

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 26, 2012
PROJECT ANALYST: Paula Quirin
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8770-12 / Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. / Acquire a replacement linear accelerator / Stanly County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Stanly Regional Medical Center, Inc. (SRMC) and Stanly Health Services, Inc. (SHS) propose to replace SRMC's existing linear accelerator. The applicants do not propose to develop beds, add services or acquire medical equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). Furthermore, there are no policies in the 2012 SMFP that are applicable to the review of this project. Therefore, this criterion 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- (2) Repealed effective July 1, 1987.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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Stanly Regional Medical Center, Inc. (SRMC) currently owns and operates one linear accelerator. SRMC’s existing Varian 2100CD linear accelerator is twelve years old. In this project, the applicants propose to replace the 12-year old Varian 2100CD linear accelerator with the Varian Trilogy or equivalent linear accelerator which is capable of more advanced treatment than the existing linear accelerator. Furthermore, the applicants state that the existing 12 -year old linear accelerator will be supported less by the manufacturer in the future and will experience greater difficulty in locating parts resulting in extended down time.

Population to be Served

In Section III.4.b, page 54, the applicants state:

“Historically 95 percent of SRMC’s Radiation Oncology Department patients have been residents of Stanly and Montgomery County. With no external forces causing a change, SRMC expects its patient origin in the future to follow historic patterns; hence, the project’s proposed primary service area includes Stanly County and Montgomery County.

....

Because two counties dominate SRMC’s Radiation Oncology Department patient origin, the applicants utilized Stanly County and Montgomery County data for forecasting total service area need.”

In Section III.4(b), page 70, the applicants provide current patient origin for external beam radiation therapy (EBRT) patients as illustrated by the table below.

| <i>County</i> | <i>Patients</i> | <i>Percent of Patients</i> |
|---------------------|-------------------|----------------------------|
| <i>Stanly</i> | <i>125</i> | <i>81.2%%</i> |
| <i>Montgomery</i> | <i>22</i> | <i>14.3%</i> |
| <i>Anson</i> | <i>1</i> | <i>0.6%</i> |
| <i>Cabarrus</i> | <i>3</i> | <i>1.9%</i> |
| <i>Cleveland</i> | <i>1</i> | <i>0.6%</i> |
| <i>Rowan</i> | <i>1</i> | <i>0.6%</i> |
| <i>Stokes</i> | <i>1</i> | <i>0.6%</i> |
| <i>Total</i> | <i>154</i> | <i>100.0%</i> |

Source: 2012 License Renewal application. Please see Exhibit 55.

In Section III.5(c), page 71, the applicants provide projected patient origin for linear accelerator services during the first two years of operation (FY 2014 and 2015).

| County | Project Year 1 FY 2012 | Project Year 2 FY 2013 |
|---------------|-----------------------------------|-----------------------------------|
| | Percent of Total | Percent of Total |
| Stanly | 80.9% | 81.1% |
| Montgomery | 14.6% | 14.3% |
| Other* | 4.5% | 4.5% |

| | | |
|-------|--------|--------|
| Total | 100.0% | 100.0% |
|-------|--------|--------|

*Other counties include Anson, Cabarrus, Cleveland, Rowan and Stokes

The applicants adequately identified the population to be served.

Demonstration of Need

In Section III.1, page 50, the applicants state the following factors support the need to replace the twelve year old linear accelerator:

- Age of the existing linear accelerator and shortage of parts.
- Clinical needs for the capabilities of the proposed equipment.
- Inability of existing linear accelerator to support Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiation Therapy (IGRT) procedures.
- The clinical need for capabilities including external beam radiation therapy (EBRT) by a growing and aging service population with an increasing prevalence and incidence of cancers.
- SRMC is the sole provider of cancer services in Stanly County and Montgomery County.

