# REQUIRED STATE AGENCY FINDINGS

# **FINDINGS**

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: February 24, 2021 Findings Date: February 24, 2021

Project Analyst: Kim Meymandi Team Leader: Gloria C. Hale

Project ID #: F-11991-20

Facility: Novant Health Huntersville Medical Center

FID #: 990440 County: Mecklenburg

Applicant(s): The Presbyterian Hospital

Novant Health, Inc.

Project: Acquire a CT Simulator

### **REVIEW CRITERIA**

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.

### NA

The Presbyterian Hospital, doing business as Novant Health Huntersville Medical Center, and Novant Health, Inc. (Novant), referred to collectively hereinafter as "the applicant" or "NHHMC", proposes to acquire a dedicated CT simulator.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2020 State Medical Facilities Plan (SMFP)

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire a dedicated CT simulator. The proposed equipment will be located in renovated space on the first floor of a medical office building connected to the medical center on the main campus of Presbyterian Hospital. In Section C.1, page 25, the applicant describes the project as follows:

"NHHMC proposes to acquire a dedicated CT simulator, specifically a Siemans SOMATOM go.Up CT System for Radiation Therapy Planning. The dedicated CT Simulator will only be utilized for radiation therapy planning and will not be utilized for diagnostic CT scanning. The dedicated CT simulator will be located in the medical office building connected to the medical center."

# **Patient Origin**

N.C.G.S. §131E-176(24a) states: "Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility." The 2020 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. In Section C, pages 36-37, the applicant defines the service area for the proposed project. The applicant states that the primary service area is Mecklenburg County and the secondary service area includes the surrounding counties of Lincoln, Cabarrus and Iredell. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 36-37, the applicant provides the historical (FY2019) patient origin for simulations performed at NHHMC on diagnostic CT scanners, and the projected patient origin for the first three full fiscal years of operation (FY2023-FY2025) of the proposed project, as shown in the following tables:

# Historical Patient Origin NHHMC Diagnostic CT Scan Services FY2019

	LAST FULL FY (1/1/19 – 12/31/19)		
COUNTY	# PATIENTS	% OF TOTAL	
Mecklenburg	279	68.6%	
Primary Service Area Subtotal	279	68.6%	
Lincoln	44	10.8%	
Cabarrus	22	5.4%	
Iredell	18	4.4%	
Secondary Service Area Subtotal	84	20.6%	
In-Migration*	44	10.8%	
Total	407	100.0%	

<sup>\*</sup>In-Migration includes 10 North Carolina counties and several states.

# **Projected Patient Origin**

r rojected rations origin								
	1 <sup>st</sup> F	ull FY	2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY			
	FY2	2023	FY2	024	FY2025			
COUNTY	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total		
Mecklenburg	342	68.6%	357	68.6%	371	68.6%		
Primary Service Area Subtotal	342	68.6%	357	68.6%	371	68.6%		
Lincoln	54	10.8%	56	10.8%	58	10.8%		
Cabarrus	27	5.4%	28	5.4%	29	5.4%		
Iredell	22	4.4%	23	4.4%	24	4.4%		
Secondary Service Area Subtotal	103	20.6%	107	20.6%	111	20.6%		
In-Migration*	54	10.8%	56	10.8%	58	10.8%		
Total	499	100.0%	520	100.0%	541	100.0%		

<sup>\*</sup>In-Migration includes 10 North Carolina counties and several states.

In Section C, page 37, the applicant states that the projected patient origin is based on the historical patient origin for simulations performed on diagnostic CT scanners at NHHMC. The applicant's assumptions are reasonable and adequately supported, based on the following:

- The projected patient origin is consistent with the historical patient origin.
- The applicant increases the number of projected future patients based on the population growth rate of Mecklenburg County and of Lincoln, Cabarrus and Iredell counties.

