	\$ 1,632,896	\$ 1,675,903
Net Income	\$ (145,515)	\$ (113,213)	\$ (92,916)

* Source: Corrected Pro Forma Financial Statements' Form C, Form D and Form E, as requested by the Project Analyst.

However, the operating statement included for VROA shows the entire hospital entity is clearly financially solvent, making a profit in each of the first three years, following completion of the project.

The assumptions used by the applicant in preparation of the pro forma financial statements and the clarifying information are reasonable, including projected utilization, costs and charges. See pages 66-67 for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 applicant proposes to replace its existing linear accelerator located at VROA-ROC.

On page 125, the 2015 SMFP defines a linear accelerator's service area as *"the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I."* Table 9I on page 134 of the SMFP shows Hertford County in Linear Accelerator Service Area 27, along with the counties of Beaufort, Bertie, Greene, Hyde, Martin, Pitt and Washington.

Thus, the service area for this facility's project is Linear Accelerator Service Area 27, consisting of Beaufort, Bertie, Greene, Hertford, Hyde, Martin, Pitt and Washington counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved linear accelerators located in Linear Accelerator Service Area 27.

Service Provider	County	Licensed Linacs	ESTVs FFY2013	Average ESTVs / Unit	Percent of Capacity
Vidant Beaufort Hospital	Beaufort	1	2,584	2,584	38.3%
Vidant Roanoke-Chowan Hospital	Hertford	1	2,813	2,813	41.7%
Leo Jenkins Cancer Center	Pitt	2	10,415	5,207	77.1%
NC Radiation Therapy-Greenville	Pitt	2	11,959	5,980	88.6%
Vidant Medical Center	Pitt	1	1,678	1,678	24.9%

As shown in the table above, the radiation therapy providers in Linear Accelerator Service Area 27 are operating below the State defined capacity threshold of 6,750 ESTVs. However, as stated by the applicant on pages 27-28:

"In summary, while the VROA-ROC service area may not have the population, number of patient [sic] receiving radiation therapy, or the volume of fractions many other radiation therapy providers are experiencing in other major urban markets, providing this service in this market is no less important or needed. Given the significant disparity between cancer incidence and mortality that exists, the significant socioeconomic burden that exists today for a largely medically underserved community, and the performance and technology limitations of a 13 year old discontinued piece of medical equipment, it is imperative VROA-ROC replace its existing linear accelerator with a newer unit as a first step in addressing these issues."

Additionally, the applicant states in Section III, pages 32 and 33, that VROA-ROC serves and will continue to serve patients originating from Hertford, Bertie, Northampton, Gates and Chowan counties, with 85% of the projected patients being from Hertford, Bertie, Northampton counties. In Section III.6(b), page 34, the applicant states that there are no other providers of radiation therapy services in Hertford, Bertie or Northampton counties.

The applicant adequately demonstrates that the proposal to replace the existing linear accelerator would not result in an unnecessary duplication of existing and approved linear accelerator services, 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, page 51, the applicant provides the current and proposed staffing, as shown in the table below.

Position	Current FTE Positions FFY2015	PY2 FTE Positions FFY2018
Administrative	0.1	0.1
Radiation Therapist	2.0	2.0
Scheduling Coordinator	1.0	1.0
Total	3.1	3.1

In the assumptions provided in Section X, page 66, the applicant states that the physicians, dosimetrists and physicists are included in Contractual Services. The applicant states that the replacement project does not require any additional staffing. In Section VII.6, page 54, the applicant describes its experience and process for recruiting and retaining staff. David Lingle, MD, is VROA's Chief of Staff. Appendix O contains VROA's medical staff listing. Appendix M contains a copy of Eleanor Harris, M.D.'s curriculum Vitae and lists Dr. Harris as the Medical Director. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 18, the applicant identifies the ancillary and support services that are required for the proposed project, including pathology, pharmacy, radiology, oncology clinic visits and respiratory therapy. The applicant states that as an existing community hospital, VROA currently has all ancillary and support services in place to support the ancillary and support needs of patients receiving radiation therapy services at VROA-ROC. The applicant discusses coordination with the existing health care system in Section V, pages 39-43. The applicant provides supporting documentation in Appendices G, K, L, and O. The information provided in these sections and exhibits is reasonable and supports a finding of conformity with 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

The applicant proposes to develop the proposed replacement project, with minimal renovation, in the existing vault space located in the VROA-ROC building across the street from the VROA hospital facility. Appendix T contains a letter from a licensed architect that estimates the total cost of the project at \$2,123,129, which corresponds to the capital cost projections provided by the applicant in Section VIII, page 62. In Section XI.7, pages 77-78, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. 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 and VI.13, page 49, the applicant provides the payor mix during FFY 2015 for VROA hospital services and VROA-ROC radiation therapy services, as illustrated in the table below:

FFY 2015 (10/1/14-9/30/15)
Patients as a Percent of Total Utilization

	VROA Entire Facility	VROA-ROC Radiation Therapy Services
Commercial / Managed Care	24.2%	19.6%
Medicaid	22.6%	13.4%
Medicare	42.6%	60.8%
Other	3.0%	0.0%
Self-Pay	7.6%	6.2%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section VI.2, page 44, the applicant states:

“VROA and VROA-ROC ensures access to health care services for all patients noted in (a) through (f). The hospital is a not-for-profit corporation formed for the purpose of providing quality hospital-related medical and health care services to all persons in its service area.”

