ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: June 28, 2013

PROJECT ANALYST: Tanya S. Rupp
CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: N-10081-13 / Southeastern Regional Medical Center, Inc. / Develop a second cardiac catheterization laboratory / Robeson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The 2013 State Medical Facilities Plan (SMFP) identifies an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in the Robeson County cardiac catheterization service area, pursuant to a petition filed by Southeast Regional Medical Center (**"SRMC"**). SRMC currently operates one unit of cardiac catheterization equipment and one unit of vascular catheterization equipment in its cardiac catheterization laboratory on the hospital campus. In this application, SRMC proposes to upgrade its existing vascular equipment in order to perform additional cardiac catheterization procedures. SRMC is an acute care hospital licensed for 452 beds, including acute care, inpatient hospice, long-term care and psychiatric. The hospital is located in Lumberton, in Robeson County.

SRMC's proposal to upgrade existing vascular equipment in order to perform cardiac catheterization procedures at the hospital will result in the development of one additional unit of fixed cardiac catheterization equipment in the Robeson County Service Area, which is conforming to the adjusted need determination in the 2013 SMFP. In addition, Policy GEN-3, on pages 42 – 43 of the 2013 SMFP is applicable to this review. This Policy states:

> "*A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical*

Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

In Section III.2, page 65, in response to the requirements of Policy GEN-3, the applicant states:

"Not applicable. The proposed project does not involve a new institutional health service. For information related to how an additional cath lab will improve access, support safety and quality, while maximizing value, please see the response to Section V.7."

Although the applicant is not proposing to acquire any new equipment and is upgrading an existing vascular catheterization unit to enable it to perform cardiac catheterization procedures, the end result will be that one additional cardiac catheterization unit will be added to the inventory in Robeson County. Furthermore, this application is being submitted in response to a need determination in the 2013 SMFP for which the applicant successfully petitioned the SHCC in 2012. Therefore, Policy GEN-3 does apply to this review.

Promote Safety and Quality

In Section V.7, page 81, the applicant states:

"SRMC believes the proposed project will foster competition by promoting quality, safety, access, and value. First, quality and safety are clearly enhanced through the development of additional cardiac catheterization capacity, as described previously. Without sufficient capacity, particularly for a service often provided on an emergent basis, like interventional cardiac catheterization, quality can suffer and patient care may not be optimal."

In addition, in Exhibit 6, pages 248 – 253, the applicant provides a copy of the SRMC Performance Improvement Plan, which includes policies that describe safety measures undertaken by the hospital to ensure patient safety. This plan states, in part:

"Southeastern Regional Medical Center (SRMC) is committed to providing a safe environment for our patients, visitors, practitioners, and staff. To that end, we place the highest priority on activities involving the improvement in patient safety and reduction in risk to our patients, visitors, volunteers, and staff including medical staff….

…

The Organization's Patient Safety and Performance Improvement (PSPI) Committee is responsible for review of The Joint Commission's (TJC) National Patient Safety Goals, Sentinel Event Alerts, and the routine coordination and management of patient safety improvement projects and initiatives. The PSPI Committee is composed of senior leaders; directors of performance improvement and risk management; the safety officer; clinical leaders of patient care services, medical leadership and leaders of ancillary and support departments."

The applicant adequately demonstrates that the proposed project will promote safety and quality in the delivery of health care services.

Promote Equitable Access

In Section V.7, page 81, the applicant states:

"Access will be improved through the allocation of a second catheterization lab. As discussed in Section III.1(a), Robeson County is a large geographic area surrounded by several counties without access to interventional catheterization in their county [sic]. *Having an additional catheterization lab in the county will provide geographic access to a region beyond Robeson. Moreover, given the need for emergent, life-saving catheterization procedures particularly in the case of patients presenting with STEMI, a second catheterization lab expands temporal access to these patients. Robeson County is also unique in its demography; the large percentage of minorities, who are also often medically underserved, will benefit from the expanded catheterization capacity in the county."*

In addition, in Section VI.2, page 83, the applicant states:

"…SRMC provides access to care for all patients regardless of age, race, national or ethnic origin, disability, gender, sexual orientation, income, or immediate ability to pay. Patients are admitted and services are rendered in compliance with:

1. *Title VI of Civil Rights Act of 1963*
2. *Section 504 of Rehabilitation Act of 1973*
3. *The Age Discrimination Act of 1975*
4. *Americans with Disabilities Act"*

The applicant adequately demonstrates that the proposal will promote equitable access to cardiac catheterization services in Robeson County. Furthermore, the applicant adequately demonstrates the availability of capacity to provide these services.

Healthcare Value

In Section V.7, page 81, the applicant states:

> *"The proposed project will also promote value. A second catheterization lab will ensure that patients – both inpatients and outpatients – receive care in a timely manner, enabling patients to be discharged within an appropriate timeframe, which will prevent unnecessary expenditures by the patients and payors. Furthermore, the project will not incur any capital costs, making it a cost effective way to increase access to this special service."*

The applicant adequately demonstrates that the proposed project will maximize healthcare value for resources expended.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 43 of the 2013 SMFP is not applicable to this review, as there is no capital cost associated with this project.-

In summary, the application is conforming to the adjusted need determination in the 2013 SMFP for one unit of shared fixed cardiac catheterization equipment in the Robeson County Service Area. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

SRMC proposes to upgrade existing vascular catheterization equipment in order to perform cardiac catheterization procedures. Currently, SRMC has vascular catheterization equipment and one unit of fixed cardiac catheterization equipment in the cardiac catheterization laboratory. SRMC is the only hospital in Robeson County.

In August of 2012, SRMC submitted a petition to the North Carolina State Health Coordinating Council (SHHC) requesting an adjusted need determination in Robeson County for one additional unit of fixed cardiac catheterization equipment. In Exhibit 2, the applicant provides a copy of the petition which describes why Robeson County, a single-provider county, needs additional cardiac catheterization capacity, even though the traditional methodology utilized in the SMFP does not result in a need determination. The applicant proposes to upgrade existing vascular catheterization equipment rather than to acquire new catheterization equipment. Therefore, following this proposal, the applicant will have two units of fixed cardiac catheterization equipment in its inventory, although no new equipment will be acquired. In Section I, pages 13 - 14, the applicant states:

> *"Diagnostic cardiac catheterization services were first offered at SRMC in 1991. In 2006, the Southeastern Heart Center, which is located on the campus of SRMC and*

managed by Duke Medicine, was dedicated. SRMC, Duke University Hospital, and Duke Cardiology of Lumberton have been providing open heart surgery and interventional cardiac catheterization procedures at the Heart Center since its dedication in 2006. The Heart Center includes two cardiothoracic operating rooms, a six-bed cardiovascular intensive care unit, echocardiography, stress testing, outpatient cardiac rehabilitation, and a cardiac catheterization laboratory."

Population to be Served

In Section III.5, page 68, the applicant projects that the population to be served with the additional unit of cardiac catheterization equipment will be identical to the historical service population, which is primarily Robeson County, and secondarily Bladen and Columbus Counties. See the table below, which illustrates historical and projected patient origin for all acute care services and for cardiac catheterization services specifically, at SRMC, as reported by the applicant in Section III.4, page 67:

SRMC Acute Care Inpatient Services, FY 2012

COUNTY	% PATIENTS
Robeson	88.3%
Bladen	6.1%
Columbus	2.2%
Other*	3.3%
Total	10.0%

*On page 67, the applicant states *other* includes Beaufort, Brunswick, Cabarrus, Chatham, Cumberland, Davidson, Duplin, Forsyth, Gaston, Greene, Guilford, Harnett, Haywood, Hoke, Jackson, Johnston, Jones, Lee, Lenoir, Lincoln, Mecklenburg, Montgomery, Moore, New Hanover, Onslow, Orange, Pender, Pitt, Randolph, Richmond, Rowan, Sampson, Scotland, Surry, Vance, Wake, Washington, Wayne, and Yadkin Counties in North Carolina and other states.

