

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 10, 2013
PROJECT ANALYST: Celia C. Inman
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10063-12 / Rex Hospital, Inc. / Replace one existing linear accelerator located at Rex Healthcare of Wakefield / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Rex Hospital, Inc. (Rex) proposes to replace one existing linear accelerator located at Rex Healthcare of Wakefield. The applicant does not propose to develop beds, add services or acquire medical equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP).

However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 SMFP, is applicable to the review of this proposal. Policy GEN-4 states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards

incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

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

In Section III.2, beginning on page 52, the applicant addresses Policy GEN-4 and the hospital's plan for energy efficiency and water conservation. The applicant states that with only minor upfits to the existing vault to accommodate the replacement equipment, the ability to improve energy efficiencies and conservation of resources rests in the efficiencies at the existing facility where engineering management seek ways to improve and conserve energy and more efficiently utilize hospital resources. The applicant states:

"Furthermore, the proposed replacement equipment was designed to use less energy than its predecessors, in particular the equipment that will be replaced. In that way, this project will improve the energy efficiencies associated with radiation therapy services at Rex."

The applicant provides a written statement describing the project's plan to assure improved energy and water conservation in accordance with GEN-4 requirements in Exhibit 19. The plan states compliance with the North Carolina State Energy Conservation Code and lists architectural, mechanical, electrical, civil and plumbing strategies that will be evaluated in relation to energy efficiency and water conservation.

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion.

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

C

Rex currently owns and operates four linear accelerators and proposes to replace the one located at Rex Healthcare of Wakefield, a Varian Clinac 21EX. Rex Healthcare of Wakefield's existing unit is twelve years old. In this project, the applicant proposes to replace the 12-year old Varian Clinac 21EX linear accelerator with a TrueBeam-comparable linear accelerator which is capable of more advanced treatment than the existing linear accelerator. In Section I, pages 16-17, the applicant states:

“Rex Healthcare of Wakefield’s existing linear accelerator, which is more than 12 years old, is at the end of its useful life. The proposed replacement equipment will enable faster treatment times and increased throughput, increased accuracy with minimal damage to adjacent tissue, greater physician and patient satisfaction, and an improved patient experience as well as enable Rex to continue in its commitment to provide exceptional, innovative cancer care to Wake County residents.”

Population to be Served

In Section III.5, page 56, the applicant states Rex Healthcare of Wakefield's proposed radiation therapy service area is Wake County and Franklin County. The applicant further states, *“In FY 2012, 92 percent of its patients originated from the proposed service area.”*

In Section III.4(b), page 56, the applicant provides current patient origin for radiation therapy patients at Rex Healthcare of Wakefield as illustrated by the table below.

**Rex Healthcare of Wakefield
FY 2012 Radiation Therapy**

County	Percent of Patients
Wake	64.7%
Franklin	27.2%
Other	8.1%
Total	100.0%

Other includes Chatham, Duplin, Granville, Johnston, Mecklenburg, Nash, Vance, and Warren counties.

In Section III.5(c), page 58, the applicant provides projected patient origin for radiation therapy services during the first two years of operation as shown in the table below.

**Rex Healthcare of Wakefield
Radiation Therapy Patient Origin
Project Years One and Two**

County	PY1 # Patients	PY1 % of Total	PY2 # Patients	PY2 % of Total
Wake	138	64.7%	151	64.7%
Franklin	58	27.2%	63	27.2%
Other	17	8.1%	19	8.1%
Total	213	100.0%	233	100.0%

Other includes Chatham, Duplin, Granville, Johnston, Mecklenburg, Nash, Vance, and Warren counties.

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.1, page 29, the applicant states, *“The primary need for the proposed project is to replace existing linear accelerator equipment that is more than 12 years old and past its seven-year useful life as measured by the American Hospital Association’s equipment lifetimes standards”*. The applicant further states the following factors contribute to the need to replace the twelve year old linear accelerator:

- The existing equipment has become less reliable than is optimal for patient care,
- Advances in linear accelerator technology, and
- Demographic, statistical and quantitative need.

In Section III, page 31, the applicant states the age of the existing equipment raises concerns relative to clinical applications that drive the need to replace the existing equipment. The applicant says the ability of the physicians to optimize treatment is hampered by the existing outdated equipment. The applicant further states:

“In particular, the existing equipment operates slowly, involves a lengthy set up process, and has antiquated capabilities when compared to newer technology available today. As a result, Rex Healthcare of Wakefield must send more complex patients to Rex Hospital to receive treatment on one of its three linear accelerators at that location.”

In Section III, page 32, the applicant states the goal of radiation therapy is to deliver a high radiation dose to the targeted site while limiting radiation exposure of healthy tissue and organs. Historically, radiation oncologists have limited adverse effects by reducing the radiation dose or by spreading the dose over multiple administrations. The applicant further states:

“However, technological advances in radiation planning and delivery have markedly improved the ability to focus radiation on targeted sites while sparing healthy tissue and organs; all of which allows for dose escalation with increased

probability of tumor control and reduced probabilities of healthy tissue complications.”

The applicant attributes the delivery of radiation therapy in a faster, more effective, safer manner to the following technological advances: new imaging modalities, such as volumetric modulated arc therapy and image guided radiotherapy (IGRT); more powerful computers and software; and new delivery systems.

In Section III, pages 32-33, the applicant states:

“Given the age of Rex’s existing equipment, it does not provide kilovoltage (KV) imaging, cone beam capabilities, 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 and KV imaging is dramatic.

...

MV imaging is becoming recognized as inferior for certain cases and has the disadvantages of low inherent soft tissue contrast and poorer detection efficiency. In contrast, KV images have a higher probability of interaction with the objects of interest, resulting in higher contrast images being produced at reduced doses. Moreover, while the current system utilizes films taken and repeat CT scans to check the plan and any changes throughout treatment, newer machines have the capability to use the KV imaging to match boney anatomy to the digitally reconstructed radiograph (DRR) daily.”

