

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 23, 2021

Findings Date: April 23, 2021

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: J-12000-20

Facility: Duke Cancer Center Green Level Radiation Oncology

FID #: 200892

County: Wake

Applicant: Duke University Health System, Inc.

Project: Acquire, replace, and relocate a linear accelerator from Franklin County Cancer Center and acquire a 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.

C

Duke University Health System, Inc. (DUHS), the applicant, proposes to acquire, replace and relocate an existing linear accelerator (linac), and to acquire a radiation oncology simulator, to create a new radiation oncology facility, Duke Cancer Center Green Level Radiation Oncology (DCC-Green Level). DCC-Green Level will be located within a medical office building under development located at 3208 Green Level W Road, Cary. At this time, radiation oncology is the only service proposed at DCC-Green Level.

The linear accelerator that is proposed to be acquired, replaced and relocated to DCC-Green Level is currently located at Franklin County Cancer Center in Franklin County.

### Need Determination

There is no need determination in the 2020 State Medical Facilities Plan (SMFP) that is applicable to this proposed project.

### **Policy**

There is one policy in the 2020 SMFP applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 SMFP, 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, Certificate of Need 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 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$5.0 million. In Section B, page 14, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- 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 because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

- (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, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

#### **Patient Origin**

In Chapter 17, page 400, the 2020 SMFP states, "*Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .*" DCC-Green Level is to be located in Wake County. In Table 17C-4, page 408 of the 2020 SMFP, Wake County is included in Linear Accelerator Service Area 20. Linear Accelerator Service Area 20 includes both Franklin County and Wake County. Thus, the service area for this linac consists of Wake and Franklin counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

Zip Code	First Full FY of Operation following Project Completion (7/1/23 to 6/30/24)		Second Full FY of Operation following Project Completion (7/1/24 to 6/30/25)		Third Full FY of Operation following Project Completion (7/1/25 to 6/30/26)	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
27701	3	2.3%	5	2.3%	8	2.3%
27703	13	10.8%	26	10.8%	40	10.8%
27707	10	8.4%	20	8.4%	31	8.4%
27713	12	9.9%	24	9.9%	37	9.9%
27709	0	0.1%	0	0.1%	1	0.1%
27650	1	1.2%	3	1.2%	4	1.2%
27613	3	2.2%	5	2.2%	8	2.2%
27517	2	1.6%	4	1.6%	6	1.6%
27617	1	0.9%	2	0.9%	3	0.9%
27615	3	2.3%	6	2.3%	9	2.3%
27612	2	2.1%	5	2.1%	8	2.1%
27523	2	1.8%	4	1.8%	7	1.8%
27519	7	5.7%	14	5.8%	21	5.7%
27513	7	5.5%	13	5.5%	20	5.5%
27607	1	0.6%	1	0.6%	2	0.6%
27606	3	2.9%	7	2.9%	11	2.9%
27511	6	4.8%	12	4.8%	18	4.8%
27312	2	1.9%	5	1.9%	7	1.9%
27518	2	2.1%	5	2.1%	8	2.1%
27603	5	4.3%	10	4.3%	16	4.3%
27502	6	4.7%	11	4.7%	17	4.7%
27539	3	2.9%	7	2.9%	11	2.9%
27562	0	0.4%	1	0.4%	2	0.4%
27540	4	3.2%	8	3.2%	12	3.2%
27559	0	0.4%	1	0.4%	2	0.4%
27526	7	6.2%	15	6.2%	23	6.2%
27330	2	1.9%	5	1.9%	7	1.9%
In-migration (all other zip codes)	11	9.3%	22	9.1%	34	9.2%
Grand Total	118	100.0%	241	100.0%	369	100.0%

Source: Section C.3, pages 17-18, of the application.

In Section Q, pages 87-95, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### Analysis of Need

In Section C.4, pages 19-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant identifies multiple reasons to support the need for the proposed service, which are summarized below.