# **Analysis of Need**

In Section C, pages 38-44 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

# Population Trends of the Service Area (pages 39-40)

The applicant uses data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth in the service area. The

applicant states that between 2020 and 2025, Mecklenburg County's population is projected to grow from 1,131,342 to 1,240,325, a 9.6 percent growth rate. During the same time period the extended service area, which includes Mecklenburg, Cabarrus, Lincoln, and Iredell counties and comprises 89.2 percent of the total projected simulation patients at NHHMC, is projected to grow from 1,620,124 to 1,769,365, a 9.2 percent growth rate. The growth rate of the 65+ population in years 2020-2025 is projected to be 25.9 percent and 24.1 percent in Mecklenburg County and the Extended Service Area respectively. The applicant also provides data showing that the incidence of cancer increases with age. The population and cancer rate data provided by the applicant is shown in the tables below.

**Projected Population Growth Mecklenburg County** 

	2015	2020	2025	2015-2020	2020-2025
			(Projected)	Percent Growth	Percent Growth
<18 Population	251,350	263,716	275,821	4.9%	4.6%
18-44 Population	424,633	451,238	486,934	6.3%	7.9%
45-64 Population	251,157	280,852	306,994	11.8%	9.3%
65+ Population	106,542	135,536	170,576	27.2%	25.9%
<b>Total Population</b>	1,033,682	1,131,342	1,240,325	9.4%	9.6%
Percent <18	24.3%	23.3%	22.2%		
Percent 18-44	41.1%	39.9%	39.3%		
Percent 45-64	24.3%	24.8%	24.8%		

13.8%

Source: Section C, page 39, 2019 NCOSBM

10.3%

12.0%

13.1%

Percent 65+

Percent 65+

**Projected Population Growth Extended Service Area** 

	Projected Population Growth Extended Service Area						
	2015	2020	2025	2015-2020	2020-2025		
			(Projected)	Percent Growth	Percent Growth		
<18 Population	357,960	371,553	386,366	3.8%	4.0%		
18-44 Population	575,914	616,159	667,664	7.0%	8.4%		
45-64 Population	376,339	420,389	452,306	11.7%	7.6%		
65+ Population	169,163	212,023	263,029	25.3%	24.1%		
<b>Total Population</b>	1,479,376	1,620,124	1,769,365	9.5%	9.2%		
Percent <18	24.2%	22.9%	21.8%				
Percent 18-44	38.9%	38.0%	37.7%				
Percent 45-64	25.4%	25.9%	25.6%				

Source: Section C, page 40, 2019 NCOSBM

# **NC Cancer Rates by Age Group**

14.9%

All Cancers	0-19	20-24	45-64	65 and above
Incidence Rate per 100,000	17.2	111.9	809.1	2,014.1
Mortality Rate per 100,000	1.9	15.7	193.6	837.6

Source: Section C, page 40, 2020 NC Central Cancer Registry

11.4%

# Mecklenburg County Life Expectancy (pages 41-42)

The applicant states the life expectancy of Mecklenburg County residents has increased in every age group, gender, and race from 1990-1992 to 2016-2018. The applicant states that the increase in life expectancy increases the chance of cancer incidence thereby increasing the need for linear accelerator treatment services and thus simulator usage. The applicant provides the following tables to demonstrate the increase in life expectancy for residents in Mecklenburg County.

1990 – 1992 Mecklenburg County Life Expectancy

	Total	Male	Female	White	African American
65-69	17.5	15.2	19.1	18.0	15.6
70-74	14.2	12.2	15.6	14.5	13.0
75-79	11.4	9.6	12.4	11.4	11.0
80-84	8.8	7.5	9.5	8.8	9.2
85+	6.8	6.0	7.1	6.6	7.9

Source: NC State Center for Health Statistics, schs.dph.ncdhhs.gov/data/lifexpectancy

2016 - 2018 Mecklenburg County Life Expectancy

	Total	Male	Female	White	African American		
65-69	20.4	18.9	21.6	21.0	19.1		
70-74	16.6	15.3	17.6	17.0	15.8		
75-79	13.1	12.0	13.9	13.3	12.7		
80-84	10.0	9.1	10.7	10.1	10.0		
85+	7.6	6.9	8.1	7.6	8.0		