The applicant states its existing equipment, though IGRT capable does not have cone beam CT (CBCT) capabilities or OBI (On-Board Imager)/KV imaging capabilities. CBCT enables the physician and therapist to monitor a patient while on the treatment table, eliminating the need to schedule a CT scan with radiology. The applicant states OBI/KV capabilities reduce treatment time by up to 15 to 20 minutes per patient.

On page 35, the applicant states the proposed TrueBeam technology allows clinicians to operate radiation therapy equipment with pinpoint accuracy which means patients can be treated with higher radiation per dose in a shorter visit time. The applicant further states TrueBeam technology is more powerful and advances the opportunity for new treatment options because it was designed as a versatile platform system that can be used for all forms of advanced external-beam radiotherapy including IGRT, stereotactic body radiotherapy (SBRT) and RapidArc radiotherapy.

In Section III, page 36, the applicant states:

“The proposed replacement equipment will not only address the age concerns associated with the existing equipment, but will also enable Rex to provide state-of-the-art radiation therapy at its location in Wakefield. 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. The precise delivery of radiation, made possible by advances in technology, improves recovery time and reduces side effects and complications associated with conventional radiation therapy treatments. This decrease in side effects can result in an improvement in patients' quality of life and may result in lower costs of radiotherapy patient management."

Though the applicant identifies the primary need for the equipment replacement as internal, it validates the need based on the proposed service area projected population and compound annual growth rate (CAGR) as presented below.

Projected Service Area Population Growth

County	2012	2017	CAGR
Franklin	62,874	69,072	1.9%
Wake	946,278	1,070,015	2.5%
Total	1,009,152	1,139,087	2.5%

Source: Claritas, Exhibit 18, per page 42 of application

Claritas (Nielson Solution Center) data provided by the applicant in Exhibit 18 illustrates a more aggressive growth rate for Wake County than the North Carolina Office of State Budget and Management (NC OSBM) as shown in the following table.

**Difference in Claritas and NC OSBM
Wake County CAGR**

Wake County	2012	2017	CAGR
Claritas, Ex 18	946,278	1,070,015	2.5%
NC OSBM	944,619	1,039,498	1.9%
Difference	1,659	30,517	0.6%

Franklin County's CAGR based on data from NC OSBM is 1.9%, as it is with the Claritas data. Therefore the combined projected CAGR for Franklin and Wake County using NC OSBM data is 1.9%.

In Section III, page 36, the applicant states Wake County and its surrounding communities are among the fastest growing regions in the country and the growth is projected to continue. NC OSBM projects the population of Wake County to grow 22.0 percent between 2010 and 2020. In addition, NC OSBM's projections show by 2020, 12.2 percent of the total population in Wake County will be age 65 and over, a growth of 72.5 percent within this decade. On page 37, the applicant states this data is significant because, as the population ages, the incidence of cancer rises. Age-adjusted SEER Incidence Rates (<http://seer.cancer.gov/faststats/selections.php>?) confirm cancer rates increase with each age group from ages 20-49, 50-64, 65-74, through 75+. The applicant further states, "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."

In Section III, page 39, the applicant grouped Wake County into five areas: Cary, Central, Holly Springs, Knightdale, and Wakefield. Rex then examined the projected growth rate from Claritas (2012 to 2017) for the five Wake County areas by zip code as shown in the following table.

Wake County Area	2012	2017	% Growth
Cary	204,343	233,334	14.2%
Central	431,810	479,351	11.0%
Holly Springs	111,497	130,465	17.0%
Knightdale	67,540	75,380	11.6%
Wakefield	183,319	211,586	15.4%

On page 39, the applicant states:

“As these data show, the Wakefield area is one of the fastest growing areas in Wake County, and for the next five years (2012 to 2017), is expected to have the second highest growth rate (15.4%). As a result of the population growth and aging in Wake County, in particular northern Wake County, the demand for healthcare services is expected to increase. Rex must prepare for this projected population growth and aging, particularly as it relates to the provision of radiation therapy services, by acquiring updated equipment to enable Rex to continue to provide its patients and families the high quality of radiation therapy services that they expect from Rex”

The applicant further discusses the Wakefield area on pages 39 and 40 and states:

“Moreover, the current population of the Wakefield area, 183,319, is more than sufficient to support a linear accelerator according to the population per accelerator greater than 120,000 standard in the SMFP. As noted in Section III.3., an alternative to the proposed project is maintaining the status quo, which would require patients to travel to Raleigh to receive treatments at Rex Hospital. Not only does Rex believe that its patients should not be forced to choose between traveling to receive state-of-the-art care or staying closer to home and receiving a lower level of services, but also as noted above, the Wakefield area is more than sufficient to fully utilize a linear accelerator. Further, as demonstrated below, several counties of similar population support one or more linear accelerators.

<i>County/Area</i>	<i># of Linear Accelerators</i>	<i>2012 Population NC OSBM*</i>
<i>Wakefield</i>	<i>1</i>	<i>183,319**</i>
<i>Cabarrus</i>	<i>2</i>	<i>178,564</i>
<i>Davidson</i>	<i>1</i>	<i>162,874</i>
<i>Johnston</i>	<i>2</i>	<i>169,669</i>
<i>Onslow</i>	<i>1</i>	<i>186,866</i>

**Please see Exhibit 17 for NC OSBM*

***The NC OSBM does not provide data by ZIP code, as such, the population data for the Wakefield area was obtained from Claritas, as shown in Exhibit 17.”*

In Section III, page 41, the applicant provides the following table illustrating historical utilization of radiation therapy services at Rex Healthcare of Wakefield. Rex’s fiscal year runs from July 1 through June 30.