- Growth in procedures at existing DUHS sites in Service Area 20 (page 21).
- Wake County Population Growth (pages 21-23).
- Enhanced Access to non-Hospital Based Services (pages 21-23 and page 28).
- Increased Geographic Access (pages 21-23).
- Coordination with Other Services at Duke Health at Green Level (page 27).
- Growth in Provider Network (pages 27-28).
- The condition and age of the existing linear accelerator (pages 20-21).

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

- The applicant relies on data from established and reliable sources and cites to the sources of any data used.
- The applicant relies on historical utilization to project future growth in utilization.
- The applicant provides data to support its projections of population growth and aging in the proposed service area.
- The applicant provides data regarding the historical utilization of linear accelerator services by the proposed service area population.
- The existing location of the linear accelerator in Franklin County, the only linear accelerator in Franklin County, is under-utilized, having performed only 33 ESTVs in FY2018 and 0 in FY2019.

Projected Utilization for DCC-Green Level

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following tables.

**DCC-GREEN LEVEL  
 LINAC RADIATION THERAPY TREATMENTS: PROJECTED**

	FY2024	FY2025	FY2026
# of Linacs	1	1	1
# of CT Simulators	1	1	1
# of Patients	118	241	369
# of CT Procedures	48	98	150
# of linac procedures	1,716	3,501	5,360
# of ESTVs Treatments*	1,834	3,744	5,732

Source: Section Q of the application.

\*ESTVs means Equivalent Simple Treatment Visits

Note: DUHS First Fiscal Year is 7/1/2023 to 6/30/2024.

In Section Q, pages 87-95, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Step 1: Identify ZIP Codes within an approximate 20-minute drive from proposed facility (pages 87-88).
- Step 2: Calculate projected population within the identified ZIP codes based on data

- from Stratosan (page 88).
- Step 3: Identify Historical Duke Linac Patients from Identified ZIP Codes (page 88).
  - Step 4: Annualize Patients for FY 2020 based on 8 months (using 1.5 factor = 12/8 months) (page 88).
  - Step 5: Project Future Patients based on Population Growth Rate from Step 2. (pages 88-90).
  - Step 6: Apply projected shift rates to projected population by ZIP code (pages 90-92).
  - Step 7: Project Patients Due to In-Migration (page 92).
  - Step 8: Project Total Patients at Duke Cancer Center Green Level Radiation Oncology (page 92).
  - Step 9: Project ESTVs and CT Simulation Procedures (pages 93-94).

**DCC-GREEN LEVEL  
 LINAC RADIATION THERAPY TREATMENTS: PROJECTED**

	FY2024	FY2025	FY2026
# of Linacs	1	1	1
# of CT Simulators	1	1	1
# of Overall Procedures	1,764	3,600	5,510
# of CT Procedures	48	98	150
# of linac procedures	1,716	3,501	5,360
# of ESTVs Treatments	1,834	3,744	5,732

- CT simulation procedures were calculated as representing 2.72% of the number of overall projected procedures at DCC-Green Level using Duke Cancer Center Cary Radiation Oncology as a baseline. The procedures that were not CT simulation procedures were all linac procedures.
- FY2024:  $1,764 \times .0272 = 47.90$  or 48
- FY2025:  $3,600 \times .0272 = 97.92$  or 98
- FY2026:  $5,510 \times .0272 = 149.8$  or 150
- ESTVs were calculated based on the values assigned in the State Medical Facilities Plan for Form C.

- Step 10: Project Patients on all DUHS linear accelerators in Service Area 20 ( pages 94-95).