Source: NC State Center for Health Statistics, schs.dph.ncdhhs.gov/data/lifexpectancy

**Change in Mecklenburg County Life Expectancy** 

	Total	Male	Female	White	African American
65-69	2.9	3.7	2.5	3.0	3.5
70-74	2.4	3.1	2.0	2.5	2.8
75-79	1.7	2.4	1.5	1.9	1.7
80-84	1.2	1.6	1.2	1.3	0.8
85+	0.8	0.9	1.0	1.0	0.1

Source: (2016-2018 Life Expectancy-1990-1992 Life Expectancy)

# % Change in Mecklenburg County Life Expectancy

	Total	Male	Female	White	African American
65-69	16.6%	24.3%	13.1%	16.7%	22.4%
70-74	16.9%	25.4%	12.8%	17.2%	21.5%
75-79	14.9%	25.0%	12.1%	16.7%	15.5%
80-84	13.6%	21.3%	12.6%	14.8%	8.7%
85+	11.8%	15.0%	14.1%	15.2%	1.3%

Source: (Change In Life Expectancy / 1990-1992 Life Expectancy)

# <u>Cancer Case and Death Trends for Mecklenburg County and the Extended Service Area</u> (Page 42)

The applicant states that number of new cancer cases and deaths is projected to increase. The applicant provides tables with the number of cases in 2015 and the projected number of cases for 2020 with the percent of increase calculated for Mecklenburg County and the extended service area. During the 5-year period of 2015 to 2020, the applicant states that the numbers in the tables show an increase in the rate of new cancer cases and an increase in the number of cancer deaths. The applicant states these increases are directly related to the need for CT simulator services given the critical role it plays in the planning and treatment of cancer. The information provided by the applicant from the 2015 and 2020 NC Central Cancer Registry is shown in the tables below.

# 2015 Cancer Cases

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	4,762	671	862	623	377
Cabarrus	1,010	148	177	138	81
Iredell	988	148	167	140	79
Lincoln	509	77	84	74	41

# **2020 Projected New Cancer Cases**

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	5,603	766	1,043	646	422
Cabarrus	1,190	167	219	140	90
Iredell	1,142	166	200	142	86
Lincoln	593	87	102	76	44

# Percent Change 2015-2020

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	17.7%	14.2%	21.0%	3.7%	11.9%
Cabarrus	17.8%	12.8%	23.7%	1.4%	11.1%
Iredell	15.6%	12.2%	19.8%	1.4%	8.9%
Lincoln	16.5%	13.0%	21.4%	2.7%	7.3%

#### 2015 Cancer Deaths

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	1,573	470	117	68	129
Cabarrus	345	104	24	16	28
Iredell	343	105	23	16	28
Lincoln	176	55	12	8	14

# **2020 Projected Cancer Deaths**

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	1,762	486	131	78	145
Cabarrus	383	107	28	17	31
Iredell	377	106	26	18	30
Lincoln	196	56	13	10	16

# Percent Change 2015-2020

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Mecklenburg	12.0%	3.4%	12.0%	14.7%	12.4%
Cabarrus	11.0%	2.9%	16.7%	6.3%	10.7%
Iredell	9.9%	1.0%	13.0%	12.5%	7.1%
Lincoln	11.4%	1.8%	8.3%	25.0%	14.3%

# NHHMC Diagnostic CT Scanner Utilization (Page 43)

The applicant states that the CT scanners at NHHMC are fully utilized, requiring simulations performed at the medical center to be compressed in to 30-minute time slots, rather than in the standard 60-minute time slot. The applicant states that due to capacity issues simulations are more difficult to perform on existing diagnostic CT scanners at NHHMC forcing patients to travel elsewhere for their simulation. The number of patients traveling to and receiving their simulation treatments at Novant Health Presbyterian Medical Center (NHPMC) has increased from 0 patients in 2018, to 49 patients in 2019, to 66 patients during the first nine months of 2020.