**Rex Healthcare of Wakefield
 Historical Radiation Therapy Utilization**

	FY2010	FY2011	FY2012	CAGR
Patients	162	178	224	17.6%
2D / 3D and IMRT Treatments	3,978	4,325	6,508	27.9%
Additional Field Check Radiographs (AFCRs)	605	655	1,130	36.7%
Equivalent Simple Treatment Visits (ESTVs)	4,281	4,653	7,073	28.5%

Source: Rex internal data, ESTVs are calculated using weights of 1.0 for 2D/3D & IMRT treatments and 0.5 for AFCRs

As shown in the table above, both patients and treatments for Rex Healthcare of Wakefield’s existing linear accelerator have increased since 2010, the facility’s first full year of operation, with CAGRs of 17.6% and 27.9% for patients and treatments, respectively. The table also shows the applicant operated above the performance standard of 6,750 ESTVs on the Rex Healthcare of Wakefield linear accelerator in FY 2012. See 10A NCAC 14C .1903(a).

In Section III, beginning on page 42, the applicant provides the methodology and assumptions used to project future linear accelerator demand at Rex Healthcare of Wakefield.

Methodology: Project future radiation therapy patients based on historical patient volume increased by an annual growth factor. Project future radiation therapy treatments based on the historical mix of type of treatment and average number of treatments.

Assumption 1- Growth Rate: The applicant applies a 1.2% annual growth rate to its FY 2012 patient volume. The applicant states this assumption is reasonable for several reasons:

“The growth rate is based on only 50 percent of the projected population growth of the two counties which account for over 90 percent of the linear accelerator volume.

If the market volumes grow at a rate equal to population growth, Rex’s projected lower growth rate would result in loss of market share. Additionally, some of the historical growth in linear accelerator volume at Rex Healthcare of Wakefield can be attributed to a shift from Rex Hospital’s main campus since the start of operations at Wakefield. Thus, by assuming that future utilization growth will result only from population growth, Rex believes it has conservatively excluded any impact that this patient shift had on historical growth.”

The applicant presents 2012 actual and future projected annual radiation therapy patients on page 43 as shown below:

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	CAGR
Patients	224	227	230	232	235	238	1.2%

Source: FY2012 – Rex internal data. Projections based on 1.2% CAGR.

The projected growth rate appears to be reasonable. The rate is less than the projected population growth rate, less than Rex Healthcare of Wakefield’s historical CAGR and less than the projected CAGR for cancer cases for Franklin and Wake Counties. (<http://www.schs.state.nc.us/schs/CCR/projections.html>).

Assumption 2 - Downtime: In Section III, page 43, the applicant states the replacement linear accelerator will be operational October 1, 2013 (at the start of the second quarter of Rex’s FY 2014). The first three months of the fiscal year will be downtime (no patients treated at Rex Healthcare of Wakefield) to accommodate the removal of the old linear accelerator and the installation, commissioning, and staff training for the new equipment. Rex Healthcare of Wakefield’s radiation therapy patients will receive treatment at Rex Hospital’s main campus. The applicant expects patient volume will ramp up during the first three months of operation and thereafter return to its pre-replacement volume and growth pattern. Based on the projections in the table above, the applicant would serve 230 radiation therapy patients in FY 2014, 58 patients a quarter. The applicant projects serving 0 patients in Quarter 1 of FY 2014 and 19 patients (one third of normal utilization) during the ramp-up period, Quarter 2 of FY 2014, the first quarter after the replacement linear accelerator becomes operational. Thereafter, the patient volume is back to its pre-replacement growth pattern, as shown in the table below.

FY 2014 Projected Patients

	Q1 FY14	Q2 FY14	Q3 FY14	Q4 FY14	FY2014 Total
Patients before Adjustment	58	58	58	58	230
Adjustment	-58	-19	0	0	-77
Adjusted Patients	0	39	58	58	155

The table above shows the quarterly projected patients after adjustment for downtime and ramp up at the project’s inception. The analyst notes there is a slight discrepancy in the number of Total Adjusted Patients as shown in the table above and on page 44 (155) and the text on page 44 above the table (153). The difference is insignificant, perhaps due to

rounding (230/4=57.5), and has no impact on volume projections for future years. The following table from page 44 provides the adjusted annual patient volumes through FY 2017.

	FY2013	FY2014	FY2015	FY2016	FY2017
Patients	227	155	232	235	238

Assumption 3 - Patient Treatment Mix: In Section III, page 45, the applicant assumes the mix of its linear accelerator patients by type (2D/3D and IMRT) in the last full fiscal year (FY 2012) will remain consistent through the project years. The following table illustrates the historical mix.

**Rex Healthcare of Wakefield
 Historical Patient Mix**

	FY 2012	% of Total
2D/3D Patients	159	71%
IMRT Patients	65	29%
Total	224	100%

The table above shows 71% of the total radiation therapy patients receive 2D/3D treatments, while 29% receive IMRT treatments. The applicant states this assumption is reasonable because it results in a distribution of projected total annual patients that replicates recent past experience. On page 45, the applicant states:

“Since the type of treatment (2D/3D versus IMRT) depends on the type of cancer and the patient’s individual treatment plan, these ratios may fluctuate; however, Rex does not expect any significant variation or know of a basis to project a departure from the most recent experience.”

The following table provides the projected treatment mix of patients determined by applying the historical mix to the projected total number of patients.

**Rex Healthcare of Wakefield
 Projected Radiation Therapy Utilization**

	% of Total	FY2013	FY2014	FY2015	FY2016	FY2017
2D/3D Patients	71%	161	110	165	167	169
IMRT Patients	29%	66	45	67	68	69
Total Patients	100%	227	155	232	235	238

Assumption 4 – Average Treatments per Patient: In Section III, pages 45-46, the applicant states Rex assumes its projected 2D/3D and IMRT patients will have the same number of treatments, on average, as FY 2012 patients and provides the following table to illustrate the number of FY 2012 treatments performed.