**Patients: Historical, Interim and Projected Patients for all DUHS linacs in Service Area 20**

Row		Historical* FY20 # of pts.	Interim FY21 # of pts.	Interim FY22 # of pts.	Interim FY23 # of pts.	OY1 (FY24) # of pts.	OY2 (FY25) # of pts.	OY3 (FY26) # of pts.	# of pts. Per machine
	<b>Prior to Shift</b>								
1	Duke Raleigh Hospital Campus	612	623	634	645	657	669	681	341
2	Duke Women’s Cancer Care Raleigh	260	265	270	275	279	284	289	289
3	Duke Cancer Center Cary Radiation Oncology	315	321	327	333	338	344	351	351
4	Annualized Growth Rate**		1.8%	1.8%	1.8%	1.8%	1.8%	1.8%	
	<b>After Shift to DCC-Green Level</b>								
5	Duke Raleigh Hospital Campus	612	623	634	645	644	643	642	321
6	Duke Women’s Cancer Care Raleigh	260	265	270	275	272	269	266	266
7	Duke Cancer Center Cary Radiation Oncology	315	321	327	333	314	294	276	276
8	Duke-Green Level***	0	0	0	0	118	241	369	369
9	Patients “shifted” from existing sites to DCC-Green Level					107	219	336	
10	Patients from in-migration to DCC-Green Level					11	22	34	

Source: Section Q, page 95

Note: Total may not foot due to rounding.

\*Annualized based on July-February.

\*\*Growth Rate applied was 1.8% based on the projected annual population growth for the area as a whole as calculated by Stratosan.

\*\*\*Total patients for Duke Green-Level (Row 8) equals Row 9 + Row 10. See Section Q, pages 91-92.

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

- The applicant relies on data from established and reliable sources and cites to the sources of any data used.
- The applicant relies on historical DUHS linear accelerator utilization and population growth/aging to project future growth in utilization.

- The proposed facility will be a freestanding, non-hospital based service with lower out-of-pocket costs for many patients compared to hospital based facilities.
- The proposed new location allows the applicant to maximize patient geographic access to new equipment that meets Duke’s standard of care and permits coordination of patient access to care with a variety of other Duke Health primary, specialty and acute care services.

**Access to Medically Underserved Groups**

In Section L.2, page 72, the applicant states,

*“DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DUHS will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. The planned diagnostic center and proposed imaging services will be available to and accessible by any outpatient, including the medically underserved, having a clinical need for the offered services.”*

In Section L, page 74, 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.

<b>Payor Category</b>	<b>Radiation Oncology Services as Percent of Total</b>
Self-Pay	2.0%
Medicare*	49.0%
Medicaid*	4.0%
Insurance*	43.0%
TRICARE	1.0%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 74 of the application.

\*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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

- (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.

### C

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

In Section D, page 42, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 42, the applicant states:

*“The linear accelerator equipment that DUHS proposed to acquire, replace and relocate is currently located in Louisburg, Franklin County... it has not provided services to patients since 2018. Accordingly, there are no patients currently utilizing the equipment who will be affected by this project. In fact, because the equipment is not currently in service, this project will serve to expand access to patients in the service area without reducing any existing services. Patients ... will now have an additional non-hospital based option in the Service Area.”*

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

In Section E, pages 47-48, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Acquire the linac without replacing it: The applicant states that the current linac is not capable of providing services consistent with Duke's standard of care as the equipment is 15 years old. Therefore, this was determined to be a less effective alternative.
- Develop the Project in a Different Location: The applicant states that the current location of the linac, Franklin County, has less than 6% of the total population of the combined Wake/Franklin service area. The current location is not the most effective for maximizing coordination of care and geographic access. Moreover, the proposed site is in a centrally located, densely populated and growing portion of the service area. Therefore, this was determined to be a less effective alternative.

On pages 47-48, the applicant states that its proposal is the most effective alternative because replacing the equipment and locating it at the proposed new location allows the applicant to maximize geographic access to new equipment that meets Duke's standard of care and permits coordination of care with a variety of other Duke Health primary, specialty and acute care services in a cost-effective manner by placing the linac in a medical office building already under construction.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following reasons:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

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. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire, replace, and relocate a linear accelerator from Franklin County Cancer Center and acquire a simulator.**
- 3. Upon completion of the project, Duke Cancer Center Green Level Radiation Oncology shall be licensed for no more than one linear accelerator and one simulator.**
- 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.**
- 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. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 7. 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.**

**8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

**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.

Site Costs	\$0
Construction Costs	\$4,840,000
Miscellaneous Costs	\$5,870,000
<b>Total</b>	<b>\$10,710,000</b>

In Section Q, 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 reasons:

- Letter from the project architect outlining the projected construction costs (see Exhibit F.1(a)).
- Copy of equipment costs quote (see Exhibit F.1(b)).