SRMC Cardiac Catheterization Services, FY 2012

COUNTY	% PATIENTS
Robeson	82.1%
Bladen	9.2%
Columbus	4.2%
Other*	4.4%
Total	10.0%

*On page 67, the applicant states *other* includes Brunswick, Cumberland, Hoke, Lenoir, Moore, New Hanover, Northampton, Pender, Richmond, Sampson, Scotland and Wake Counties in North Carolina and other states.

The applicant adequately identifies the population proposed to be served.

Demonstration of Need

In Section III.1, pages 46 – 47, the applicant describes the historical context within which it initiated its appeal for an adjusted need determination in the 2013 SMFP. On page 46, the applicant states that, in 2001 SRMC and Duke University Health System together petitioned the North Carolina State Health Coordinating Council (SHHC) for an adjusted need determination in Robeson County for an open heart surgery program at SRMC. On pages 46 – 47, the applicant states:

> *"SRMC's affiliation with Duke Medicine focused not only on the implementation of an open heart program, but also an expansion of the existing cardiovascular medicine program to include twenty-four hour, seven-day-a-week on-site cardiology services and on-site coronary interventional procedures. By offering these services through a joint program with Duke, SRMC is able to provide care locally that would otherwise have caused residents to travel long distances for care. The program has been a tremendous success. Prior to 2006, on average over 50 cardiovascular patients a month were transferred from SRMC to a higher level of care. Today, the number of cardiovascular patients requiring transfer for a higher level of care is less than 2 patients per month. …*
>
> *In August 2012, SRMC submitted a second special need petition "to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County in the 2013 State Medical Facilities Plan." In the petition discussion, SRMC explained to the SHCC why, in the case of SRMC's cardiac catheterization program, the standard methodology would not be reasonable for projecting need for a second cardiac catheterization unit in Robeson County and why patient care would be compromised if a second catheterization laboratory was not made available. The SHCC agreed …. Therefore, based on the adjusted need determination for an additional unit of cardiac catheterization equipment in Robeson County, SRMC submits an application proposing to operate one additional cardiac catheterization laboratory."*

In Section III.1, pages 47 - 64, the applicant presents the assumptions and methodology used to support its proposal for additional cardiac catheterization services at SRMC. These include patient safety, quality and access; value and operational needs; demographic and socioeconomic factors; and utilization volumes and capacity constraints. Each of the factors is discussed below.

Patient Safety, Quality and Access

On pages 48 – 49, the applicant discusses the need that is internal to SRMC for a second cardiac catheterization unit in order to maintain patient safety and quality of care that are paramount to SRMC and Duke Cardiology of Lumberton. On page 49, the applicant states:

> *"*[SRMC and Duke Cardiology's efforts were recognized by] *HealthGrades as #2 for Cardiology Services and #3 for overall Cardiac Services in North Carolina in 2013. In addition, SRMC was ranked in the top 10 percent nationally for both cardiology and cardiac services in 2012. SRMC's goal is to continue its top performance in*

these services; however, as the only open heart provider in the state with a single catheterization lab, SRMC faces greater constraints in its ability to treat patients on a timely basis. Cardiac catheterization, particularly for patients presenting with ST-elevated myocardial infarction, or STEMI, is provided on an emergency basis to save patients' lives. When the single lab is being used for another case, either diagnostic or interventional, and a patient presents with a need for emergency intervention, the lack of a second lab can lengthen the time until that care is available. This scenario has already occurred several times. In those cases, time to intervention was delayed by as much 16 to 23 minutes, which represents as much as 25 percent of the optimal 90 minute door-to-balloon window. Each time, the cardiologist and cath team have dealt with the issue in an effective, evidence-based manner, but the potential exists for a suboptimal procedure for the patient on the table as the team completes the case expeditiously, and it clearly delays treatment of the STEMI patient. With two cath labs, such a scenario would be much less likely to occur."

Additionally, on pages 49 – 50, the applicant states that the American College of Cardiology has established a program called *Door to Balloon* campaign that emphasizes that STEMI patients need to receive interventional treatment within 90 minutes of arrival at the hospital. On page 50, the applicant states:

"When SRMC's only cath lab is being utilized during this crucial time, it is more challenging to meet the lifesaving guideline. Moreover, the geographic size of Robeson County - and thus longer transport time to SRMC, the only provider of interventional catheterization - makes minimizing time once the patient arrives at SRMC even more critical than in smaller geographic areas. In addition, Robeson County borders several counties that do not have interventional catheterization programs, including Columbus, Bladen, Scotland, and Hoke in North Carolina and Dillon and Marlboro in South Carolina. While SRMC is not the closest interventional provider for patients in the entirety of those counties, it is certainly the closest for many patients in those counties."

Therefore, the applicant states, a second cardiac catheterization unit is critical to ensure patient safety, improve access to cardiac catheterization services in Robeson County, and potentially reduce patient mortality.

Value/Operational Concerns

In Section III.1, pages 50 – 51, the applicant describes the operational issues within SRMC that led to the need for a second cardiac catheterization unit. With only one unit, it is difficult to treat non-emergent patients when emergent patients present for cardiac evaluation. Thus, length of stay for non-emergent patients is often longer than is optimal, thereby decreasing patient satisfaction and quality of care. On page 50, the applicant states:

"In the wake of these capacity constraints, SRMC has begun to limit the number of outpatient catheterization patients it will allow on each day's schedule as an attempt to limit inpatient delays. However, this is not a satisfactory long-term solution for

> *outpatients either, as they may be forced to wait longer or be held in the Emergency Department pending the availability of the catheterization lab. While emergency cases will always have priority, a second lab will minimize these issues."*

In addition, the applicant states the quality of care that SRMC and Duke Cardiology have historically provided could potentially be compromised and thus patient safety risked if a second cardiac catheterization lab is not developed.

Demographic/Socioeconomic Factors

In Section III.1, pages 51 – 57, the applicant describes the demographic and socioeconomic factors that are unique to Robeson County and that impact the need for additional cardiac catheterization services. On page 52, the applicant states:

> *"The initiation of the open heart/interventional catheterization program at SRMC has contributed to lower death rates. At the time the SHCC first granted a special need adjustment that allowed SRMC to develop its open heart program, Robeson County's age-adjusted heart disease death rate was 358.3, the state's 7th highest death rate from the disease. Based on the latest data, Robeson County's death rate from heart disease has decreased significantly to 226.7, and it has dropped to being the 15th highest death rate from heart disease among North Carolina counties. Thus, improvements have been made. However, Robeson County continues to experience heart disease death rates that are significantly above those of other counties with open heart and interventional catheterization programs, as well as the North Carolina rate overall."*

Additionally, the applicant states on page 52 that in North Carolina, most of the counties that have open heart surgery and interventional cardiac catheterization capability have a correspondingly lower heart disease mortality rate. However, Robeson County still has higher mortality rates from heart disease compared to other counties with open heart and interventional cardiac catheterization providers. Furthermore, Robeson County's mortality rate for persons with heart disease is higher than the mortality rate for persons with heart disease in the state as a whole. On page 53, the applicant states:

> *"Despite availability of open heart surgery and interventional catheterization at SRMC, as well as the hospital's ongoing efforts to improve access via heart disease screening programs, community education and outreach, and reduced time to clinic appointments, the county clearly continues to need improved access to cardiology services."*

Thus, with SRMC being the only hospital in Robeson County, and with the death rate from heart disease high, the applicant states it needs an additional unit of cardiac catheterization equipment.