**Rex Healthcare of Wakefield
 FY 2012 Treatments per Patient**

	Patients	Treatments	Treatments per Patient
2D/3D Patients	159	4,289	27.0
IMRT Patients	65	2,219	34.1
Total	224	6,508	29.1

The table above shows 2D/3D patients receive an average of 27 treatments per patient and IMRT patients receive an average of 34.1 treatments per patient. The following table provides the projected number of treatments by type determined by applying the historical average treatments per patient to the projected number of patients through FY 2017.

**Rex Healthcare of Wakefield
 Projected Radiation Therapy Utilization**

	FY2013	FY2014	FY2015	FY2016	FY2017
2D/3D Patients	161	110	165	167	169
2D/3D Treatments per Patient	27	27	27	27	27
2D/3D Treatments	4,342	2,968	4,449	4,503	4,558
IMRT Patients	66	45	67	68	69
IMRT Treatments per Patient	34.1	34.1	34.1	34.1	34.1
IMRT Treatments	2,246	1,535	2,302	2,330	2,358
Total Treatments	6,588	4,503	6,751	6,833	6,916

Note: Totals may not sum due to rounding.

Assumption 5 – Additional Field Check Radiograph (AFCR): In Section III, pages 46-47, the applicant states Rex projects AFCRs by assuming that patients will have 5.0 AFCRs, on average, based on its FY 2012 experience, and consistent with an average of one per week of treatment. The applicant further states that though AFCRs are not treatments, they are performed weekly for most patients and receive ESTV weighting; therefore the applicant provides its historical AFCRs as follows:

**Rex Healthcare of Wakefield
 AFCRs per Patient**

	FY 2012
Patients	224
AFCRs	1,130
AFCRs per Patient	5.0

The following table demonstrates the projected AFCRs determined by applying the FY 2012 average AFCRs per patient from the table above to the projected number of patients through FY 2017.

**Rex Healthcare of Wakefield
 Projected AFCRs**

	FY2013	FY2014	FY2015	FY2016	FY2017
Total Patients	227	155	232	235	238
AFCRs per Patient	5.0	5.0	5.0	5.0	5.0
Total AFCRs	1,144	782	1,172	1,186	1,201

Assumption 6 – Equivalent Simple Treatment Value (ESTV): In Section III, pages 47-48, the applicant states it converts its projected utilization to ESTVs using the weight factors from the 2012 SMFP: 2D/3D and IMRT treatments = 1.0 and AFCRs = 0.5, resulting in the following projection of radiation therapy utilization at Rex Healthcare of Wakefield through FY 2017. The following table shows total projected ESTVs based on the standard weighting factors.

**Rex Healthcare of Wakefield
 Projected Radiation Therapy Utilization**

	FY2013	FY2014	FY2015	FY2016	FY2017
2D/3D Patients	161	110	165	167	169
IMRT Patients	66	45	67	68	69
Total Patients	227	155	232	235	238
2D/3D Treatments	4,342	2,968	4,449	4,503	4,558
IMRT Treatments	2,246	1,535	2,302	2,330	2,358
Total 2D/3D & IMRT Treatments	6,588	4,503	6,751	6,833	6,917
AFCRs	572	391	585	593	600
Total ESTVs	7,160	4,894	7,336	7,426	7,517

Note: the applicant’s table on page 48 shows the unweighted AFCRs, however, the applicant applied the factor and used the weighted AFCRs in the calculation of total ESTVs as shown above. Totals may not sum due to rounding.

Assumption 7 – Conversion from Fiscal Year to Project Year: In Section III, pages 48-50, the applicant converts its projected fiscal year utilization to proposed project years based on the replacement equipment becoming operational on October 1, 2013, the beginning of the applicant’s second quarter of fiscal year 2014. Rex’s fiscal year runs July 1 through June 30.

PY1: 10/1/2013 to 9/30/2014 = 100 % of FY 2014 + 25% x FY 2015
 PY2: 10/1/2014 to 9/30/2015 = 75% x FY 2015 + 25% x FY 2016
 PY3: 10/1/2015 to 9/30/2016 = 75% x FY 2016 + 25% x FY 2017

In Section III, page 49, the applicant states:

“...Rex has accounted for the three months of downtime (i.e. no patients) that will occur at the start of FY 2014, appropriately by attributing all FY 2014 patients to Project Year One. As noted above, because there will be three months of downtime, all of the FY2014 patients will be treated after the project year one start date of October 1, 2013. Thus, while the time period for the PY1 calculation above includes

15 months, only 12 months of treatments are shown, consistent with the first project year.

...

The following table provides project year patients, treatments, and ESTVs using these calculations.”

**Rex Healthcare of Wakefield
Projected Radiation Therapy Utilization**

	PY 1	PY 2	PY 3
2D/3D Patients	151	165	167
IMRT Patients	62	68	68
Total Patients	213	233	236
2D/3D Treatments	4,080	4,462	4,517
IMRT Treatments	2,111	2,309	2,337
Total 2D/3D & IMRT Treatments	6,191	6,771	6,854
AFCRs	538	588	595
Total ESTVs	6,728	7,359	7,449

Note: the applicant’s table on page 49 shows the unweighted AFCRs, however, the applicant applied the factor and used the weighted AFCRs in the calculation of total ESTVs as shown above. Totals may not sum due to rounding.

The applicant projects treating 236 radiation therapy patients (an increase of 12 patients or 5.2%) by the third project year, and performing well above the linear accelerator performance standard of 6,750 ESTVs. See 10A NCAC 14C .1903(a). In Section III, page 40, the applicant states:

“Clearly, the outdated equipment must be replaced in order to allow Rex to continue to provide the quality of radiation therapy services needed to properly treat its patients at its Wakefield location.”

The applicant adequately demonstrates the need to replace its existing linear accelerator to continue to provide radiation therapy services to the population proposed to be served. The applicant adequately demonstrates projected utilization is based on reasonable, credible and supported assumptions.