In Section F, pages 51-54, the applicant projects there will be no start-up or initial operating expenses for the project because the facility will be operated as part of the Duke University Health System and will not have separate financial statements.

**Availability of Funds**

In Section F, page 50, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	DUHS	Total
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$10,710,000	\$10,710,000
Bonds	\$0	\$ 0
Other (Specify)	\$0	\$ 0
<b>Total Financing</b>	<b>\$10,710,000</b>	<b>\$10,710,000</b>

\* OE = Owner’s Equity

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

- The applicant provided a letter dated November 12, 2020 from the Chief Financial Officer for DUHS documenting that the funds will be made available for the capital costs of the project (see Exhibit F.2).
- The audited financial statements for DUHS which indicated the health system had \$157.8 million in cash and cash equivalents, \$7.3 billion in assets, and \$3.4 billion in net assets without donor restrictions, as of June 30, 2020 (see Exhibit F.2).

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that operating expenses will exceed revenues for this project the first three full fiscal operating years of the project, as shown in the table below.

	1 <sup>st</sup> Full Fiscal Year*	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
Total Treatments**	1,882	3,842	5,882
Total Gross Revenues (Charges)	\$4,520,899	\$9,412,019	\$14,696,100
Total Net Revenue	\$860,653	\$1,786,105	\$2,780,093
Average Net Revenue per Treatment*	\$457	\$465	\$473
Total Operating Expenses (Costs)	\$3,348,457	\$3,416,867	\$3,487,696
Average Operating Expense per Treatment	\$1,779	\$889	\$593
Net Income	(\$2,487,805)	(\$1,630,762)	(\$707,602)

\*DUHS First Fiscal Year is 7/1/2023 to 6/30/2024

\*\*Treatments include both ESTV treatments and CT simulator procedures.

However, the applicant states that the facility will be operated as part of the Duke University Health System and will not have separate financial statements. The applicant provided pro forma financial statements for the Duke University Health System, including the proposed project, for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues for the Duke University Health System,

including the proposed project, will exceed operating expenses in the first three full fiscal operating years of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year*</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>	<b>3<sup>rd</sup> Full Fiscal Year</b>
Total Gross Revenues (Charges)	\$14,182,888,000	\$14,461,194,000	\$14,743,485,000
Total Net Revenue	\$4,506,684,000	\$4,619,214,000	\$4,730,948,000
Total Operating Expenses (Costs)	\$4,277,734,000	\$4,384,638,000	\$4,490,786,000
Net Income	\$228,950,000	\$234,576,000	\$240,162,000

\*DUHS First Fiscal Year is 7/1/2023 to 6/30/2024

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 reasons:

- Radiation oncology gross revenue is based on Duke Raleigh Hospital CPT Code pricing.
- Extensive detailed assumptions for Forms F.2 and F.3 for both Duke University Health System and the facility/radiation oncology service provided in Section Q.
- 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
- Written comments
- Responses to comments

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 of the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all of 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.

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

In Chapter 17, page 400, the 2020 SMFP states, “Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .” DCC-Green Level is to be located in Wake County. In Table 17C-4, page 408 of the 2020 SMFP, Wake County is included in Linear Accelerator Service Area 20. Linear Accelerator Service Area 20 includes both Franklin County and Wake County. Thus, the service area for this linac consists of Wake and Franklin counties. Facilities may also serve residents of counties not included in their service area.