Minority Population

In Section III.1, pages 54 – 57, the applicant discusses the impact of demographics on the incidence of heart disease in Robeson County. On page 54, the applicant states:

> *"A significant contributing factor to the higher heart disease death rates is the high minority population, both Native and African American, residing in Robeson County. According to data from the North Carolina Office of Budget and Management (OSBM), Robeson County has a much higher percentage of minority residents than the state as a whole…."*

The applicant states further that the Native American population in Robeson County is higher than in the state as a whole. Citing information obtained from the American Heart Association, the applicant states that the risk of cardiovascular disease is higher for the American Indian, Mexican American, Hawaiian and Asian American populations. See the table below that illustrates the incidence of heart disease in Robeson County and in North Carolina in different demographic groups, as reported by the applicant on page 54:

RACE	ROBESON COUNTY %OF TOTAL	NORTH CAROLINA % OF TOTAL
White	32.5%	71.9%
Black or African American	24.6%	21.9%
American Indian and Alaska Native	39.5%	1.6%
Asian	1.0%	2.5%
Other	2.4%	2.0%

*Source: application page 54

Furthermore, the applicant cites statistics from the Centers for Disease Control (CDC) which indicate that 20% more American Indians and Alaska Natives die from heart disease at a young age than the rest of the population, and that heart disease is the leading cause of death among that same group. In Section III, page 55, the applicant states:

> "[The] *disparity in morbidity and mortality from heart disease affects Robeson County disproportionately, as over one-third (33.9 percent) of the total number of American Indians in North Carolina reside in Robeson County alone, and when the contiguous counties are considered (Hoke, Cumberland, Scotland, Bladen and Columbus), more than one-half of the state's American Indian population resides in the area. This population anomaly has been a fact in North Carolina for many years and is not expected to change in the foreseeable future. Robeson County is projected to continue being the county in the state with the highest proportion of historically 'minority' groups, specifically American Indians and African Americans."*

Therefore, considering the large population of American Indians and other minority population groups in Robeson County and the increased incidence of heart disease, the applicant states a second cardiac catheterization unit is needed at SRMC.

Utilization Volumes and Capacity Constraints

In Section III, pages 57 – 58. the applicant discusses the impact of SRMC's association with Duke Cardiology of Lumberton on the growth in the number of cardiac catheterization procedures performed at SRMC. The applicant states that, initially, high risk cardiology patients who presented to SRMC were referred to Duke University Hospital; however, current high risk cardiology patients are treated as effectively at SRMC. On page 57, the applicant states:

> *"Since 2006, the number of cardiologists with the practice has grown from just two in 2006 - one invasive and one interventional provided on a rotating basis - to six: one general cardiologist, one invasive cardiologist, and four interventional cardiologists. The most recent interventional cardiologist joined the practice in July 2012. Not only has this newly added interventionalist increased the capacity of Duke Cardiology of Lumberton to serve additional patients, but* ***this physician in particular is serving a portion of Robeson County that has historically been underserved****. Because of the physician's roots in that community, it is expected that he will garner a much more significant portion of those patients with a shared cultural heritage.* [emphasis in original]*."*

The applicant also states that Duke is actively recruiting a cardiothoracic surgeon. Therefore, because of the potential improvement in cardiac catheterization quality and resultant patient safety; the operational concerns of SRMC; and the unique demographic composition of Robeson County, the applicant states an additional cardiac catheterization unit will benefit its patients.

Utilization Projections

Historical Utilization

In Section III.1(b), pages 59 – 64, and Section IV.1, page 74, the applicant provides historical utilization for cardiac catheterization services at SRMC. On page 60, the applicant states:

> *"… since FY 2009, interventional procedures have increased significantly, growing at a CAGR of 24.0 percent in the last three years and at an even higher growth rate in the last two years, at 48.1 percent. Although diagnostic procedures declined in FY 2010, the growth rate from FY 2010 to FY 2012 clearly shows a growing demand for diagnostic procedures at SRMC as well. Overall, cardiac catheterization procedures at SRMC grew by a CAGR of 6.0 percent from FY 2009 to FY 2012 and 24.9 percent from FY 2010 to FY 2012.*
>
> *It should be noted that, as shown in SRMC's 2012 HLRA, total cardiac catheterization procedures at SRMC equaled 1,208 in FY 2011. For purposes of calculating diagnostic-equivalent procedures, 101 electrophysiology procedures that were included on the HLRA were excluded from the FY 2011 data for this application."*

On pages 59 – 60, the applicant provides two tables to illustrate the number of actual procedures performed at SRMC and the number of weighted procedures, calculated according to 10A NCAC 14C .1601(2). See the following table, prepared by the analyst, which combines the data provided by the applicant in two tables:

Fiscal Year	# Adult diagnostic Procedures	Weighting Factor per Rule	# Weighted Adult Diagnostic Procedures	# Therapeutic Procedures	Weighting Factor per Rule	# of Weighted Therapeutic Procedures	Total Weighted Procedures	% Utilization (% of Capacity)
2009	813	X 1.00	813	214	X 1.75	375	1,188	79.2%
2010	598		598	186		326	924	61.6%
2011	766		766	341		597	1,363	90.9%
2012	816		816	408		714	1,530	102.0%
CAGR*	0.1%		0.1%	24.0%		24.0%	8.8%	

*Compound Annual Growth Rate for all years

For two of the last four fiscal years, the utilization of the existing cardiac catheterization equipment has been above 80% (FY 2011 and FY 2012). The utilization standard for existing cardiac catheterization equipment promulgated in 10A NCAC 14C .1603(c), which must be met before additional cardiac catheterization capacity can be added, is 80%. Therefore, the applicant maintains that the last two years' utilization alone warrants additional cardiac catheterization capacity at SRMC.

In addition, in supplemental information, the applicant provided the historical utilization of the existing vascular equipment, which the applicant proposes to upgrade to perform cardiac catheterization procedures as well as continued vascular catheterization procedures. See the following table, as provided by the applicant:

Fiscal Year	# Procedures
2009	97
2010	98
2011	84
2012	126
CAGR	9.1%

The applicant demonstrates that the number of procedures performed on the existing vascular catheterization equipment has grown by a compound annual growth rate of 9.1% over the last three fiscal years.

Projected Utilization

In Section III.1, pages 61 – 63, in Section IV.1, pages 74 – 75, and in supplemental information provided by the applicant, SRMC projects utilization on the two units of cardiac catheterization equipment for both cardiac and vascular catheterization procedures. On page 61, the applicant states:

"Diagnostic cardiac catheterization procedures were conservatively projected forward using the historical FY 2009 - FY 2012 CAGR of 0.1 percent while the interventional cardiac catheterization procedures were projected using one-half of the FY 2009 - FY 2012 CAGR, which is 12.0 percent. SRMC believes this assumption is very conservative, particularly given that the actual CAGRs of 16.8 percent and 48.1 percent in diagnostic and interventional catheterization procedures, respectively, from FY 2010 to FY 2012, far exceed the growth rates utilized for the projections."

Also on page 61, the applicant states it projects the project to be operational on October 1, 2013; therefore, the first three project years are the same as fiscal years 2014 – 2016. See the following table with cardiac catheterization growth projections, as reported by the applicant:

FISCAL YEAR	# ADULT DIAGNOSTIC PROCEDURES	# THERAPEUTIC PROCEDURES	TOTAL
2013	817	457	1,274
2014	818	512	1,330
2015	819	573	1,392
2016	820	642	1,462
CAGR	0.12	12.0	

In order to further test the reasonableness of its projections, the applicant prepared a linear regression analysis of the adult diagnostic and therapeutic cardiac catheterization data for fiscal years 2009 through 2012 at SRMC. On page 62, the applicant states:

"In particular, the linear regression would be expected to show that the diagnostic service, as a mature service with low growth rates, would continue to grow at a low rate; for the interventional service, a newer service, the analysis should show continued growth, but at a slowing rate."