# NHHMC Linear Accelerator Utilization (Page 43)

The applicant states that since FY2015 the number of patients treated on the linear accelerator at NHHMC has increased seven-fold and the numbers are expected to continue to increase in the future. Linear accelerator utilization is shown in the following table.

### **Linear Accelerator Patients**

	FFY2015	FFY2016	FFY2017	FFY2018	FFY2019
Patients	107	250	412	448	752
<b>Annual Growth</b>		133.6%	64.8%	8.7%	67.9%

The information is reasonable and adequately supported based on the following:

- Population growth and aging trends for Mecklenburg County and the extended service area demonstrate an increase for the population most likely to use the services being proposed.
- The Mecklenburg County life expectancy from 1990 to 2018 has increased and supports the assumption that the services being proposed will also increase.
- The percent change for the majority of cancer types and mortality for Mecklenburg County and the extended service area has increased.
- Linear accelerator utilization has increased 602.8 percent from 2015 to 2019.

# **Projected Utilization**

On Form C in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

		Histo	rical and P	rojected C	T Simulations	3		
Year	2018	2019	2020	2021	Partial Year 2022	2023	2024	2025
CT Simulator Unit		Diagnostic	CT Scanne	r	Both	Ded	icated CT S	imulator
# of Simulations at NHHMC	595	595	558	672	700	729	759	790
Simulations referred out to NHPMC	*	49	88					
Total NHHMC Volume	595	644	646	672	700	729	759	790
Simulation Patients	*	441	441	460	479	499	520	541

<sup>\*</sup> Information not provided

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states that utilization of the simulator in the first 6 months of 2020 is not an accurate representation of simulator volumes because due to the COVID-19 pandemic, NCDHHS had initially recommended that everyone stay at home and avoid all travel thereby decreasing the number of outpatient visits and procedures. The applicant states that outpatient visits and procedures only began increasing once the stay at home recommendation was lifted during the second half of 2020. Therefore, the applicant uses volume rates from 2018 and 2019 to project future use.
- The applicant arrives at an annual change rate of 8.2% by subtracting the 2018 (previous year) volume of 595 from the 2019 (current year) volume of 644 and dividing the result by the previous year volume [644 595 = 49/595 = 0.0823 or 8.2%].
- The applicant calculates 2020 simulations by annualizing the COVID-19 affected, 2020 6-month simulation volume of 279 simulations and adding 88 simulations referred to NHPMC [279 x 2 + 88 = 646 simulations].
- The applicant projects simulations in years 2021 through 2025 by taking the calculated previous year's volume and multiplying it by 100.0% plus half the calculated change rate 4.1% (8.2% / 2 = 4.1%) or 104.1%.
- The applicant projects the number of simulation patients using the 2019 simulation to patient ratio of 1.5 simulations per patient to project the number of simulation patients for 2020 through 2025.

Project utilization is reasonable and adequately supported based on the following reasons:

- The applicant documents projected population growth in the population groups most likely to need simulator services.
- Projected utilization is based on the applicant's historical experience with the existing simulators at NHHMC.
- The applicant uses one-half of the actual average annual change rate experienced by NHHMC simulator utilization from CY 2018 to CY 2019 to project future simulator utilization.
- The applicant provides reasonable and adequately supported information to justify the need for acquiring a dedicated CT simulator.

# **Access to Medically Underserved Groups**

In Section C, page 49, the applicant states:

"Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) [persons with disabilities], (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians."

In Section L, page 83, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

NHHMC Projected Payor Mix – FY 3 (CY 2024)			
Payor Source	Entire Facility	Dedicated CT	
		Simulator	
Self-Pay	1.3%	0.4%	
Charity Care	3.6%	**	
Medicare *	43.2%	45.2%	
Medicaid *	6.0%	3.8%	
Insurance *	42.2%	48.5%	
TRICARE	0.5%	1.1%	
Other	1.1%	1.0%	
Total	100.0%	100.0%	

<sup>\*</sup> Including any managed care plans

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides its projected payor mix, which includes underserved groups, and states its projected payor mix is based on its historical payor mix.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

<sup>\*\*</sup> Charity Care represents 1.0% of all simulation patients represented across payors

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately support their assumptions.
- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to acquire a dedicated CT simulator.