Access

In Section V, page 71, the applicant states, *“Rex accepts all patients that are referred for radiation therapy services regardless of their ability to pay or any other perceived level of underservice.”*

The applicant further addresses accessibility to its proposed service in Section VI, pages 73-81. The applicant states:

“...Rex Healthcare prohibits the exclusion of services to any patients on the basis of age, race, sex, creed, religion, disability, or the patient’s ability to pay. Please see Exhibit 23 for a copy of Rex’s Admission Policy as well as its Patient Rights and Responsibilities Policy, which details Rex’s commitment to serve any patient, regardless of age, race, sex, creed, religion, disability or the patient’s ability to pay. In particular, as stated in Rex’s Patient Rights and Responsibilities Policy, patients have the right to receive “care that is free of discrimination” and “medically necessary treatment regardless of your ability to pay”.”

On page 90, the applicant provides the following payor mix for the second full fiscal year of the proposed project.

**Rex Healthcare of Wakefield
Radiation Therapy Payor Mix
FY 2016 (July 1, 2015- June 30, 2016)
Treatments as Percent of Total Utilization**

Payors	Percent
Self Pay/Indigent/Charity	5.4%
Medicare/Medicare Managed Care	48.2%
Medicaid	3.1%
Managed Care/Commercial Insurance	42.9%
Other (Work Comp and Other Gov’t payors)	0.4%
TOTAL	100%

The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need to replace the existing linear accelerator and adequately demonstrates all residents of the area will have access to the proposed 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 Sections III and V, pages 52-54 and 70, the applicant discusses the alternatives considered prior to submission of this application.

Maintain the Status Quo

On page 53, the applicant states maintaining the status quo is not in the best interest of Rex's patients because it would not be providing the current standard in radiation therapy technology. The applicant further states the existing equipment is obsolete, at the end of its useful life and incapable of providing a platform for use of the technology advances which have occurred in the last 12 years. On page 39, the applicant states that maintaining the status quo would require patients to travel to Raleigh to receive treatments at Rex Hospital and it does not believe that its patients should be forced to choose between traveling to receive state-of-the-art care or staying closer to home and receiving a lower level of services. As such, Rex states maintaining the status quo is not an effective alternative to meet the need.

Replace the Equipment for Under \$2,000,000

On page 53, the applicant states it considered replacing the existing equipment for under \$2,000,000 which would not require a Certificate of Need. However, it determined acquiring the less costly replacement equipment would result in less effective equipment with fewer capabilities and would not provide Rex's patients with the same state-of-the-art radiation therapy services as the chosen alternative. As such, Rex rejected the alternative of replacing its existing equipment with less costly equipment.

Joint Venture

In Section V, page 70, the applicant states a joint venture is neither applicable nor feasible for this project because Rex proposes only to replace outdated equipment in order to continue providing outstanding care.

Develop the Project as Proposed

On page 54, the applicant states it believes the alternative that meets all the needs of its patients, physicians, staff and community is to replace the aging 21EX linear accelerator with the leading-edge technology of the proposed Varian TrueBeam linear accelerator. The applicant further states the new equipment will be state-of-the-art and will allow Rex to more effectively and efficiently treat patients, enabling *"the delivery of radiation therapy in a more effective, safer manner, and often in much less time than in the past."*

The applicant demonstrates adequate consideration of other alternatives in determining how best to meet the demonstrated need to replace its existing linear accelerator at Rex Healthcare of Wakefield. On page 53, the applicant states, *"Rex believes it is in the best interest of its*

patients to provide technology that has been clinically proven as a best practice.” On page 72, the applicant states:

“...Rex believes the proposed project will promote safety and quality in the delivery of healthcare services while promoting equitable access and maximizing healthcare value for resources expended for the residents of Wake and surrounding counties.”

Therefore, the applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

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

- 1. Rex Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Rex Hospital, Inc. shall acquire no more than one linear accelerator to replace the existing Varian Clinac 21EX linear accelerator located at Rex Healthcare of Wakefield for a total of no more than four linear accelerators upon project completion.**
 - 3. Rex Hospital, Inc. shall dispose of the Varian Clinac 21EX linear accelerator by removing it from North Carolina.**
 - 4. Rex Hospital, 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.**
 - 5. Rex Hospital, 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, page 101, the applicant projects the total capital cost will be \$3,995,225, which includes \$46,600 for construction costs, \$3,884,025 for fixed equipment, and \$64,600 for consultant fees.

In Section IX, page 107, the applicant states there will be no start-up or initial operating expenses for this project. In Section VIII.3, page 102, the applicant states that the total capital cost will be funded with the accumulated reserves of Rex Healthcare. Exhibit 26 contains a letter from the Chief Financial Officer of Rex Healthcare and Rex Hospital which states,

“Rex Healthcare will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the line items “Cash and Cash Equivalents” and “Assets Limited As To Use” in the audited financial statements included with this Certificate of Need application.”

Exhibit 27 contains the audited financial statements for Rex Healthcare, Inc. and Subsidiaries for years ending June 30, 2011 and 2012. According to the financial statements, as of June 30, 2012, Rex had \$70,527,000 in Cash and Cash Equivalents, \$230,948,000 in Assets Limited as to Use, \$708,468,000 in total assets and \$448,193,000 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.

The applicant provides pro forma financial statements for the first three years of the project. 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.

Rex Healthcare of Wakefield Radiation Therapy Services

	First Full FY 2015	Second Full FY 2016	Third Full FY 2017
Projected # of Procedures	6,750	6,833	6,917
Projected Average Charge (Gross Patient Revenue / Projected # of Procedures)	\$ 2,359	\$ 2,430	\$ 2,503
Gross Patient Revenue	\$ 15,924,100	\$ 16,602,902	\$ 17,310,640
Deductions from Gross Patient Revenue	\$ 11,603,919	\$ 12,098,563	\$ 12,614,293
Net Patient Revenue	\$ 4,320,181	\$ 4,504,339	\$ 4,696,347
Total Expenses	\$ 2,125,553	\$ 2,292,951	\$ 2,361,361
Net Income	\$ 2,194,628	\$ 2,211,388	\$ 2,334,986

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the pro forma “Financials” for Form C Assumptions, Form D Assumptions and Form E Assumptions regarding costs and charges. Projected average charge is based on FY 2012 average charge per treatment for the radiation therapy service, inflated three percent annually. 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.