There are eleven linear accelerators (10 existing and 1 approved) in Linear Accelerator Service Area 20. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2017 – 9/30/2018, as summarized from Table 17C-1, page 403 of the 2020 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVS* PER LINEAR ACCELERATOR
Franklin County Cancer Center	1	Franklin	33	33
Duke Raleigh Hospital	4	Wake	19,929	4,982
Rex Hospital	4	Wake	22,514	5,628
UNC Hospitals Radiation Oncology-Holly Springs**	1	Wake	0	0
UNC REX Cancer Care of East Raleigh	1	Wake	5,370	5,370

\*The 2020 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 17C-1.

\*\*The 2014 SMFP contained a need determination for a linac in Linac Service Area 20 which, upon settlement, was approved for UNC Hospitals Radiation Oncology-Holly Springs. A Certificate of Need was issued effective April 29, 2016. The project has not yet been developed and a material compliance to change the site was approved on September 16, 2020. See Project ID #J-10318-14.

In Section G, pages 57-58. the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved linear accelerator services in Linear Accelerator Service Area 20. The applicant states:

*“This project is the replacement and relocation of existing equipment in the service area inventory, and will not increase the total number of radiation oncology service locations. Rather, this project entails the upgrade of equipment to meet current standards of care and its relocation to a more densely populated and fast growing part of the service area.”*

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 reasons:

- The proposal would not result in an increase in linacs in Linear Accelerator Service Area 20.

- The applicant adequately demonstrates that the linac proposed is an existing and licensed linac in Linear Accelerator Service Area 20 which is being relocated to a different location within Linear Accelerator Service Area 20.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described 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.

C

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development.

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

Position	Projected FTE Staff		
	1 <sup>st</sup> Full Fiscal Year (7/1/23-6/30/24)	2 <sup>nd</sup> Full Fiscal Year (7/1/24-6/30/25)	3 <sup>rd</sup> Full Fiscal Year (7/1/25 to 6/30/26)
Registered Nurses II	1.00	1.00	1.00
Registered Nurses III	1.00	1.00	1.00
Radiation Therapist	4.44	4.44	4.44
Dosimetrist	2.00	2.00	2.00
Dosimetrist Supervisor	0.25	0.25	0.25
Chief Radiation Therapist	1.00	1.00	1.00
<b>Total</b>	<b>9.69</b>	<b>9.69</b>	<b>9.69</b>

Source: Section Q, Form H.

The assumptions and methodology used to project staffing are provided in Section Q, Form H and Assumptions. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3 Operating Costs. In Section H.2-3, pages 59-60, the applicant describes the methods used to be used to recruit or fill new positions and its proposed training and continuing education programs.



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

- The coverage model required to meet equipment utilization dictated staffing hours and resulting FTEs.
- DUHS relied on its experience at its other radiation oncology sites and projected volumes to establish staffing positions.
- Radiation oncology is the only service proposed for the facility at this time, therefore staffing for the facility and the radiation oncology service line are the same.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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.

C

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development.

### **Ancillary and Support Services**

In Section I.1, page 61, the applicant identifies the necessary ancillary and support services for the proposed services. On page 61, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following reasons:

- DUHS employed staff will provide all ancillary services except for laundry/housekeeping and physics support;
- Third parties will provide laundry/housekeeping support;
- Duke University School of Medicine, which is affiliated with DUHS, will provide physics support; and
- Private Diagnostic Clinic, PLLC, will provide professional services.

## **Coordination**

In Section I.2(b), page 62, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the facility's integration with the existing Duke University Health System and DUHS's specialty program affiliations with other hospitals throughout the region and DUHS's contributions to such community groups as Project Access.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development.

In Section K, pages 65-66, the applicant states that the project involves renovating 16,500 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 66, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following reasons:

- The applicant relied on the professional advice of experienced architects and project managers.
- The architect based the projected upfit and design cost on a review of the actual costs of similar projects.
- The project was designed to meet both the current and anticipated clinical needs and patient satisfaction.