The applicant provided a table, reproduced below, to illustrate the linear regression analysis:

FISCAL YEAR	# ADULT DIAGNOSTIC PROCEDURES	# THERAPEUTIC PROCEDURES	TOTAL
2009	813	214	1,027
2010	598	186	784
2011	766	341	1,107
2012	816	408	1,224
2013	793	472	1,264
2014	810	545	1,355

2015	828	619	1,447
2016	846	693	1,538
CAGR	0.6%	18.3%	5.9%

Thus, on page 62, the applicant states the linear regression analysis of the adult diagnostic and therapeutic cardiac catheterization data from fiscal years 2009 – 2012, and projected through the third project year yields a CAGR of 0.6% in diagnostic catheterization procedures, and 18.3% in therapeutic catheterization procedures. Therefore, the applicant's utilization projections that are based on a CAGR of 0.1% for adult diagnostic cardiac catheterization procedures, and a CAGR of 12.0% for therapeutic cardiac catheterization procedures are reasonable. Moreover, when that analysis is combined with the demographic and socioeconomic analysis and population growth projections provided by the applicant, the projections are reasonable.

In Section III.1, on page 63, the applicant provides two tables to show its projections for both unweighted and weighted adult diagnostic and therapeutic cardiac catheterization procedures, using the growth factors noted above. See the following tables from page 63:

FISCAL YEAR	# ADULT DIAGNOSTIC PROCEDURES	# THERAPEUTIC PROCEDURES	TOTAL
2013	817	457	1,274
2014	818	512	1,330
2015	819	573	1,392
2016	820	642	1,462

FISCAL YEAR	# WEIGHTED ADULT DIAGNOSTIC PROCEDURES	# WEIGHTED THERAPEUTIC PROCEDURES	TOTAL WEIGHTED DIAGNOSTIC EQUIVALENT PROCEDURES	% CAPACITY ON TWO CARDIAC CATHETERIZATION UNITS*
2013	817	800	1,617	54.0%
2014	818	896	1,714	57.1%
2015	819	1.003	1,822	60.7%
2016	820	1,123	1,943	64.8%

*Calculated by the Project Analyst

As the above tables demonstrate, the applicant projects that two units of cardiac catheterization equipment at SRMC will be utilized at 64.8% of capacity by the end of the third project year, which is above the 60% of capacity as required by 10A NCAC 14C .1601(a)(1).

With regard to the vascular catheterization procedures projected to be performed by the applicant, the following analysis is from supplemental information provided by the applicant:

> *"… SRMC proposes to upgrade the existing vascular catheterization equipment to perform cardiac catheterization procedures in addition to vascular catheterization procedures. Upon project completion, vascular catheterization procedures will continue to be performed on the existing, upgraded equipment. SRMC conservatively*

projects vascular catheterization procedures to grow by on-half of the historical compound annual growth rate, 4.6 percent."

The applicant provides a table, reproduced below, to illustrate the growth projections of vascular catheterization procedures at SRMC:

FISCAL YEAR	# VASCULAR PROCEDURES
2013	132
2014	138
2015	144
2016	151
CAGR	4.6%

In addition, in Section IV.1, page 75, the applicant states:

"While both the existing and proposed cardiac catheterization laboratories will be adequately utilized for cardiac catheterization procedures, the remaining capacity on the existing vascular laboratory (which is proposed to be authorized for cardiac catheterization procedures in this application) will allow vascular procedures to continue being performed on that equipment."

Therefore, the applicant projects to serve its patients by providing both vascular catheterization procedures and cardiac catheterization procedures on two units of cardiac catheterization equipment. The historical utilization of existing equipment, combined with the unique demographic characteristics of Robeson County and the projected population growth reasonably demonstrate a need for a second unit of cardiac catheterization equipment in Robeson County. Furthermore, SRMC is the sole provider of open heart services in Robeson County, and the only provider of cardiac catheterization services in Robeson County.

In addition, in Section III.12, pages 91 – 92, the applicant shows that, in FY 2012, 78.3% of its patients were covered by Medicare / Medicaid; and 72.6% of its cardiac catheterization patients were covered by some form of Medicare / Medicaid. Furthermore, in Section VI.8, the applicant states that, in fiscal year 2012, 8.2% of its net revenue, which does not include bad debt, was charity care.

In summary, the applicant adequately identifies the population it projects to serve, adequately demonstrates the need that population has for the proposed cardiac catheterization services, and adequately demonstrates it will continue to provide access to services for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups in need of the services it provides. Consequently, 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

The applicant will continue to provide vascular catheterization procedures on the existing equipment following the upgrade to provide cardiac catheterization procedures.

(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 65 – 66, the applicant discusses the alternatives it considered before submitting this application.

- Maintain the Status Quo: the applicant considered maintaining the status quo; however, the applicant has operated with the existing cardiac catheterization equipment and states that maintaining a high quality of care with regard to emergent and non-emergent patients is challenging. The applicant states on page 66 that to maintain the status quo will not provide adequate access to cardiac catheterization services for its patients.
- Provide Mobile Catheterization Service: the applicant also considered expanding cardiac catheterization capacity by operating a mobile catheterization service. On page 66 the applicant states that this option is not an optimal long-term solution to the increasing need in Robeson County for additional cardiac catheterization services.
- Special Need adjustment petition: the applicant chose to petition the SHCC for a special need determination in Robeson County for an additional unit of fixed cardiac catheterization equipment. This is the alternative selected by the applicant because this project will enable SRMC to upgrade existing vascular equipment to perform cardiac catheterization procedures and most effectively serve the high number of patients in its service area who are at risk for and who have heart disease.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria and thus, is approvable. An application that cannot be approved cannot be an effective alternative.

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

1. **Southeastern Regional Medical Center, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Southeastern Regional Medical Center, Inc. shall upgrade its existing vascular catheterization equipment to develop one unit of cardiac**

catheterization equipment for a total of two units of cardiac catheterization equipment.

3. **Southeastern Regional Medical Center, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

4. **Southeastern Regional Medical Center, 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.2, pages 101 – 102, the applicant projects no capital costs associated with this project, since the existing vascular equipment is already in the cardiac catheterization laboratory and needs only to be upgraded. Therefore, there are no construction costs, consultant fees, or equipment costs associated with this project. Likewise, in Section IX.1, page 107, the applicant states there are no start up costs associated with this project, because the application involves an existing service.

In the Financials Section of the application, on pages 119 – 123, the applicant provides Forms A-E. In Form B, the applicant provides a statement of revenue and expenses for the entire facility; and in Form C, the applicant provides a statement of revenue and expenses for the cardiac catheterization services as proposed in this application. The table below summarizes the Net Income (total revenue – total expenses) contained in these two forms for Southeastern Regional Medical Center and also for the cardiac catheterization service for the first three full project years (FY 2014 – FY 2016).