Projected Utilization

In Section IV, pages 79-80, the applicants provide the following table illustrating historical and projected utilization for radiation oncology department cases.

| | FY 2010 | FY 2011 | Interim Full FY FY 2012 | Interim Full FY FY 2013 | Project Year 1 FY 2014 | Project Year 2 FY 2015 | Project Year 3 FY 2016 |
|----------------------------|---------|---------|-------------------------|-------------------------|------------------------|------------------------|------------------------|
| # of Linear Accelerators | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| # Radiation Oncology Cases | 271 | 245 | 250 | 168 | 283 | 300 | 320 |
| EBRT Cases | 167 | 154 | 157 | 106 | 178 | 189 | 201 |

In Section III, pages 54- 64 and in Section IV.(d), pages 83-94, the applicants provide the methodology and related assumptions used to project utilization of the projecting utilization, which are described below.

Step 1: The applicants reviewed NCOSM population estimates and cancer incidence rates from North Carolina Central Cancer Registry [NCCCR] and North Carolina State Center for Health Statistics [NCSCHS] for Stanly and Montgomery counties for years FY 2008 – FY 2011, then projected cancer incidence rates for the two counties through FY 2016 assuming that the new cancer rate for each county will increase annually during FY2012 – FY 2016 at a rate equal to 50% of the historical CAGR, as shown in the tables below.

Historical and Projected New Cancer Case Incidence Rate for Stanly and Montgomery

| County | Historical CAGR FY 2008 – FY 2011 | Projected CAGR FY 2012 – FY 2016 [50% of Historical CAGR] |
|------------|--------------------------------------|---|
| Stanly | 3.81% | 1.91% |
| Montgomery | 5.16% | 2.58% |

Historical and Projected Cases for Stanly and Montgomery Counties

| | FY2008 | FY2009 | FY2010 | FY2011 | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Stanly Population | 59,906 | 60,205 | 60,714 | 61,102 | 61,556 | 61,971 | 62,408 | 62,836 | 63,267 |
| Cancer Rate/1,000 | 5.33 | 5.35 | 5.75 | 5.96 | 6.07 | 6.19 | 6.30 | 6.42 | 6.55 |
| Stanly Cancer Cases | 319 | 322 | 349 | 364 | 374 | 383 | 393 | 404 | 414 |
| Montgomery Population | 27,715 | 27,799 | 27,992 | 28,226 | 28,498 | 28,761 | 29,021 | 29,257 | 29,480 |
| Cancer Rate/1,000 | 5.07 | 5.65 | 5.68 | 5.92 | 6.07 | 6.23 | 6.39 | 6.55 | 6.72 |
| Montgomery Cancer Cases | 141 | 157 | 159 | 167 | 173 | 179 | 185 | 192 | 198 |
| Total Cases Stanly & Montgomery | 460 | 479 | 508 | 531 | 547 | 562 | 579 | 595 | 612 |

Step 2: To project total cancer cases treatable with EBRT on a linear accelerator, the applicants assumed that 50% of total cancer cases will receive EBRT on a linear accelerator and that 7.8% of new cancer cases will receive a second treatment.

Projected New Cancer Cases Treated with EBRT

| | FY2008 | FY2009 | FY2010 | FY2011 | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|-----------------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| 50% Stanly Cancer Cases | 160 | 161 | 175 | 182 | 187 | 192 | 197 | 202 | 207 |
| 7.8% Re-treat cases | 12 | 13 | 13 | 14 | 14 | 15 | 15 | 16 | 16 |
| Total Stanly | 172 | 174 | 188 | 196 | 201 | 207 | 212 | 218 | 223 |
| 50% Montgomery Cancer Cases | 71 | 79 | 80 | 84 | 86 | 90 | 93 | 96 | 99 |
| 7.8% Re-treat cases | 5 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 8 |
| Total Montgomery | 76 | 85 | 86 | 90 | 93 | 97 | 100 | 103 | 107 |
| TOTAL CASES | 248 | 258 | 274 | 286 | 295 | 303 | 312 | 321 | 330 |

Step 3: To project market share, the applicants reviewed SRMC’s market share of Stanly and Montgomery County EBRT cases based on actual EBRT cases reported in SRMC’s 2009 – 2012 Hospital License Renewal Applications. The applicants assumed that EBRT market share for FY2012 would remain unchanged from FY2011 and that EBRT market share for Stanly and Montgomery counties would increase annually by 3.5% starting in FY 2013.