Appendix G contains a copy of VROA’s EMTALA policy, which states:

“It is the policy of this hospital that patients shall not be denied evaluation, screening, treatment or stabilization on the basis of means or ability to pay, race, creed, color, national origin, age, sex, or actual or perceived disability.”

Appendix N contains copies of VROA’s admission and charity care policies. The applicant states that as part of VROA’s compliment of services, these policies extend to VROA-ROC.

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. The following counties comprise the projected counties of residence for the patients to be served by the proposed services.

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Hertford	25.6%	12.7%	21.5%
Bertie	26.7%	13.8%	20.4%
Northampton	27.7%	14.5%	21.7%
Gates	15.3%	7.0%	19.7%
Chowan	22.7%	10.7%	20.8%
Statewide	16.5%	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 imaging 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 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, women, or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at VROA and VROA-ROC. 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 48, the applicant states:

“VROA, and by extension VROA-ROC, is bound by the Civil Rights Act, Hill-Burton Community Services obligation as well as its admissions policy to provide equal access to care without discrimination and without regard to race, color, creed, national origin, or source of payment. VROA has fulfilled its required volume of uncompensated care services in compliance with Hill-Burton regulations. However, there exists into perpetuity the Hill-Burton requirement that VROA provide access to all those in need. In fact, over the last five fiscal years, VROA has provided almost \$36.5 million in charity care services.”

In Section VI.10, page 48, the applicant states there have been no civil rights equal access complaints filed against the hospital within 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.15, page 50, the applicant provides the projected payor mix for radiation therapy services for the second full operating year following project completion, as shown in the table below.

**VROA-ROC Radiation Therapy Services
Projected Patient Utilization as a Percent of Total
FFY 2019**

Payor Category	% of Total Utilization
Commercial / Managed Care	19.6%
Medicaid	13.4%
Medicare	60.8%
Self-Pay	6.2%
Total	100.0%

On page 50, the applicant states that it assumes the projected payor mix will approximate FFY2015's payor mix. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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 47, the applicant describes the range of means by which a person will have access to the proposed services, stating that services will be available by appointment during normal operating hours and that patients will be referred by a physician or other health care provider. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, 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 38, the applicant describes how VROA serves as a primary care training facility for medical, allied health and nursing students. The applicant states that VROA maintains working agreements with numerous educational institutions including Roanoke-Chowan Community College, East Carolina University School of Nursing, and Halifax Community College. The applicant further states that VROA will continue to provide

opportunities for clinical training for students enrolled in these institutions, including training and education related to radiation therapy treatment. Appendix J contains a sample of one of VROA’s clinical training agreement. The information provided is reasonable and adequately supports a determination that 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

The applicant proposes to replace an existing linear accelerator located at VROA-ROC.

On page 125, the 2015 SMFP defines a linear accelerator’s service area as *“the linear accelerator planning area in which the linear accelerator is located. The linear accelerator planning areas are the 28 multicounty groupings shown in Figure 9I.”* Table 9I on page 134 of the SMFP shows Hertford County in Linear Accelerator Service Area 27, along with the counties of Beaufort, Bertie, Greene, Hyde, Martin, Pitt and Washington.

Thus, the service area for this facility’s project is Linear Accelerator Service Area 27, consisting of Beaufort, Bertie, Greene, Herford, Hyde, Martin, Pitt and Washington counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved linear accelerators located in Linear Accelerator Service Area 27.

Service Provider	County	Licensed Linacs	ESTVs FFY2013	Average ESTVs / Unit	Percent of Capacity
Vidant Beaufort Hospital	Beaufort	1	2,584	2,584	38.3%
Vidant Roanoke-Chowan Hospital	Hertford	1	2,813	2,813	41.7%
Leo Jenkins Cancer Center	Pitt	2	10,415	5,207	77.1%
NC Radiation Therapy-Greenville	Pitt	2	11,959	5,980	88.6%
Vidant Medical Center	Pitt	1	1,678	1,678	24.9%

As shown in the table above, the radiation therapy providers in Linear Accelerator Service Area 27 are operating below the State defined capacity threshold of 6,750 ESTVs. However,

in Section III, pages 32 and 33, the applicant states that VROA-ROC serves and will continue to serve patients originating from Hertford, Bertie, Northampton, Gates and Chowan counties, with 85% of the projected patients being from Hertford, Bertie, Northampton counties. In Section III.6(b), page 34, the applicant states that there are no other providers of radiation therapy services in Hertford, Bertie or Northampton counties.

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination methodology in the 2015 SMFP.

In Section V.7, pages 41-42, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

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

The information provided by the applicant in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to replace the existing linear accelerator. The discussions regarding analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

In Section I.11, page 5, the applicant provides an explanation of the corporate ownership of VROA and VROA-ROC. University Health Systems of Eastern Carolina, Inc. d/b/a Vidant Health is the parent company for East Carolina Health. East Carolina Health acts as a parent company for a number of community hospitals, including Vidant Roanoke-Chowan Hospital, which provides the radiation therapy services at VROA-ROC. East Carolina Health is also

the sole membership interest in Radiation Services of North Carolina, LLC, which owns the linear accelerator and the VROA-ROC building. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Vidant Health in North Carolina. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all Vidant facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

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