C

Rex currently owns and operates a total of four linear accelerators systemwide, one of which is located on the Rex Healthcare of Wakefield campus. The applicant proposes to replace the existing linear accelerator at Rex Healthcare of Wakefield.

In Section III.1, pages 29-50, the applicant adequately demonstrates the demand for state-of-the-art enhanced radiation therapy services at Rex Healthcare of Wakefield, which is based on current utilization. In Section IV, page 62, the applicant projects that the proposed replacement linear accelerator will perform 7,517 ESTVs in the third project year (FFY 2017).

In supplemental information provided by Rex in response to the analyst’s request for additional information, Rex provides the following analysis of its linear accelerator service, showing a CAGR of 7.62% in the utilization of Rex’s four existing linear accelerators.

Historical Utilization (ESTVs) for Rex Hospital Linear Accelerators in Area 20

	FY08*	FY09	FY10	FY11	FY12	CAGR (2009-12)
Rex Hospital Main Campus	7,880	15,805	13,778	13,493	13,031	-6.23%
Rex Hospital Wakefield		324	4,281	4,653	7,073	179.48%
Total Rex Healthcare	7,880	16,129	18,059	18,146	20,104	7.62%

*FY 2008 data is only available after 10/15/08 and therefore not included in the analysis

The applicant states that during the years in the analysis above,

“Rex replaced two of its linear accelerators, relocated a third to Wakefield and completed renovations to its Cancer Center. Yet, even with the downtime, ramp-up and complications associated with the equipment replacement and renovations, overall radiation therapy volume at Rex increased significantly. Moreover, while

the main campus volume shown in the table above appears to decline, the decline is far less than would be expected with the commencement of the Wakefield radiation therapy service. For example, if the approximately 7,000 treatments had all shifted from the main campus, then the volume at the main campus would be as low as 8,800 treatments, rather than the more than 13,000 treatments provided there in 2012. Put another way, Rex transferred 25 percent of its total linear accelerator capacity to Wakefield, yet no more than 17.6 percent of its volume shifted from 2009 to 2012 ($15,805 - 13,031 = 2,774 / 15,805 = 17.6\%$). Thus, both Rex's main campus and the Wakefield campus are experiencing increased utilization, a trend which can reasonably be expected to continue."

In the supplemental information, Rex details the use of the three linear accelerators at its main campus. The applicant explains the targeted uses of the new Tomo Therapy unit and the two remaining units, the differences in the treatment planning for the Tomo Therapy unit and the other two units, and the need for all three machines on the main campus to provide state of the art IMRT treatments, 2D/3D treatments and back-up for downtime. The Tomo Therapy unit performs only IMRT treatments, which leaves the other two units to provide all 2D/3D treatments, additional IMRT treatments and backup services. The applicant states, "With only two linear accelerators on the main campus, both would be at threshold utilization, necessitating additional capacity."

In Section III.1, page 29, the applicant states, "The primary need for the proposed project is to replace existing linear accelerator equipment that is more than 12 years old and past its seven-year useful life as measured by the American Hospital Association's equipment lifetimes standards". The applicant adequately demonstrates that the replacement will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, for the following reasons:

- The applicant proposes to replace the existing twelve year old linear accelerator currently in use at Rex Healthcare of Wakefield;
- In Section III, page 59, the applicant states the identified need is internal to Rex as it involves the replacement of existing outdated equipment to accommodate the patients it serves;
- The proposal will not result in a change in the inventory of linear accelerators located in Linear Accelerator Service Area 20, consisting of Wake, Harnett and Franklin counties;
- The applicant performed 6,508 2D/3D and IMRT treatments (7,073 ESTVs) during FY 2012 on its existing linear accelerator at Rex Healthcare of Wakefield; and
- Rex projects performing 6,917 procedures (7,517 ESTVs) in FY 2017, the third full fiscal year of operation following replacement

The applicant does not propose to develop any new services or acquire any additional equipment. 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, pages 92-93, the applicant provides the current and proposed staffing for Rex Healthcare of Wakefield, as shown in the following table. The applicant states the acquisition of a replacement linear accelerator will not require any new positions to be established for the proposed project.

**Rex Healthcare of Wakefield
Radiation Therapy Services
Current and Proposed Staffing**

Position	Current # FTEs	Proposed # FTEs (Year Two)
Radiation Therapist	2.5	3.0
Coordinator/ Radiation Therapy	1.0	1.0
Physicist	0.5	1.0
Staff Nurse	1.0	1.5
Dosimetrist	1.0	1.0
Medical Office Assistant/Adm	1.0	1.0
Total	7.0	8.5

The applicant expects to encounter no difficulty staffing the increase in FTEs for the radiation therapist, physicist or staff nurse positions and will continue to utilize existing recruitment strategies to fill vacancies. In Section VII, page 95, the applicant states a commitment to the retention of nursing and non-nursing staff, reviewing salary and benefits annually to ensure market competitiveness. In Section V, page 68, the applicant states Dr. Justin Wu serves as Chairman and Medical Director of Rex Radiation Oncology, including radiation services at Rex Healthcare of Wakefield. The letter from Dr. Wu in Exhibit 22 documents his intent to continue serving in these positions following completion of the proposed project. Dr. Roger Anderson, the Medical Director of Rex Healthcare of Wakefield will continue to serve as the site supervising physician for Rex Healthcare of Wakefield.

The applicant demonstrates the availability of adequate health manpower for the continued provision of radiation therapy 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, page 22, the applicant states all ancillary and support services are in place and no additional services will be required. See Exhibit 7 for a letter from Rex Healthcare

President documenting the availability of ancillary and support services for the radiation therapy service at Rex Healthcare of Wakefield.