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|--------|--------|--------|--------|--------|
|--|--------|--------|--------|--------|--------|

| | | | | | |
|--|------------|------------|------------|------------|------------|
| Stanley Market Share | 63.7% | 65.9% | 68.35 | 70.6% | 73.1% |
| % annual increase | 0.0% | 3.5% | 3.5% | 3.5% | 3.5% |
| Stanley EBRT Cases | 201 | 207 | 212 | 218 | 223 |
| SRMC EBRT Cases from Stanly* | 128 | 136 | 144 | 153 | 163 |
| Montgomery Market Share | 24.4% | 25.3% | 26.2% | 27.1% | 28.0% |
| % annual increase | 0.0% | 3.5% | 3.5% | 3.5% | 3.5% |
| Montgomery EBRT Cases | 93 | 97 | 100 | 103 | 107 |
| SRMC EBRT Cases from Montgomery | 22 | 24 | 26 | 27 | 29 |
| SRMC EBRT Cases from Stanly and Montgomery TOTAL | 150 | 160 | 170 | 180 | 192 |
| EBRT cases from Outside Stanly & Montgomery** | 7 | 8 | 8 | 9 | 9 |
| TOTAL SRMC EBRT Cases | 157 | 168 | 178 | 189 | 201 |

* SRMC EBRT Cases from Stanly is 63.7% of all Stanley EBRT cases [201X0.637=128].

** EBRT cases from outside Stanly & Montgomery is [TOTAL SRMC EBRT Cases – Total EBRT Cases from Stanly & Montgomery. Example: 157-150= 7].

Step 4: To project SRMC EBRT cases by quarter for years FY 2012 – FY 2016, the applicants initially divided projected annual EBRT cases by 4, and then adjusted cases for each quarter to allow for installation time and ramp-up, as shown in the table below. The applicants assume that the existing linear accelerator will be taken off line in the first quarter of FY2013.

Projected SRMC EBRT Cases by Quarter

| SRMC | FY2012 | | | | FY2013 | | | | FY2014 | | | | FY2015 | | | | FY2016 | | | |
|---------------------|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|
| | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 |
| | 39 | 39 | 40 | 40 | 41 | 41 | 42 | 43 | 44 | 44 | 45 | 45 | 46 | 47 | 48 | 48 | 49 | 50 | 51 | 51 |
| Annual Total | 157 | | | | 168 | | | | 178 | | | | 189 | | | | 201 | | | |
| Adjusted Quarter | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 |
| | 39 | 39 | 40 | 40 | 0 | 21 | 42 | 43 | 44 | 44 | 45 | 45 | 46 | 47 | 48 | 48 | 49 | 50 | 51 | 51 |
| Annual Total | 157 | | | | 168 | | | | 178 | | | | 189 | | | | 201 | | | |

Step 5: The applicants divided FY 2011 total radiation oncology department cases by the FY 2011 Total EBRT Cases to determine the ratio of total radiation oncology department cases to EBRT cases for FY2011. [245 Total Radiation Oncology Department Cases / 154 Total EBRT Cases = 1.59]. The applicants state that since SRMC provides services and bills for services of the Radiation Oncology Department that are not provided using the linear accelerator, (such as counseling, simulation and follow up exams), these service counts are included in the department’s income and therefore, need to be accounted for to produce complete financial proformas for the service. Thus, to project SRMC Radiation Oncology Department Cases, the applicants multiplied projected SRMC EBRT cases for each quarter times 1.59, the ratio of total radiation oncology department cases to EBRT cases, as shown in the table below. The applicants assume that their will be zero EBRT cases and or other type Radiation Oncology visits in the first quarter of FY2013.