In Section E., the applicant states there are no alternative methods of meeting the needs for the proposed project. On page 60, the applicant states that NHHMC is currently having to use its existing diagnostic CT scanners for simulation and having to send overflow patients to NHPMC which is inconvenient, time consuming, and expensive for cancer patients. The applicant states that the only solution to increasing service efficiencies and staff and patient satisfaction is to acquire and operate a dedicated CT simulator. Therefore, no alternatives were considered for this application.

# Conclusion

The Agency reviewed the:

- application
- exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Presbyterian Hospital and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
  - 2. The certificate holder shall acquire a dedicated CT Simulator which shall be operated at Novant Health Huntersville Medical Center.
  - 3. Upon completion of the project, the certificate holder shall be licensed for no more than one CT simulator at Novant Health Huntersville Medical Center.
  - 4. Progress Reports:
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
    - b. The certificate holder shall complete all sections of the Progress Report form.
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
    - d. The first progress report shall be due on August 1, 2021.
  - 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
  - 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
    - a. Payor mix for the services authorized in this certificate of need.

- b. Utilization of the services authorized in this certificate of need.
- c. Revenues and operating costs for the services authorized in this certificate of need.
- d. Average gross revenue per unit of service.
- e. Average net revenue per unit of service.
- f. Average operating cost per unit of service.
- 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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.

 $\mathbf{C}$ 

The applicant proposes to acquire a dedicated CT simulator.

# **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

# **NHHMC Capital Cost**

Construction/Renovation Costs	\$700,000
Architectural/Engineering Fees	\$59,500
Medical Equipment Costs	\$1,060,258
Consultant Fees	\$28,100
Other Costs/Contingency	\$105,000
Total	\$1,952,858

In Exhibit F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F.1, the applicant provides documentation from the manufacturer regarding prices for all items associated with the delivery and installation of the proposed equipment and these costs are included in the projected capital cost
- In Exhibit F.1, the applicant provides documentation from an architect projecting construction plans and capital costs which are included in the projected capital cost.

In Section F.3, pages 63-64, the applicant projects there will be no start-up costs or initial operating expenses associated with the proposed project because NHHMC is an existing facility which already offers CT simulation services.

# **Availability of Funds**

In Section F.2, page 62, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing** 

Туре	Novant Health	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$1,952,858	\$1,952,858
Bonds	\$0	\$0
Other (Tenant Allowance)	\$0	\$0
Total Financing	\$1,952,858	\$1,952,858

<sup>\*</sup> OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter dated November 10, 2020, from the Senior Vice President of Operational Finance & Revenue Cycle for Novant Health documenting its intention to provide accumulated reserves to finance the proposed project. Exhibit F.2-2 contains the Consolidated Financial Statements for Novant Health, Inc. and affiliates for the year ending December 31, 2019 and 2018. As of December 31, 2019, Novant had adequate cash and assets available to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from an appropriate individual confirming the availability of the type of funding proposed for the capital needs of the project and the commitment to using that funding for the capital needs of the project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital and working capital needs of the project.

# **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects revenues will exceed operating expenses in the first three full fiscal years following completion of the project, and provided the calculations shown in the table below.

NHHMC Projected Revenue & Expenses – FYs 1-3 (CYs 2023-2025)					
	FY 1 (CY 2023)	FY 2 (CY 2024)	FY 3 (CY 2025)		
Total # of Dedicated CT Simulations	499	520	541		
Total Gross Revenue (Charges)	\$1,688,705	\$1,810,945	\$1,941,457		
Total Net Revenue	\$539,504	\$578,557	\$620,253		
Average Net Revenue per Simulation	\$1,081	\$1,113	\$1,146		
Total Operating Expenses (Costs)	\$460,109	\$470,155	\$480,618		
Average Operating Expense per Simulation	\$922	\$904	\$888		
Net Income	\$79, 395	\$108,402	\$139,635		

Given data and assumptions provided by the applicant, the Project Analyst recalculated the projected revenues and expenses and notes some minor errors in the applicant's calculation. The errors were found to be minor and did not change the overall determination of financial feasibility under this criterion.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the
  discussion regarding projected utilization in Criterion (3) which is incorporated herein by
  reference.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 acquire a dedicated CT simulator.