SOUTHEASTERN REGIONAL MEDICAL CENTER NET REVENUE, EXPENSES AND NET INCOME SUMMARY (FORM B)			
	Project Year 1 10/01/13 to 9/30/14	**Project Year 2 10/01/14 to 9/30/15**	**Project Year 3 10/01/15 to 9/30/16**
Revenue	$305,394,322	$323,770,655	$343,256,603
Expenses	$297,847,967	$316,100,473	$335,419,270
Net Income	**$ 7,546,355**	**$ 7,670,182**	**$ 7,837,333**
SOUTHEASTERN REGIONAL MEDICAL CENTER CARDIAC CATHETERIZATION SERVICES NET REVENUE, EXPENSES AND NET INCOME SUMMARY (FORM C)			
Revenue	$15,042,949	$16,378,961	$17,887,958
Expenses	$ 7,765,254	$ 8,411,838	$ 9,130,202
Net Income	**$ 7,277,695**	**$ 7,967,123**	**$ 8,757,756**

In Form B (the projected revenue and expense statement), on page 120, the applicant projects that revenues for the entire hospital system will exceed total operating expenses in each of the first three years of the project.

In Form C (the projected revenue and expense statement for SRMC Cardiac Catheterization services), on page 121, the applicant projects that revenues will exceed operating expenses in each of the first three years of the project.

In Forms D and E, on pages 122 - 123, the applicant provides projected average charges for cardiac catheterization services for the first three project years, as shown in the table below:

SOUTHEASTERN REGIONAL MEDICAL CENTER GROSS REVENUE CARDIAC CATHETERIZATION SERVICES			
Project Year 1 (10/01/13 – 09/30/14)			
	% of Total	**# Procedures**	**Projected Average Charge**
Self Pay/Indigent/Other	12.9%	171	$32,874
Managed Care/Commercial	14.5%	193	$32,874
Medicaid	14.7%	196	$32,874
Medicare/Medicare Managed Care	57.9%	770	$32,874
Total	100.0%	1,330	$32,874
Project Year 1 (10/01/14 – 09/30/15)			
	% of Total	**# Procedures**	**Projected Average Charge**
Self Pay/Indigent/Other	12.9%	179	$34,189
Managed Care/Commercial	14.5%	202	$34,189
Medicaid	14.7%	205	$34,189
Medicare/Medicare Managed Care	57.9%	806	$34,189
Total	100.0%	1,392	$34,189
	% of Total	**# Procedures**	**Projected Average Charge**
Self Pay/Indigent/Other	12.9%	188	$35,557
Managed Care/Commercial	14.5%	212	$35,557
Medicaid	14.7%	216	$35,557
Medicare/Medicare Managed Care	57.9%	846	$35,557
Total	100.0%	1,462	$35,557

In summary, the SRMC adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

C

SRMC is the only acute care hospital in Robeson County, the only provider of open heart services, and the only provider of cardiac catheterization services in the service area, which is designated by the SMFP as Robeson County. In Section III, page 69, the applicant

provides a map that illustrates its secondary service area, which includes Bladen and Columbus Counties. There is one hospital in Bladen County, which is operated by Cape Fear Valley HealthCare, LLC; but that facility does not provide cardiac catheterization services. Likewise, Columbus Regional Healthcare System is an acute care hospital in Columbus County, but has no fixed cardiac catheterization services (there is a mobile cardiac catheterization provider that serves Columbus Regional Hospital on a limited basis). The applicant has demonstrated that, as a result of the unique demographic composition of Robeson County and other factors, there is an increasing demand for cardiac catheterization services. See Criterion (3) for discussion regarding projected utilization and which is incorporated hereby as if set forth fully herein.

The 2013 SMFP shows a need determination for one cardiac catheterization unit in the Robeson County Service Area, as a direct result of the applicant's petition to the SHCC for an adjusted need determination. SRMC states that this need was identified due to the volume of cardiac catheterization procedures at SRMC, the unique demographic composition of Robeson County, and the increasing number of patients being served by SRMC's and Duke University System's cardiac program.

In Section IV.1, page 74, the applicant provides historical utilization for the existing cardiac catheterization unit at SRMC. The table below shows SRMC's cardiac catheterization utilization for the full two years prior to the submission of the application.

CEMC CARDIAC CATHETERIZATION HISTORICAL UTILIZATION 2012 - 2012		
Cardiac Catheterization	**Prior Full FY 10/1/10 – 9/30/11**	**Last Full FY 10/1/11 – 9/30/12**
#Units	1	1
#Diagnostic Procedures	766	816
#Therapeutic Procedures	341	408
#Diagnostic Equivalent Procedures	1,363	1,530

The applicant adequately demonstrates the need to upgrade its existing vascular equipment to perform cardiac catheterization procedures; thereby increasing its inventory of cardiac catheterization equipment to two units. Projected utilization is based on reasonable, credible, and supported assumptions. A description of the methodology and assumptions that SRMC uses to project utilization is provided in Section III.1(b), pages 59-64. See Criterion (3) of these findings for a summary of the methodology and assumptions regarding projected utilization. Criterion (3) is incorporated as if fully set forth herein. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

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

C

In Section VII.1(a), on page 95,the applicant provides a table, reproduced below, which illustrates current staffing for the cardiac catheterization services provided at SRMC.

POSITIONS	TOTAL NUMBER OF FTES
Clinical Assistant	0.90
Clerical Assistant	0.90
Cardiovascular Technician	2.70
Manager	0.25
Registered Nurse	6.40
Total	11.15

In Section VII.1(b), on page 96, the applicant provides a table, reproduced below, which illustrates proposed staffing for the cardiac catheterization services that will be provided at SRMC on the two units.

POSITIONS	TOTAL NUMBER OF FTES
Clinical Assistant	0.90
Clerical Assistant	0.90
Cardiovascular Technician	4.50
Manager	0.25
Registered Nurse	7.30
Total	13.85

The number of FTE positions proposed by the applicant are consistent with the current staffing; adding clinical positions to cover the additional cardiac catheterization unit.

In Section VII.3(a), on page 97, the applicant states:

> *"No new positions will be established as a result of the proposed project. All positions identified in Table VII.1 already exist at SRMC. Incremental FTEs to be added by the second full fiscal year of the project are identified in Table VII.1(b)."*

In Section VII.8, page 99, the applicant identifies Dr. Joseph Roberts as the Chief Medical Officer at SRMC. Since this is an application to upgrade the capability of existing equipment, it is reasonable to assume that hospital leadership will remain the same following project completion. In addition, in Exhibit 19, the applicant provides 11 physician letters, each indicating support for the proposed project. The applicant demonstrates the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, page 17, the applicant states that since cardiac catheterization is an existing service at SRMC, all necessary ancillary and support services are currently in place and will continue to be available following the addition of a cardiac catheterization unit by upgrading existing equipment. In Exhibit 3, the applicant provides a February 15, 2013 letter from the President of Southeastern Regional Medical Center, which documents that these services will continue to be provided following completion of the project. Furthermore, in Section V.2, page 77, the applicant states existing transfer agreements between SRMC and area healthcare providers are currently in place, and will continue following project completion. In Exhibit 14, the applicant provides a list of area healthcare providers with which it currently has transfer agreements, including but not limited to:

- Duke Raleigh Hospital
- University of North Carolina Hospitals
- Vidant Medical Center (formerly Pitt County Memorial Hospital, Inc.)
- NC Baptist Hospital
- Woodhaven Nursing and Alzheimer's Care Center
- Duke University Health Systems, Inc.

The applicant also provides a copy of an existing transfer agreement in Exhibit 14. The applicant provides letters of support for the proposal from area physicians in Exhibit 19. The applicant adequately demonstrates the availability of necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

(11) Repealed effective July 1, 1987.