In Section V, pages 64-70, the applicant describes the existing relationships the hospital has with other health care providers, facilities and physicians. Exhibit 8 contains a comprehensive list of all facilities with which transfer agreements are in place.

On page 68, the applicant states physicians were involved in determining the need for replacement equipment and in the selection of the equipment. Exhibit 30 contains letters of support for the proposed project. On page 67, the applicant states,

“As an established regional tertiary facility, Rex maintains strong working relationships with its medical staff that are located throughout Wake, Durham, Franklin, Harnett, Nash, Sampson, and Johnston counties, as well as in surrounding areas.”

The applicant adequately demonstrates that the necessary ancillary and support services are and will continue to be available 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.

NA

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

C

In Section VI.12, page 89, the applicant provides the payor mix for Rex Healthcare and for Rex Healthcare of Wakefield's radiation therapy services for FY 2012 as shown in the following tables, respectively.

**Rex Healthcare
Patient Days as Percent of Total Utilization
FY 2012**

Payor	Percent
Self Pay/Indigent/Charity	4.2%
Medicare/Medicare Managed Care	44.2%
Medicaid	5.7%
Managed Care/Commercial Insurance	44.9%
Other (Work Comp and Other Gov't payors)	1.0%
TOTAL	100%

**Rex Healthcare of Wakefield
 Radiation Therapy
 Treatments as Percent of Total Utilization
 FY 2012**

Payor	Percent
Self Pay/Indigent/Charity	5.4%
Medicare/Medicare Managed Care	48.2%
Medicaid	3.1%
Managed Care/Commercial Insurance	42.9%
Other (Work Comp and Other Gov't payors)	0.4%
TOTAL	100%

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

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 Percent Uninsured (Estimate by Cecil G. Sheps Center) *
Wake	10%	3.35%	18.4%
Franklin	18%	7.40%	19.7%
Statewide	17%	6.71%	19.7%

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

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

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 45.9% for those age 20 and younger and 30.6% 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 and 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. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations have adequate access to existing services; 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 88, the applicant states:

“Rex Hospital has had no obligations to provide uncompensated care, community service or access to care by medically underserved, minorities or handicapped persons during the last three years.”

The applicant further states that in order to maintain its §501(c)(3) tax-exempt status, it is necessary to fulfill a general obligation to provide access to healthcare services for all patients needing care, regardless of their ability to pay. In 2012 Rex Healthcare provided approximately \$110 million in bad debt and charity care. Exhibit 24 contains The Rex Assistance Policy, establishing criteria for the determination of eligibility for charity care.

In Section VI, page 82, the applicant states:

“As part of Rex Healthcare, Rex Healthcare of Wakefield's radiation therapy service follows the policies used by Rex Hospital. Rex provides access to care to all patients regardless of age, race, national or ethnic origin, disability, sex, income, or ability to pay. Patients are admitted and services are rendered in compliance with:

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

In Section VI.10, page 88, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against Rex in the last five years. On page 89, the applicant states Rex is in full compliance with Title III of the Americans with Disabilities Act, the Civil Rights Act, and all other federally

mandated regulations concerning minorities and handicapped persons. 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, page 78, the applicant states Rex provides outreach that targets the 65+ population and provides tailored treatment based on a functional assessment. On page 76, the applicant states:

“Rex does not discriminate with regard to patient access to care on the basis of race, creed, ethnicity or sex. Equal access to Rex services has been and will continue to be provided to all patients.”

In Section VI.15, page 90, the applicant provides the projected payor mix for Rex Healthcare of Wakefield radiation therapy services in the second full fiscal year of operation following the equipment replacement, as shown in the following table.

**Rex Healthcare of Wakefield
Radiation Therapy
Treatments as Percent of Total Utilization
FY 2016**

Payor	% of Total
Self Pay/Indigent/Charity	5.4%
Medicare/Medicare Managed Care	48.2%
Medicaid	3.1%
Managed Care/Commercial Insurance	42.9%
Other (Work Comp and Other Govt payors)	0.4%
Total	100.00%

As illustrated above, projected payor mix mirrors historical payor mix. In Section VI.13, page 91, the applicant states it does not expect any change to its payor mix as a result of the proposed project.

On page 79, the applicant states Rex’s services have been and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. On page 81, the applicant states Rex complies with the Americans with Disabilities Act (ADA) to ensure access to services and facilities for handicapped individuals. The applicant demonstrates the elderly and medically underserved populations will have adequate access to linear accelerator services at Rex Healthcare of Wakefield.

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 87, the applicant describes the means by which patients will have access to the proposed linear accelerator services. The applicant states it receives referrals to its facilities from physicians and other healthcare facilities in the region through established relationships. The applicant further states that most patients are referred by their physician or are admitted through the emergency department, but patients can also access services by making a new consult appointment with a physician and persons will have access to Rex Services through referrals from physicians on the medical staff. The applicant adequately demonstrates that it will offer a range of means of 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 64, the applicant states:

“As a part of Rex Healthcare, Rex Healthcare of Wakefield has extensive relationships with area clinical training programs. Rex has more than 60 agreements with health professional training programs throughout the Southeast, as demonstrated in Exhibit 21.”

In addition to its academic relationships, the applicant states it supports community-based healthcare professional organizations. Rex is a member of the Healthcare Works! Coalition, a coordinated effort between local facilities and community colleges to enhance the careers of healthcare workers in the region. Rex serves as a Wake Area Health Education Center-affiliated training site and provides healthcare-related educational programs and services to workers and facilities throughout the region.

The applicant adequately demonstrates that it will continue to accommodate the clinical needs of health professional training programs in the area. 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

Rex currently owns and operates four linear accelerators and proposes to replace the one located at Rex Healthcare of Wakefield. The applicant proposes to replace the 12-year old Varian Clinac 21EX linear accelerator with a TrueBeam-comparable linear accelerator which is capable of more advanced treatment than the existing linear accelerator.