N.C. Gen. Stat. §131E-176(24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 36-37, the applicant

defines the service area for the proposed project. The applicant states that the primary service area is Mecklenburg County and the secondary service area includes the surrounding counties of Lincoln, Cabarrus and Iredell. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all simulator providers in Mecklenburg, Cabarrus, Lincoln and Iredell counties during FFY 2019. The information was obtained from the 2020 Hospital License Renewal Application, Question 11.d. and the Registration and Inventory of Medical Equipment, Linear Accelerator Equipment, January 2020, Section 2.

County	Facility	Simulators	Radiation Therapy
			Treatment Patients
	Atrium Health Pineville	1	531
	Atrium Health University City	1	747
	Carolinas Medical Center	2	2,134
Mecklenburg	Matthews Radiation Oncology Center		447
	Novant Health Huntersville Medical Center	0	752
	Novant Health Presbyterian Medical Center	2	1,758
Cabarrus	Atrium Health Cabarrus	1	663
Lincoln	CaroMont Regional Medical Center	1*	759*
Iredell	Iredell Memorial Hospital	1	327
	Lake Norman Radiation Oncology Center	1	301

<sup>\*</sup>Gaston and Lincoln counties, combined

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved simulation services in Mecklenburg County. The applicant states it is not projecting to serve patients currently served in another facility but rather the simulator is needed to serve the projected patient census at NHHMC. Projected utilization starts with the historical patient population and grows that patient census.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates that acquiring a dedicated CT simulator is necessary to accommodate the projected utilization.
- The applicant adequately demonstrates that acquiring a dedicated CT simulator is needed in addition to the existing simulators in the service area.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(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.

 $\mathbf{C}$ 

The applicant proposes to acquire a dedicated CT simulator.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as summarized in the table below.

NHHMC Simulator Current and Projected Staff					
Position	Position   Interim/Partial   FY 1   FY 2   FY 3   (CY 2022)   (CY 2023)   (CY 2024)   (CY 2025)				
Radiation Therapist	1.0	2.0	2.0	2.0	
Registered Nurse	0.1	0.2	0.2	0.2	
Total	1.1	2.2	2.2	2.2	

The assumptions and methodology used to project staffing costs are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 70-71, the applicant states that existing staff will be trained to perform CT simulations and describes its existing training and continuing education programs. In Section I, page 74, the applicant identifies the current medical director. In Exhibit I.2., the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H.3. and I.2., the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it needs to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3 in Section Q.
- The applicant provides adequate documentation of staff and its existing training and continuing education programs.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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.

 $\mathbf{C}$ 

The applicant proposes to acquire a dedicated CT simulator.

# **Ancillary and Support Services**

In Section I, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of the ancillary and support services.
- The applicant states the existing providers will continue to provide the necessary ancillary and support services.

# **Coordination**

NHHMC is an existing facility. In Section I, page 73, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.1. On page 73, the applicant states that NHHMC is part of the Novant Health system and has since 2004 retained established relationships with local health care and social service providers in the area. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant provides documentation that it has existing relationships with other local health care and social service providers.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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 acquire a dedicated CT simulator.

In Section K, page 77, the applicant states the project involves renovating 2,000 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 78, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant explains why the cost, design, and means of construction chosen are more cost-effective than other alternatives.
- In Exhibit K-3., the applicant provides supporting documentation of the proposed costs that are consistent with projections elsewhere in the application.

On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The design of the proposed project is in compliance with all requirements for energy efficiency and consumption.
- The applicant states it is using existing space without developing any new square footage, which the applicant states will keep the capital cost to develop the project lower than it would be if it constructed additional space.