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

NA

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12, page 91, the applicant provides the current payor mix for all services provided at SRMC during FY 2012, as shown in the table below:

Entire Facility FY 2012 (10/01/11 – 09/30/12)

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	9.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	24.5%
Managed Care/ Commercial Insurance	12.3%
Total	**100.0%**

*On page 91, the applicant states *"Other"* includes *"workers comp and other government payors."*

In addition, in Section VI.13, page 92, the applicant provides the current payor mix for cardiac catheterization services provided at SRMC during FY 2012, as shown in the table below:

Cardiac Catheterization Services FY 2012
(10/01/11 – 09/30/12)

CURRENT PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	12.9%
Medicare/Medicare Managed Care	57.9%
Medicaid	14.7%
Managed Care/ Commercial	14.5%
Total	**100.0%**

*On page 92, the applicant states *"Other"* includes *"workers comp and other government payors."*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Robeson	31.0%	13.2%	23.9%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the cardiac catheterization services provided by SRMC, which does not perform cardiac catheterizations on pediatric patients.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or

women utilizing health services such as the cardiac catheterization services offered at SRMC. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that SRMC currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.2, pages 83 - 84, the applicant describes SRMC's commitment to providing services for all patients, *"regardless of age, race, national or ethnic origin, disability, gender, sexual orientation, income, or immediate ability to pay."* In Exhibit 15, the applicant provides a copy of SRMC's charity and collection policies, which outline the poverty standards and the applicant's expectations. On page 84, the applicant states SRMC provided more than $68 Million, which is 8.0% of gross revenue, in uncompensated care (charity care and bad debt) in FY 2012. In Section VI.10, page 90, the applicant states no civil rights equal access complaints were filed against SRMC 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 Sections VI.14 and VI.15, pages 92 - 94, the applicant projects the following payor mix for all of SRMC's services and for cardiac catheterization services for the second project year (FY 2015):

Entire Facility FY 2015 (10/01/14 – 09/30/15)

ENTIRE FACILITY PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION (FY 2015)	PERCENT
Self Pay/Indigent/Charity/Other*	9.5%
Medicare/Medicare Managed Care	53.8%
Medicaid	24.5%
Managed Care/ Commercial	12.3%
Total	**100.0%**

*On page 92, the applicant states *"Other"* includes *"workers comp and other government payors."*

Cardiac Catheterization Services
FY 2016 (10/01/15 – 09/30/16)

PATIENT DAYS/PROCEDURES AS A PERCENT OF TOTAL UTILIZATION	PERCENT
Self Pay/Indigent/Charity/Other*	12.9%
Medicare/Medicare Managed Care	57.9%
Medicaid	14.7%
Managed Care/ Commercial	14.5%
Total	**100.0%**

*On page 93, the applicant states *"Other"* includes *"workers comp and other government payors."*

As shown in the tables above and the tables in Criterion (13a), the applicant assumes no change in payor mix following the linear accelerator replacement.

In Section VI.4, page 84, the applicant states it will provide access to care to *"…all patients regardless of ability to pay."* The applicant demonstrates that SRMC will continue to provide adequate access to medically underserved groups following project completion. 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 89, the applicant states persons currently have and will continue have access to cardiac catheterization services at SRMC through physician referrals, as well as referrals from other area healthcare providers. The applicant states the project is not expected to effect current referral patterns. 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 76, the applicant states the hospital currently has training agreements in place with many area health professional training programs, and will continue those affiliations when the project is complete. In Exhibit 13, the applicant provides a list of those facilities with which it currently has and will have clinical training agreements. Those facilities include, but are not limited to:

- Bladen Community College
- Campbell University
- University of North Carolina at Chapel Hill

- Duke University
- East Carolina University
- Robeson Community College

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

SRMC currently operates one cardiac catheterization lab at the hospital in Lumberton. In this application, SRMC proposes to upgrade existing vascular catheterization equipment, which is already in the cardiac catheterization lab area, so that the vascular catheterization equipment will have the capability to perform cardiac catheterization procedures as well as vascular procedures. The current and projected utilization exceeds the planning standard for cardiac catheterization equipment in the 2013 SMFP.

In Section III.6, page 70, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access to cardiac catheterization services. The applicant states:

> *"SRMC is the only provider of cardiac catheterization services in the cardiac catheterization equipment service area of Robeson County, as designated by the 2013 SMFP. See Section IV.1 of this application for utilization of cardiac catheterization services during the last full fiscal year."*

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service

area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to upgrade its existing vascular catheterization equipment to perform cardiac catheterization procedures and that it is a cost-effective alternative;
- The applicant adequately demonstrates it will continue to provide quality services; and
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

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 certified by the Centers for Medicare and Medicaid for participation in the Medicare and Medicaid programs, and licensed by the NC Division of Health Service Regulation as an acute care hospital. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming to all applicable Criteria and Standards for Cardiac Catheterization Equipment, promulgated in 10A NCAC 14C .1600, as discussed below.

.1602 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to acquire cardiac catheterization or cardiac Angioplasty equipment shall use the acute care facility/medical equipment application form.

-C- The applicant used the acute care facility/medical equipment application form.

(b) The applicant shall provide the following additional information based on the population residing within the applicant's proposed cardiac catheterization service area:

(1) the projected annual number of cardiac catheterization procedures, by CPT or ICD-9-CM codes, classified by adult diagnostic, adult therapeutic and pediatric cardiac catheterization procedure, to be performed in the facility during each of the first three years following completion of the proposed project, including the methodology and assumptions used for these projections:

-C- In Section II.8, page 26 and III.1(b), page 61, the applicant provides the projected number of adult diagnostic and therapeutic cardiac catheterization procedures to be performed in SRMC's cardiac catheterization lab for each of the first three years following completion of the project. In Section III.1(b), pages 26 - 27 and Section III.3, page 30, the applicant projects the annual number of cardiac catheterization procedures, and the assumptions and methodology used for these projections. In Section II.8, page 26, the applicant states that the proposed cardiac catheterization equipment will be used to perform adult diagnostic and therapeutic cardiac catheterization procedures. SRMC does not perform pediatric cardiac catheterization procedures, and does not propose to perform pediatric cardiac catheterization procedures.

(2) *documentation of the applicant's experience in treating cardiovascular patients at the facility during the past 12 months, including:*
(A) The number of patients receiving stress tests:

-C- In Section II.8, page 27, the applicant states that SRMC performed 3,227 stress tests during calendar year 2012.

(B) The number of patients receiving intravenous thrombolytic therapies:

-C- In Section II.8, page 28, the applicant states it provided 116 intravenous thrombolytic therapies at SRMC during calendar year 2012.

(C) The number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction:

-C- In Section II.8, page 28, the applicant states that in CY 2012, a total of 326 acute myocardial infarction patients presented to SRMC, six of whom were treated in the emergency room and 320 of whom were non-emergent.

(D) The number of patients referred to other facilities for cardiac catheterization procedures or open heart surgery procedures, by type of procedure:

-C- In Section II.8, page 28, the applicant states that SRMC did not refer any cardiac catheterization or open hear surgery procedures to another facility in CY 2012, because it has a comprehensive heart surgery and cardiac program.

(E) The number of diagnostic and therapeutic cardiac catheterization procedures performed during the twelve-month period reflected in the most recent licensure form on file with the Division of Health Service Regulation."

-C- In Section II.8, page 29, the applicant states that SRMC performed 818 diagnostic cardiac catheterization procedures and 408 therapeutic cardiac catheterization procedures in FFY 2012.