| | FY2012 | | | | FY2013 | | | | FY2014 | | | | FY2015 | | | | FY2016 | | | |
|--------------------------------|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|------------|-----|-----|-----|
| SRMC | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 |
| Radiation EBRT Cases | 39 | 39 | 40 | 40 | 0 | 21 | 42 | 43 | 44 | 44 | 45 | 45 | 46 | 47 | 48 | 48 | 49 | 50 | 51 | 51 |
| Annual Total | 157 | | | | 106 | | | | 178 | | | | 189 | | | | 201 | | | |
| | FY2012 | | | | FY2013 | | | | FY2014 | | | | FY2015 | | | | FY2016 | | | |
| | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 | Q 1 | Q 2 | Q 3 | Q 4 |
| Radiation Oncology Dept cases* | 61 | 62 | 63 | 64 | 0 | 33 | 67 | 68 | 69 | 70 | 72 | 72 | 74 | 74 | 76 | 77 | 78 | 79 | 81 | 82 |
| Annual Total | 250 | | | | 168 | | | | 283 | | | | 300 | | | | 320 | | | |

Radiation EBRT cases x 1.59. Example: 157 annual total EBRT cases X 1.59 = 250 annual total Radiation Oncology Department cases.

Step 6: The applicants reviewed the License Renewal Applications for SRMC for FY2008 – FY2011 and determined the historical average procedures per EBRT case is 29.2 procedures per EBRT Case. To project the average procedures per EBRT case for years FY 2012 – FY 2016, the applicants multiplied the average procedures per EBRT case for years FY2008 – FY2011 [29.2] times the projected EBRT cases for years FY2012 – FY2016 from Step 3 as shown in the table below.

SRMC Projected EBRT Procedures FY2012-FY2016

| | FY 2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---------------------------------|---------|--------|--------|--------|--------|
| Projected EBRT Cases | 157 | 106 | 178 | 189 | 201 |
| Average Procedure per EBRT Case | 29.2 | 29.2 | 29.2 | 29.2 | 29.2 |
| | 4,585 | 3,087 | 5,196 | 5,501 | 5,868 |

Step 7 The applicants reviewed the License Renewal Applications to determine SRMC historical distribution of EBRT procedures for years FY2008 – FY2011 for five categories as shown in the table below.

SRMC' Historical Distribution of EBRT Procedures

| EBRT Category | FY2008 | FY2009 | FY2010 | FY2011 |
|-------------------------|---------------|---------------|---------------|---------------|
| Simple Treatment | 4.2% | 4.0% | 3.4% | 2.7% |
| Intermediate Treatment | 0.2% | 0.0% | 0.2% | 0.6% |
| Complex Treatment | 71.6% | 70.9% | 71.2% | 69.7% |
| IMRT Treatment | 0.0% | 0.0% | 0.0% | 0.0% |
| Additional Field Checks | 24.0% | 25.1% | 25.2% | 27.0% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% |

Step 8 The applicants project distribution of EBRT procedures for years FY2012 – FY2016 for five categories as shown in the table below. The applicants note that the new accelerator will be capable of IMRT procedures starting in FY2013 and assume a slow build up in IMRT procedures, with a projected 7.5% annual increase beginning in FY2013. The applicants assume that complex procedures will decrease proportionately to maintain a total of 100%.

SRMC's Projected EBRT Procedures Distribution FY2012-FY2016

| EBRT Category | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|-------------------------|---------------|---------------|---------------|---------------|---------------|
| Simple Treatment | 2.7% | 2.7% | 2.7% | 2.7% | 2.7% |
| Intermediate Treatment | 0.6% | 0.6% | 0.6% | 0.6% | 0.6% |
| Complex Treatment | 69.7% | 62.2% | 54.7% | 47.2% | 39.7% |
| IMRT Treatment | 0.0% | 7.5% | 15.0% | 22.5% | 30.0% |
| Additional Field Checks | 27.0% | 27.0% | 27.0% | 27.0% | 27.0% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Step 9 The applicants projected annual procedures for each category, by distributing the total projected annual EBRT procedures from Step 6 based on the projected percentage of each procedure category as shown above in Step 9. The table below illustrates projected procedures by EBRT category for FY2012 – FY2016.