On page 78, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 ... persons [with disabilities], 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;

In Section L, page 82, the applicant provides the historical payor mix during FY 2019 for the proposed services, as shown in the table below.

NHHMC Historical Payor Mix – FY 2019				
Payor Source	Entire Facility	Simulation Service		
Self-Pay	1.3%	0.4%		
Charity Care	3.6%	**		
Medicare *	43.2%	45.2%		
Medicaid *	6.0%	3.8%		
Insurance *	42.2%	48.5%		
TRICARE	0.5%	1.1%		
Other (Specify)**	1.1%	1.0%		
Total	100.0%	100.0%		

Source: NHHMC Internal Data

In Section L, page 81, the applicant provides the following comparison.

	Percentage of Total Patients Served by NHHMC	Percentage of Total Patients Served- Simulation	Percentage of the Population in the Service Area*
Female	60.1%	77.9%	51.9%
Male	39.9%	22.1%	48.1%
Unknown	0.1%	0.0%	0.0%
64 and Younger	68.1%	51.6%	88.5%
65 and Older	31.9%	48.4%	11.5%
American Indian	0.3%	0.7%	0.8%
Asian	1.6%	2.0%	6.3%
Black or African-American	24.0%	21.9%	33.0%
Native Hawaiian or Pacific Islander	0.1%	0.0%	0.1%
White or Caucasian	66.5%	72.5%	57.3%
Other Race	5.2%	2.9%	2.5%
Declined / Unavailable	2.4%	0.3%	0.0%

**Sources:** NHFMC internal data; \*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <a href="https://www.census.gov/quickfacts/fact/table/US/PST045218">https://www.census.gov/quickfacts/fact/table/US/PST045218</a>. Just enter the name of the county.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

<sup>\*</sup> Including any managed care plans

<sup>\*\*</sup> Charity care represents 1.0% of all simulation patients

existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. 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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

 $\mathbf{C}$ 

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 82, the applicant states it has no such obligation.

In Section L, page 82, the applicant states that during the last five years no patient civil rights access complaints have been filed against Novant Health facilities and programs located in North Carolina.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

 $\mathbf{C}$ 

In Section L, page 83, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

NHHMC Projected Payor Mix – FY 3 (CY 2024)				
Payor Source	Entire Facility	Dedicated CT		
		Simulator		
Self-Pay	1.3%	0.4%		
Charity Care	3.6%	**		
Medicare *	43.2%	45.2%		
Medicaid *	6.0%	3.8%		
Insurance *	42.2%	48.5%		
TRICARE	0.5%	1.1%		
Other (Specify)**	1.1%	1.0%		
Total	100.0%	100.0%		

**Source:** NHHMC internal data \*Including any managed care plans;

As shown in the table above, during the third full fiscal year of operation, the applicant projects 1.3 percent and 0.4 percent of total facility services and CT simulator services, respectively, will be provided to self-pay patients; 3.6 percent and 1.0 percent of total facility services and CT simulator services, respectively, will be provided to charity care patients; 43.2 percent and 45.2 percent of total facility services and CT simulator services, respectively, will be provided to Medicare patients; and 6.0 percent and 3.8 percent of total facility services and CT simulator services, respectively, will be provided to Medicare patients; and 6.0 percent and 3.8 percent of total facility services and CT simulator services, respectively, will be provided to Medicaid patients.

On page 83, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected patient payor mix is consistent with the historical patient payor mix.
- The applicant does not propose to develop any services or make any changes to its
  facility that could foreseeably impact the projected patient payor mix in more than
  minor ways.

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

<sup>\*\*</sup>Charity care represents 1.0% of all simulation patients

(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.

 $\mathbf{C}$ 

In Section L, page 85, the applicant adequately describes the range of means by which patients will have access to the proposed services.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant proposes to acquire a dedicated CT simulator.

In Section M, page 87, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area for which it already provides access at NHHMC and other Novant facilities.
- The applicant states it will continue to provide access to NHHMC as it has in the past.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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.

 $\mathbf{C}$ 

The applicant proposes to acquire a dedicated CT simulator.