On page 66, 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 reasons:

- The project is proposed to be developed in a MOB already under development.
- Duke Health's network design and accessibility is enhanced by the proposed development of a new freestanding facility in Wake County.
- Certain patients and payors will have lower costs based on the facility having non-hospital-based service rates.

- The proposed project will not result in increased projected reimbursement or charges.

On pages 66-67, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1(c)-1.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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;

NA

The proposed facility is not an existing facility. In Section L, page 71, the applicant states "*The existing facility* [from which the linear accelerator will be acquired] *has not provided services to any patients since 2018.*"

Therefore, Criterion (13a) is not applicable to this review.

- (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;

C

The facility is not an existing facility.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 71-72, the applicant states *“The proposed facility has no federal obligations regarding care, service, or access. Upon information and belief, the facility from which the linear accelerator will be acquired has no such obligations... For information purposes, Duke University Health System hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. Further, they comply with the provisions of section 501(r) of the Internal Revenue Code including provisions requiring a published financial assistance policy, limiting charges to self-pay patients, and periodically conducting a Community Health Needs Assessment.”*

In Section L, pages 73-74, the applicant states that during the last five years six patient civil rights access complaints have been filed against DUHS. The applicant reports that three have been closed without further investigation, one was voluntarily dismissed, and two complaints are pending

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

C

In Section L, page 74, 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.

<b>Payor Category</b>	<b>Radiation Oncology Services as Percent of Total</b>
Self-Pay	2.0%
Medicare*	49.0%
Medicaid*	4.0%
Insurance*	43.0%
TRICARE	1.0%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 74 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.0% of total services will be provided to self-pay patients, 49.0% to Medicare patients and 4.0% to Medicaid patients.

On page 75, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on an historic aggregate of DUHS patient population receiving similar treatments in the area including an anticipated shift of 3.8% from private insurance to Medicare based on input from DUHS Corporate Finance.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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 L, page 76, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

In Section M, page 77, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. 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 reasons:

- DUHS has existing, long-standing training agreements and relationships with health care professionals in the area and states that it will “*extend training opportunities to the new site as well.*”
- DUHS is affiliated with the Duke University School of Nursing and the Duke University School of Medicine and will provide training to health care professionals as students, residents and fellows.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

C

The applicant proposes to acquire, replace and relocate an existing linear accelerator, and to acquire a radiation oncology simulator, to create a new radiation oncology facility within a medical office building under development located at 3208 Green Level W Road, Cary.

In Chapter 17, page 400, the 2020 SMFP states, *“Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas... .”* DCC-Green Level is to be located in Wake County. In Table 17C-4, page 408 of the 2020 SMFP, Wake County is included in Linear Accelerator Service Area 20. Linear Accelerator Service Area 20 includes both Franklin County and Wake County. Thus, the service area for this linac consists of Wake and Franklin counties. Facilities may also serve residents of counties not included in their service area.

There are eleven linear accelerators (10 existing and 1 approved) in Linear Accelerator Service Area 20. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2017 – 9/30/2018, as summarized from Table 17C-1, page 403 of the 2020 SMFP.

	# LINEAR ACCELERATORS	COUNTY	TOTAL PROCEDURES*	AVERAGE ESTVs* PER LINEAR ACCELERATOR
Franklin County Cancer Center	1	Franklin	33	33
Duke Raleigh Hospital	4	Wake	19,929	4,982
Rex Hospital	4	Wake	22,514	5,628
UNC Hospitals Radiation Oncology-Holly Springs**	1	Wake	0	0
UNC REX Cancer Care of East Raleigh	1	Wake	5,370	5,370

\*The 2020 SMFP equates Equivalent Simple Treatment Visits (ESTVs) with procedures in Table 17C-1.