SRMC Projected Procedures for FY2012-FY2016

| EBRT Category | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|-------------------------|---------------|---------------|---------------|---------------|---------------|
| Simple Treatment | 124 | 83 | 140 | 148 | 158 |
| Intermediate Treatment | 26 | 17 | 29 | 31 | 33 |
| Complex Treatment | 3,197 | 1,921 | 2,844 | 2,598 | 2,331 |
| IMRT Treatment | 0 | 232 | 779 | 1,238 | 1,760 |
| Additional Field Checks | 1,239 | 834 | 1,404 | 1,486 | 1,585 |
| Total | 4,585 | 3,087 | 5,196 | 5,501 | 5,868 |

Step 10 The applicants projected ESTVs for each EBRT category by multiplying the projected EBRT procedures from the previous step times the ESTV values as set forth in the 2012 SMFP. The applicants note that all procedures have a value of 1.0, except for field checks which have a value of 0.5.

SRMC Projected ESTVs for FY2012 – FY2016

| EBRT Category | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|-------------------------|---------------|---------------|---------------|---------------|---------------|
| Simple Treatment | 124 | 83 | 140 | 148 | 158 |
| Intermediate Treatment | 26 | 17 | 29 | 31 | 33 |
| Complex Treatment | 3,197 | 1,921 | 2,844 | 2,598 | 2,331 |
| IMRT Treatment | 0 | 232 | 779 | 1,238 | 1,760 |
| Additional Field Checks | 619 | 417 | 702 | 743 | 793 |
| Total | 3,965 | 2,670 | 4,494 | 4,758 | 5,076 |

Projected utilization is based on reasonable and supported assumptions.

In summary, the applicants adequately identified the population to be served and adequately demonstrated the need to replace the existing linear accelerator. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.3, pages 66-68, the applicants discuss the alternatives that were considered prior to submission of this application.

“Upgrade Existing Linear Accelerator

In order to upgrade the existing Varian 2100CD linear accelerator to perform IMRT, SRMC would incur over one million dollars in additional equipment costs for new multi-leaf collimators, on-board imaging, portal imaging, and treatment planning software, among other items. Even then, the IMRT that the Varian 2100CD linear accelerator would provide would be less effective for certain head, neck, and prostate cancers than the IMRT that could be provided on the Varian Trilogy, or equivalent, linear accelerator. Additionally, Varian is phasing out the 2100CD linear accelerator and is becoming increasingly difficult to obtain parts for machine.

...

Build New Vault

Although building a new vault would have eliminated the three months when SRMC will not have linear accelerator radiation therapy available, this alternative was rejected for cost and disruptions reasons.

...

Joint Venture

There is no need to include this project in a joint venture. SRMC can afford the project and has the space and the staff.”...

Furthermore, the application is conforming to all other statutory review criteria. See Criteria (3), (5), (6), (7), (8), (13), (14), (18a), and (20). Therefore, the applicant adequately demonstrates that its proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall materially comply with all representations made in the certificate of need application and supplemental documents. In those instances where representations conflict, Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall materially comply with the last-made representation.**
 - 2. Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall acquire no more than one linear accelerator to replace the existing Varian 2100CD linear accelerator for a total of no more than one linear accelerator upon project completion.**
 - 3. Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall dispose of the Varian 2100CD linear accelerator by removing it from North Carolina.**
 - 4. Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application that would otherwise require a certificate of need.**
 - 5. Stanly Regional Medical Center, Inc. and Stanly Health Services, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1-2, pages 128-129, the applicants project the total capital cost will be \$2,520,093, which includes \$202,099 for construction costs, \$1,984,767 for fixed equipment, \$122,500 for consultant fees and \$210,727 for contingency.

In Section IX, page 134, the applicants state there will be no start-up or initial operating expenses for this project. In Section VIII.3, page 130, the applicants state that the total capital cost will be funded with the accumulated reserves of SRMC. Exhibit 37 contains a letter from the Chief Financial Officer of SRMC which states,

“Stanly Regional Medical Center hereby commits to provide all funds necessary to successfully develop and operate the proposed project. Funds necessary for any capital expenditure or working capital will be supplied from accumulated reserves.”

Exhibit 44 contains the audited financial statements for SRMC for years ending September 30, 2009 and 2010. According to the financial statements, as of September 30, 2010, SRMC had \$17,814,572 in cash and cash equivalents, \$41,943,959 in total current assets, \$123,431,907 in total assets and \$75,635,468 in total net assets (total assets less total liabilities).