(3) *the number of cardiac catheterization patients, classified by adult diagnostic, adult therapeutic and pediatric, from the proposed cardiac catheterization service area that the applicant proposes to serve by patient's county of residence in each of the first three years of operation, including the methodology and assumptions used for these projections:*

-C- In Section II.8, pages 29 - 30, the applicant provides the number of adult cardiac catheterization patients from its proposed cardiac catheterization service area by county of residence. In Section III.1(b), pages 59-64 and Section III.5(d), page 70, SRMC provides the assumptions and methodology used in the projections. SRMC does not provide pediatric cardiac catheterization services and does not propose to provide these services in the future. See the tables below, reproduced from page 30, which illustrate patient projections:

SRMC Patient Origin Project Year 1 - FY 2014			
County	**Diagnostic**	**Therapeutic**	**Total**
Robeson	672	420	1,092
Bladen	76	47	123
Columbus	35	22	56
Total	782	489	1,271

SRMC Patient Origin Project Year 2 - FY 2015			
County	**Diagnostic**	**Therapeutic**	**Total**

Robeson	672	471	1,143
Bladen	76	53	129
Columbus	35	24	59
Total	783	548	1,331

SRMC Patient Origin Project Year 3 - FY 2016			
County	**Diagnostic**	**Therapeutic**	**Total**
Robeson	673	527	1,200
Bladen	76	59	135
Columbus	35	27	62
Total	784	614	1,397

(4) documentation of the applicant's projected sources of patient referrals that are located in the proposed cardiac catheterization service area, including letters from the referral sources that demonstrate their intent to refer patients to the applicant for cardiac catheterization procedures:

-C- In Section II.8, page 37, the applicant states, "As the leader in cardiac *services in Robeson County, SRMC receives referrals from most of the physicians on staff at the medical center. In addition, SRMC has the support of the physicians at Duke University Hospital as well as Duke Cardiology of Lumberton."* In Exhibit 19, SRMC provides 11 letters of support from area physicians.

(5) evidence of the applicant's capability to communicate with emergency transportation agencies and with an established comprehensive cardiac services program:

-C- In Section II.8, page 32, SRMC states that, in FFY 2012, over 74,600 people were cared for in the emergency department, which is operational 24 hours per day, 7 days per week. Additionally, SRMC maintains radio communication with EMS personnel.

(6) the number and composition of cardiac catheterization teams available to the applicant:

-C- In Section II.8, page 31, the applicant states that each of the cardiac catheterization units will have a team, which will consist of at least three RNs and two techs. In Section VII, pages 95 - 96, the applicant provides current and projected staffing for the proposed cardiac catheterization equipment, which confirms the team composition. Furthermore, the applicant states it will continue to operate 24 hours, seven days per week following project completion.

(7) documentation of the applicant's in-service training or continuing education programs for cardiac catheterization team members:

-C- In Exhibit 8, the applicant provides a copy of its policy regarding in-service training for its cardiac catheterization team members. In addition, in Section II.8, on page 32, the applicant states it provides opportunities for cardiac staff members to attend education workshops annually.

(8) written agreement with a comprehensive cardiac services program that specifies the arrangements for referral and transfer of patients seen by the applicant and that includes a process to alleviate the need for duplication in cardiac catheterization procedures:

-NA- In Section II.8, page 32, the applicant states, "*SRMC is a comprehensive cardiac services program, including community outreach, emergency treatment of cardiovascular illnesses, non-invasive diagnostic imaging modalities, diagnostic and therapeutic catheterization procedures, open heart surgery and cardiac rehabilitation services. As such, a written agreement with another comprehensive cardiac service program is not necessary*."

In addition, the applicant states if a patient presents who needs treatment that is beyond the capability of SRMC, such as a pediatric cardiac patient, immediate electronic communication and transport to Duke Cardiology or another facility as appropriate.

(9) a written description of patient selection criteria, including referral arrangements for high risk patients:

-C- In Section II.8, page 33, SRMC states that it follows the patient selection criteria set forth in the American College of Cardiology and the Society for Cardiac Angiography and Interventions. SRMC states that both are endorsed by the American Heart Association (AHA) and the Diagnostic and Interventional Catheterization Committee of the Council on Clinical Cardiology of the AHA. SRMC's referral procedures for patients outside the criteria for heart services as proposed by SRMC are transferred to Duke or another facility as stated in 10A NCAC 14C .1602 (8).

(10) a copy of the contractual arrangements for the acquisition of the proposed cardiac catheterization equipment including itemization of the cost of the equipment:

-NA- The applicant is not proposing to acquire new equipment; instead, the applicant proposes to upgrade existing vascular catheterization equipment to be able to perform cardiac catheterization procedures. There is no equipment cost associated with this project.

(11) documentation that the cardiac catheterization equipment and the procedures for operation of the equipment are designed and developed based on the

American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (June 2001) report.

-C- In Section II.8, page 33, the applicant states that all cardiology programs at SRMC have been developed and designed based on the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards. The applicant further states that all cardiac catheterization equipment performs all procedures based on those guidelines. In Exhibit 9, the applicant provides a copy of those guidelines.

.1603 REQUIRED PERFORMANCE STANDARDS

.1603(a)(1) *An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards: (1) each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity, excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project.*

-C- In Section II.8, pages 34 – 36, SRMC projects utilization for two cardiac catheterization units during the fourth quarter of the third year following project completion. The standard is 60% of capacity for each item of cardiac catheterization equipment. According to 10A NCAC 14C .1601, one therapeutic procedure is valued at 1.75 diagnostic equivalent procedure; while capacity of one unit of catheterization equipment is 1,500 diagnostic-equivalent procedures per year. Therefore, two units of cardiac catheterization equipment as SRMC proposes equates to 3,000 total diagnostic-equivalent procedures per year. Therefore, 60% of 3,000 diagnostic-equivalent procedures is 1,800 diagnostic-equivalent procedures. SRMC projections meet that standard as shown in the following four tables, from pages 35 – 36 of the application.

SRMC PROJECT YEAR 3 CARDIAC CATHETERIZATION UTILIZATION (PROCEDURES)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Diagnostic	161	211	224	224	820
Therapeutic	164	183	160	135	642
Total	324	394	385	359	1,462

*On page 35, the applicant notes that numbers do not foot due to computer rounding.

SRMC PROJECT YEAR 3 CARDIAC CATHETERIZATION UTILIZATION (DIAGNOSTIC-EQUIVALENT PROCEDURES)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Diagnostic	161	211	224	224	820

Therapeutic	286	319	281	237	1,123
Total	447	530	505	461	1,943

SRMC PROJECT YEAR 3 CARDIAC CATHETERIZATION CAPACITY (DIAGNOSTIC-EQUIVALENT PROCEDURES)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Total Procedures	750	750	750	750	3,000

SRMC PROJECT YEAR 3 CARDIAC CATHETERIZATION UTILIZATION (PERCENT OF CAPACITY)					
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Total**
Total Procedures	59.6%	70.7%	67.3%	61.5%	64.8%

The applicant projects that each of the two units of cardiac catheterization equipment will exceed the standard of 60% of capacity in the fourth quarter of the third project year, as set forth in this rule.

.1603(a)(2) *If the applicant proposes to perform therapeutic cardiac* catheterization *procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;*

-C- In Section II.8, page 36, SRMC provides the following chart which shows that it projects to perform 321 therapeutic procedures per catheterization team by Year 3, which exceeds the standard of 100 therapeutic procedures as set forth by this rule.

SRMC ANNUAL THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES			
	Project Year 1	**Project Year 2**	**Project Year 3**
Therapeutic Procedures	512	573	642
# Catheterization Teams	2	2	2
Procedures per Team	256	286	321

.1603(a)(3) *if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;*

-C- In Section II.8, page 37, SRMC provides the following chart which shows that it projects to perform 410 therapeutic procedures per catheterization team by the end of the third year following project completion, which exceeds the standard set forth in this rule.