N.C. Gen. Stat. §131E-176(24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 36-37, the applicant defines the service area for the proposed project. The applicant states that the primary service area is Mecklenburg County and the secondary service area includes the surrounding counties of Lincoln, Cabarrus and Iredell. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all simulator providers in Mecklenburg, Cabarrus. Lincoln and Iredell counties during FFY 2019. The information was obtained from the 2020 Hospital License Renewal Application, Question 11.d. and the Registration and Inventory of Medical Equipment, Linear Accelerator Equipment, January 2020, Section 2.

County	Facility	Simulators	Radiation Therapy
			<b>Treatment Patients</b>
	Atrium Health Pineville	1	531
	Atrium Health University City	1	747
	Carolinas Medical Center	2	2,134
Mecklenburg	Matthews Radiation Oncology Center	1	447
	Novant Health Huntersville Medical Center	0	752
	Novant Health Presbyterian Medical Center	2	1,758
Cabarrus	Atrium Health Cabarrus	1	663
Lincoln	CaroMont Regional Medical Center	1*	759 <sup>*</sup>
Iredell	Iredell Memorial Hospital	1	327
	Lake Norman Radiation Oncology Center	1	301

<sup>\*</sup>Gaston and Lincoln counties combined

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 89, the applicant states:

"NHHMC expects the acquisition of the dedicated CT simulator to have a positive effect on competition in the service area because it will not require CT simulation to occur on the heavily-utilized NHHMC diagnostic CT scanners and will permit cancer patients to have their simulations performed on a dedicated simulator without having to travel away from the NHHMC campus."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 89, the applicant states:

"Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care. .... Ultimately this type of care provides value-safe, more affordable care with better outcomes-and is centered on our patients' unique needs. .... Novant Health is collaborating with payors and partners to identify payment models that match Novant Health's value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health's new approach to delivering remarkable healthcare, so that people can get better and stay healthy."

See also Sections C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 91, the applicant states:

"The Novant Health Utilization Review Plan is used at NHHMC. Utilization Review consists of interdisciplinary professionals and supporting team members providing a wide range of functions for patients and the organization. This includes the patients, their caregivers, internal and external partners, and the healthcare community. The UR team strives to ensure the achievement of quality and the most effective level(s) of care.

. . .

Additionally, Novant Health has twice received the prestigious Ernest A. Codman award for improving systemwide the quality and safety of care provided to patients.

. .

...NHHMC will continue to strive to meet Novant Health's high level of quality when it operates the dedicated CT simulator."

See also Sections B, C, and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 91-92, the applicant states:

"NHFMC will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. ...

..

Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians."

See also Sections C, and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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.

On Form A in Section Q, the applicant identifies the medical centers located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of eleven facilities located in North Carolina. Based on clarifying information received, only three of the eleven facilities identified operate simulators.

In Section O, page 96, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, the facilities owned, operated, or managed by the applicant which offer simulator services are in compliance with all CMS Conditions of Participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at three facilities, the applicant provided 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.

G.S. 131E-183 (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.

 $\mathbf{C}$ 

The applicant proposes to acquire a dedicated CT simulator. The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment, NCAC 14C .1900. The specific criteria are discussed below.

# SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT 10A NCAC 14C .1903 PERFORMANCE STANDARDS

- (a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:
- (1) an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;
- (2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and

- (3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.
- -NA- The applicant does not propose to acquire a linear accelerator.
- (b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.
- -NA- The applicant does not propose to acquire a linear accelerator.
- (c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:
- (1) the number of patients who are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and
- -NA- The applicant states the proposed CT simulator will not perform patient treatments.
- (2) the maximum number and type of procedures that the proposed equipment is capable of performing.
- -C- In Section C, page 45, the applicant projects the proposed CT simulator will have the capacity for a maximum of 5 patients per day of operation and that the equipment will be operational approximately 250 days per year for a maximum annual capacity of 1,250 patients, annually.
- (d) The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.
- -C- In Section C, page 45, the applicant provides the assumptions and methodology it used to project utilization of the CT simulator. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.