\*\*The 2014 SMFP contained a need determination for a linac in Linac Service Area 20 which, upon settlement, was approved for UNC Hospitals Radiation Oncology-Holly Springs. A Certificate of Need was issued effective April 29, 2016. The project has not yet been developed and a material compliance to change the site was approved on September 16, 2020. See Project ID #J-10318-14.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 79, the applicant states:

*“This project will benefit competition by creating a new outpatient/non-hospital based radiation oncology service in Apex. This new center will expand provider choice for patients, particularly those in Apex, Cary, and surrounding areas.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 79, the applicant states:

*“This project will create a new, non-hospital based radiation oncology site. The proposed structure typically has lower reimbursement than hospital facilities and is more cost effective for many payors and patients depending on their plan terms.”*



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

Regarding the impact of the proposal on quality, in Section N.2(b), page 79, the applicant states:

*“Patients will have access to high-quality state-of-the-art services for which Duke is renowned in a new location and with a different reimbursement structure. This will also improve coordination of care for patients seeking other services within the Duke Health system.”*

See also Sections C and O of the application and any exhibits, including Exhibit O.1.

Regarding the impact of the proposal on access by medically underserved groups, in Section C.11, page 33, the applicant states:

*“The services of Duke University Health System facilities, including the proposed radiation oncology facility, are open to all area and non-area residents. Imaging services are generally provided by physician referral. There is no discrimination on the basis of race, ethnicity, age, gender or disability. ... The facility will meet all ADA requirements...”*

See also Section C, L and N 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.
- 3) 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
- Written comments
- Responses to comments
- 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 based on all the reasons described 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.

C

In Section Q, Form A, the applicant identifies the radiation oncology facilities located in the service area owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in the service area.

In Section O, page 84, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in no DUHS facility. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all DUHS 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.

C

The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment. The specific criteria are discussed below.

**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;

- C- As demonstrated in Section C, page 36, and in Section Q- Utilization Projections and Form C Utilization, and shown in the table below, the applicant shows that each of DUHS’s four existing linear accelerators in Linear Accelerator Service Area 20 served more than 250 patients in the last full fiscal year, FY2020 (July 2019-June 2020). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

	<b>Duke Raleigh Hospital Campus</b>	<b>Duke Women’s Cancer Care Raleigh</b>	<b>Duke Cancer Center Cary Radiation Oncology</b>
# of Units	2	1	1
# of Patients	578	300	301
# of Patients per Machine	289	300	301

- (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

- C- In Section C, page 36, and in Section Q, the applicant projects 369 patients at the proposed linear accelerator at DCC-Green Level during the third year of operation. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (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.

- C- In Section Q, the applicant demonstrates that DUHS’s four existing linear accelerators in Linear Accelerator Service Area 20 are projected to be utilized at an annual rate of at least 250 patients per machine during the third year of operation, as shown in the table below. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

	<b># of Units</b>	<b>OY1 (FY24) # of pts.</b>	<b>OY2 (FY25) # of pts.</b>	<b>OY3 (FY26) # of pts.</b>	<b>FY 26 Patients/Machine</b>
Duke Raleigh Hospital Campus	2	644	643	642	321
Duke Women’s Cancer Care Raleigh	1	272	269	266	266
Duke Cancer Center Cary Radiation Oncology	1	314	294	276	276

Source: Section Q, page 95

- (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 use the linear accelerator exclusively for clinical research and teaching. Therefore, this Rule is not applicable.
  
- (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
  
- C- The applicant also proposed to acquire a CT-simulator to be used for treatment simulations for patients at the proposed DCC-Green Level location. In Section C, pages 37-39, the applicant provides the number of patients who are projected to receive treatment from the proposed CT-simulator classified by diagnosis, treatment procedure, and county of residence. The applicant projects performing 48, 98 and 150 simulator procedures in OY1, OY2 and OY3, respectively.
  - (2) the maximum number and type of procedures that the proposed equipment is capable of performing.
  
- C- In Section C, page 39, the applicant states that 20 procedures per week (average 4 per day) is the projected maximum number of procedures the equipment is capable of performing.
  
- (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 Q, the applicant documents its assumptions and provides data supporting the methodology used to determine its utilization projections. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.