According to the 2012 SMFP, Linear Accelerator Service Area 20 (Wake, Franklin and Harnett counties) served a total population of 1,128,311 in 2011 with 9 accelerators, distributed as shown in the following table.

County	Provider	# of Linear Accelerators	Total # of ESTVs	Average # of ESTVs per Unit
Franklin	Franklin County Cancer Center	1	NR	NR
Wake	Raleigh Hematology Oncology /Cancer Centers of NC	2	11,506	5,753
	Duke Raleigh Hospital	1	7,572	7,572
	Rex Healthcare	4	19,636	4,909
	Wake Radiology / Oncology	1	5,633	5,633
Total		9	44,347	4,927
Statewide				4,884

Notes:

1. There are no existing linear accelerators in Harnett County.
2. Cary Urology, PA was issued certificate of need for Project ID # J-9331-09 to acquire one dedicated linear accelerator as part of a statewide demonstration project. The unit is not counted in the regular inventory of linear accelerators.
3. Project ID# J-7941-07 (Raleigh Hematology Oncology Associates, now Cancer Centers of NC) has a projected completion date of July 2015.

As the table above illustrates, Linear Accelerator Service Area 20 does not meet the SMFP performance standard of 6,750 ESTVs per accelerator; nor does Rex Healthcare. Rex Healthcare and Service Area 20 are operating at 115 and 101 percent, respectively, of the statewide average number of ESTVs per unit and 73 percent of the 6,750 ESTVs performance standard.

In supplemental information provided by Rex in response to the analyst’s request for additional information, Rex provides the following analysis of its linear accelerator service, showing a CAGR in the utilization of Rex’s four existing linear accelerators of 7.62%.

Historical Utilization (ESTVs) for Rex Hospital Linear Accelerators in Area 20

	FY08*	FY09	FY10	FY11	FY12	CAGR (2009-12)
Rex Hospital Main Campus	7,880	15,805	13,778	13,493	13,031	-6.23%
Rex Hospital Wakefield		324	4,281	4,653	7,073	179.48%
Total Rex Healthcare	7,880	16,129	18,059	18,146	20,104	7.62%

*FY 2008 data is only available after 10/15/08 and therefore not included in the analysis

The applicant states that during the years above,

“Rex replaced two of its linear accelerators, relocated a third to Wakefield and completed renovations to its Cancer Center. Yet, even with the downtime, ramp-up and complications associated with the equipment replacement and renovations, overall radiation therapy volume at Rex increased significantly. Moreover, while the main campus volume shown in the table above appears to decline, the decline is far less than would be expected with the commencement of the Wakefield radiation therapy service. For example, if the approximately 7,000 treatments had all shifted from the main campus, then the volume at the main campus would be as low as 8,800 treatments, rather than the more than 13,0000 treatments provided there in 2012. Put another way, Rex transferred 25 percent of its total linear accelerator capacity to Wakefield, yet no more than 17.6 percent of its volume shifted from 2009 to 2012 (15,805 – 13,031 = 2,774 / 15,805 = 17.6%). Thus, both Rex’s main campus and the Wakefield campus are experiencing increased utilization, a trend which can reasonably be expected to continue.”

If Rex’s linear accelerator volume continued to grow at its historical growth rate, utilization would appear as in the following table.

Projected Utilization (ESTVs) for Rex Hospital Linear Accelerators in Area 20

	FY12	FY13	FY14	FY15	FY16	FY17
Rex Healthcare Utilization	20,104	21,636	23,284	25,059	26,968	29,023
Utilization per Linac (4)	5,026	5,409	5,821	6,265	6,742	7,256

However, the applicant is not proposing to add additional capacity or to acquire an additional linear accelerator; rather, the applicant is seeking to replace an existing, obsolete unit at Rex Healthcare of Wakefield. Equipment replacement projects are not required to meet performance standards in order to be approved. Moreover, Rex Healthcare of Wakefield is currently performing and is projected to perform above the performance standard of 6,750 ESTVs per accelerator.

In Section V.7, pages 70-72, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

“The proposed project is consistent with the basic policies of the 2012 SMFP. The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area and will thus be in compliance with the spirit and legislative intent of the CON Law.”

The applicant states the following in regard to cost effectiveness of the proposed project:

- The existing equipment is fully depreciated and has reached the end of its useful life;
- The new equipment can deliver higher doses of radiation much faster, with greater accuracy, and with less side effects and complications which may result in lower costs of radiotherapy patient management; and
- The most effective, value-based alternative is to expend capital for better equipment and avoid increasing operational costs for an outdated accelerator.

In regard to how the proposed project will promote safety and quality, the applicant states:

- The existing equipment is at the end of its useful life and has begun to hamper efficiencies;
- The proposed equipment has such enhanced precision that patients can be treated with higher radiation per dose, with shorter visit times per treatment, and with minimal damage to adjacent healthy tissue or organs;
- Precise delivery of radiation may improve recovery time and reduce side effects and complications which may result in an improvement in patients’ quality of life; and
- The proposed project will raise the bar for quality of care in the marketplace and drive other providers to deliver the highest quality of care in order to compete.

In regard to how the proposed project will promote access to the proposed services, the applicant states:

- Rex accepts all referred patients regardless of their ability to pay or any other perceived level of underservice; and
- The proposed project will improve access to state-of-the-art radiation therapy services in the service area.

Also, in Section VI.15, page 90, the applicant indicates that in the second full fiscal year, the payor mix for radiation therapy patients will reflect historical payor mix and will be 48.2% Medicare, 3.1% Medicaid and 5.4% self pay/charity care. See Sections II, III, V, VI and VII where the applicant also 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 services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to replace its existing linear accelerator at Rex Healthcare of Wakefield and that it is a cost-effective alternative;
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

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

C

Rex Hospital is certified by the Centers for 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

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