The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

In Form B of the proformas, page 151, the applicants project that revenues will exceed expenses for the entire facility in each of the first three years of operation following project completion. In Form C, page 157, the applicants project that revenues will exceed expenses for the service component in each of the first three years of operation following project completion. In the proformas, pages 154, the applicants provide the assumptions used to project revenues and expenses. The assumptions used by the applicants in preparation of the pro formas are reasonable, including projected utilization, costs and charges. Therefore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicants adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities, for the following reasons: The applicants propose to replace the existing twelve year old linear accelerator currently in use at SRMC. The SRMC linear accelerator is one of only 3 in North Carolina that cannot perform IMRT procedures which is a standard course of radiation therapy treatment. Linear Accelerator Service Area #9 which is comprised of Stanly County and Cabarrus County contains a total of three linear accelerators. One linear accelerator is in Stanly County at SRMC and two additional linear accelerators are located in Cabarrus County at CMC-Northeast. The Stanly County linear accelerator and the two linear accelerators in Cabarrus County averaged 4,290 and 5,905 procedures respectively, in 2010, compared with a state-wide average of 4,884 procedures in 2010. SRMC projects performing 5,868 procedures in 2016. SRMC is 26.4 miles from CMC-Northeast, an estimated driving time of 39 minutes. The applicants do not propose to develop any new services or acquire any additional equipment. The application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, pages 116-117, the applicants provide the current and proposed staffing for SRMC's Radiation Oncology Department, as shown in the following table. The applicants state that no additional staff will be added as the result of the acquisition of a replacement linear accelerator.

Current and Proposed Staffing for SRMC's Radiation Oncology Department

| | Current # FTEs | Proposed # FTEs (Year Two) |
|---------------------|-----------------------|---------------------------------------|
| Technologists | 2.0 | 2.0 |
| Lead Technologist | 0.0 | 1.0* |
| Department Director | 1.0 | 1.0 |
| Clerical | 1.0 | 1.0 |
| Dosimetrist | 1.0 | 1.0 |
| Tumor Register | 1.0 | 1.0 |
| Physicist | 0.4 | 0.4 |
| RNs | 1.0 | 1.0 |
| Social Workers | 0.5 | 0.5 |
| Total | 7.9 | 8.9* |

*Applicants states that lead technologist is being hired as part of ACR accreditation requirements, not as result of the proposed project.

In Section VII, page 118, the applicants state that it is expected that a lead technologist will be hired in FY 2012 as part of the ACR accreditation requirements. SRMC expects to encounter no difficulty in filling the lead technologist position and will continue to utilize existing recruitment strategies to fill vacancies. Exhibit 35 contains a letter from Medical Director for Radiation Oncology Services at SRMC which states she has agreed to continue to serve as Medical Director. The applicants demonstrate the availability of adequate health manpower for the continued provision of radiation therapy services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V, pages 95-97, the applicants describe the existing relationships the hospital has with other health care providers and facilities. The applicants state that as a member of CHS, SRMC can transfer patients to any CHS facility. In Section II, pages 37-38, the applicants list the ancillary and support services that are currently available to the Radiation Oncology Department. The applicants adequately demonstrate that the necessary ancillary and support services are and will continue to be available and that the proposed services will be coordinated with the existing health care system. Therefore the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section VI.13, page 113, the applicants provide payor mix information for Radiation Oncology Department services for FY2011, as illustrated in the table below.

| Payor | % of Total |
|--|------------|
| Medicare/Medicare Managed Care | 58.0% |
| Commercial Insurance (includes Managed Care) | 26.5% |
| Medicaid | 7.3% |
| Other (Government Payors)) | 6.1% |
| Self Pay/Indigent/Charity | 2.0% |
| Total | 100.00% |

In Section VI., pages 107 and 108, the applicants state:

“SRMC’s policies and procedures make it clear that patients are to be admitted, transferred and discharged as directed by their physician based on their medical needs and SRMC’s ability to meet those needs and SRMC’s ability to provide those needs, not on the patient’s ability to pay for services.”

SRMC will provide medically necessary healthcare to all persons without regard to the person’s ability to pay. Please see Exhibit 38 for a copy of SRMC’s Financial Assistance Policy.”