SRMC ANNUAL DIAGNOSTIC-EQUIVALENT CARDIAC CATHETERIZATION PROCEDURES			
	Project Year 1	**Project Year 2**	**Project Year 3**
Diagnostic Procedures	818	819	820

# Catheterization Teams	2	2	2
Diagnostic-Equivalent Procedures per Team	409	409	410

.1603(a)(4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*

-C- In Section III.5(c), page 70, SRMC identifies Robeson County as its primary cardiac catheterization service area with approximately 82.1% of cardiac catheterization procedures originating from that county. Furthermore, SRMC states its secondary cardiac catheterization service area consists of Bladen and Columbus Counties. See the following table, reproduced from page 70, which shows the patient origin with regard to cardiac catheterization procedures:

COUNTY	PROJECTED # CARDIAC CATH PTS PY 1	PERCENT OF TOTAL PATIENTS PY 1	PROJECTED # CARDIAC CATH PTS PY 2	PERCENT OF TOTAL PATIENTS PY 2
Robeson	1,092	82.1%	1,143	82.1%
Bladen	123	9.2%	129	9.2%
Columbus	56	4.2%	59	4.2%
Other*	59	4.4%	61	4.4%
Total	1,330	100.0%	1,392	100.0%

.1603(b) *An applicant proposing to acquire mobile cardiac catheterization shall:*

(1) demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Facility Services;

(2) demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;

(3) demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;

(4) demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site

in the proposed cardiac catheterization service area in the applicant's third year of operation; and

(5) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

-NA- SRMC is not proposing to acquire mobile cardiac catheterization equipment.

.1603(c) *An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization equipment shall*:

(1) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Facility Services;

-C- In Section II.8, page 39, SRMC states that 818 diagnostic and 408 therapeutic cardiac catheterization procedures were performed at the medical center in FFY 2012. Further, the applicant states that each therapeutic procedure was multiplied by 1.75, and each diagnostic procedure was multiplied by 1.00, and that SRMC's utilization (as shown in the chart below) was 102% of capacity, which exceeds the 80% threshold required by 10A NCAC 14C .1601.

SRMC CARDIAC CATHETERIZATION UTILIZATION FFY 2012	
Diagnostic Procedures	818
Therapeutic Procedures	408
Total Procedures	1,226
Therapeutic Adjustment	1.75
Diagnostic Equivalent Procedures	1,532
Capacity per Unit	1,500
Number of Units	1
Total Capacity at SRMC	1,500
Utilization as a % of Capacity	102%

*Source: Application page 40

(2) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and"

-C- See the response to 10A NCAC 14C .1603(a)(1) above which shows that SRMC projects to have an average annual rate of 64.8%, which will exceed the average annual rate of 60% of capacity during the fourth quarter of the third project year.

(3) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

-C- In Section III(1)(b), pages 59-64, SRMC provides the assumptions and methodology used in development of the projections for the cardiac catheterization equipment.

.1603(d) *An applicant proposing to acquire shared fixed cardiac catheterization as defined in the applicable State Medical Facilities Plan shall:*

(1) demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project;

-NA- SRMC is not proposing to acquire shared fixed cardiac catheterization equipment.

(2) provide documentation of all assumptions and data used in the development of the projections required in this rule.

-NA- SRMC is not proposing to acquire shared fixed cardiac catheterization equipment.

.1603(e) *If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria*:

(1) the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under;

(2) the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.

-NA- In Section II.8, page 41, the applicant states it does not propose to perform cardiac catheterization procedures on patients age 14 and under.

.1604 REQUIRED SUPPORT SERVICES

.1604(a) *If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility*.

-C- In Section II.8, page 42, the applicant states that open heart surgery has been performed at the medical center since 2006 and is performed within the same facility as the proposed cardiac catheterization laboratory, as documented in the 2013 SMFP.

.1604(b) *If the applicant proposes to perform diagnostic cardiac catheterization procedures, the applicant shall document that its patients will have access to a facility which provides open heart surgery services, and that the patients can be transported to that facility within 30 minutes and with no greater risk than if the procedure had been performed in a hospital which provides open heart surgery services; with the exception that the 30 minute transport requirement shall be waived for equipment that was identified as needed in the State Medical Facilities Plan based on an adjusted need determination or the determination of a need for shared-fixed cardiac catheterization equipment.*

-C- In Section II.8, page 42, the applicant states that open heart surgery is performed within the same facility as the cardiac catheterization laboratory, and that the proposed second cardiac catheterization laboratory will not change access to open heart surgery for its patients.

.1604(c) *The applicant shall provide documentation to demonstrate that the following services shall be available in the facility:*

(1) electrocardiography laboratory and testing services including stress testing and continuous cardiogram monitoring;
(2) echocardiography service;
(3) blood gas laboratory;
(4) pulmonary function unit;
(5) staffed blood bank;
(6) hematology laboratory/coagulation laboratory;
(7) microbiology laboratory;
(8) clinical pathology laboratory with facilities for blood chemistry;
(9) immediate endocardiac catheter pacemaking in case of cardiac arrest; and
(10) nuclear medicine services including nuclear cardiology.

-C- In Section II.8, page 43, the applicant states that it provides all of the above listed services, and will continue to provide them following project completion. In Exhibit 3, the applicant provides a letter from Joann Anderson, President of SRMC which verifies that the medical center provides all the services listed in this rule.

.1605 REQUIRED STAFFING AND STAFF TRAINING

.1605(a) *An applicant proposing to acquire cardiac catheterization equipment shall provide documentation to demonstrate that the following staffing requirements shall be met:*

(1) one physician licensed to practice medicine in North Carolina who has been designated to serve as director of the cardiac catheterization service and who has all of the following credentials:

(A) board-certified in internal medicine by American Board of Internal Medicine, pediatrics by American Board of Pediatrics, or radiology by American Board of Radiologists;

(B) subspecialty training in cardiology, pediatric cardiology, or cardiovascular radiology; and

(C) clinical experience in performing physiologic procedures, angiographic procedures, or both;

-C- In Section VII.8, pages 43 - 44, the applicant states that Dr. Robert Everhart is the clinical director of the cardiac catheterization department and that Dr. Everhart is board certified in internal medicine. The applicant states that Dr. Everhart will continue to serve as clinical director of cardiology services after project completion. In Exhibit 10, Dr. Everhart's curriculum vitae confirms his qualifications as required by this rule.

.1605(a)(2) *at least one team to perform cardiac catheterizations, composed of at least the following professional and technical personnel:*

(A) one physician licensed to practice medicine in North Carolina with evidence of training and experience specifically in cardiovascular disease and radiation sciences;
(B) one nurse with training and experience specifically in critical care of cardiac patients, cardiovascular medication, and catheterization equipment; and
(C) at least two technicians with training specifically in cardiac care who are capable of performing the duties of a radiologic technologist, cardiopulmonary technician, monitoring and recording technician, and darkroom technician.

-C- SRMC describes its proposed cardiac catheterization teams in Section II.8, page 44. In addition, in Section VII.1, page 96, the applicant provides a staffing chart that illustrates current and proposed cardiac catheterization team composition.

.1605(b) *An applicant proposing to acquire cardiac catheterization equipment shall provide documentation to demonstrate that the following staff training shall be provided for members of cardiac catheterization teams:*

(1) American Red Cross or American Heart Association certification in cardiopulmonary resuscitation and advanced cardiac life support; and

-C- In Section II.8., page 45, the applicant states, "*All clinical staff must be BCLS certified and all registered nurses must be ACLS certified. As each cardiac team consists of one or more registered nurses and one or more radiologic technologists, the appropriate certifications required for each team are already in place*."

(2) an organized program of staff education and training which is integral to the cardiac services program and ensures improvements in technique and the proper training of new personnel.

-C- In Section II.8, page 45, the applicant states it encourages staff training and provides opportunities for the training each year. In addition, the applicant states mentoring for cardiac catheterization staff is in place to ensure quality performance. Furthermore, in Exhibit 8, the applicant provides a copy of SRMC's orientation and training policies.