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2009. The data in the table was obtained on April 1, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

| | Total # of Medicaid Eligibles as % of Total Population | Total # of Medicaid Eligibles Age 21 and older as % of Total Population | % Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) |
|---------------|--|---|--|
| Stanly County | 17.0% | 7.6% | 18.3% |
| Montgomery | 23.0% | 9.7% | 23.6% |
| Statewide | 17.0% | 6.5% | 19.7% |

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Stanley Regional Medical Center.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons

eligible for dental services with the number actually receiving services. The statewide percentage was 45.9% for those age 20 and younger and 30.6% for those 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of April 1, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicants demonstrate that medically underserved populations currently have adequate access to linear accelerator services provided at SRMC. The application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.4, page 107, the applicants state *"SRMC is EMTALA compliant and will provide medically necessary healthcare services to all persons without regard to the person's ability to pay."*

In Section VI.10, page 112 the applicants state that there have been no civil rights access complaints filed against SRMC or SHS in the last five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.15, page 115, the applicants provide the projected payor mix for the Radiation Oncology Department services in the second operating year, as shown in the following table.

| Payor | % of Total |
|-------|------------|
|-------|------------|

| | |
|--|---------|
| Medicare/Medicare Managed Care | 58.0% |
| Commercial Insurance (includes Managed Care) | 26.5% |
| Medicaid | 7.3% |
| Other (Government Payors)) | 6.1% |
| Self Pay/Indigent/Charity | 2.0% |
| Total | 100.00% |

In Section VI.13, page 113, the applicants show that they based projected payor mix on historical payor mix for the radiation Oncology Department during the last full fiscal year. The applicants demonstrate that medically underserved populations will have adequate access to linear accelerator services at SRMC

Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, page 110, the applicants describe the means by which patients will have access to the proposed linear accelerator services. The applicant states that referrals typically come from a patient's specialty care, surgeon or medical oncologist among others, that any licensed physician may refer patients, and that patients may be admitted after presenting at the emergency department. The applicants adequately demonstrate that it will offer a range of means of access to the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1, page 95, the applicants state that it has existing relationships with various professional training programs including: Stanly Community College, Montgomery Community College, South Piedmont Community College, Cabarrus College of Health Sciences, Pfeiffer University, Wingate University, UNC-Charlotte/Carolinas Medical Center Nurse Anesthesia Program and Central Piedmont Community College. The applicants adequately demonstrate that they will continue to accommodate the clinical needs of health professional training programs in the area. Therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.

- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

In Section V.7, page 101 the applicants discuss how the project will promote cost-effectiveness, quality and access to the proposed services. The applicants state the following in regard to cost effectiveness of the proposed project:

- Financing the proposed project with existing cash reserves avoids interest payments on borrowed funds.
- Locating the proposed replacement linear accelerator within the existing vault will reduce costs compared to installing a new vault.
- Installation of a new chiller will decrease utility costs by conserving water and energy.
- Treating patients on technologically advanced equipment will result in cost savings to the patients and the hospital.

In regard to how the proposed project will promote quality, the applicants state:

- The new capabilities of the proposed linear accelerator include cone-beam CT, IMRT and IGRT and note that SRMC is one of only three oncology treatment centers out of a total of 72 within the State that cannot offer IMRT services.

In regard to how the proposed project will promote access to the proposed services, the applicants state:

- The proposed replacement linear accelerator will enhance patient access to advanced technologies including IMRT, IGRT and cone-beam CT procedures and reduce the need to travel substantial distances for treatment.
- SRMC's policies ensure that all persons including medically indigent and underserved persons are provided medically necessary care, regardless of their ability to pay.

Also, in Section VI.15, page 115, the applicants indicate that in year two, the payor mix for oncology department patients will reflect historical payor mix and will be 58% Medicare, 7.3% Medicaid and 2% self pay/charity care.

Therefore, the application is conforming to this criterion.

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

C

SRMC is a licensed, acute care hospital and is accredited by the Joint Commission. SRMC plans to be accredited as an American College of Surgeons' Commission on Care Community Cancer Program (ASC CoC) by FY2013. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

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

NA

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