

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 28, 2012

PROJECT ANALYST: Fatimah Wilson

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: R-8846-12 / Albemarle Hospital Authority / Acquire one da Vinci Si Surgical System / Pasquotank 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

Albemarle Hospital Authority proposes to acquire a da Vinci Si Surgical System (“Da Vinci Surgical System”) to be located on the 2<sup>nd</sup> floor of the existing surgical department at Albemarle Hospital located at 1144 North Road Street, Elizabeth City. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire 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 this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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

Albemarle Hospital Authority proposes to acquire a da Vinci Si Surgical System (“da Vinci Surgical System”) to be located on the 2<sup>nd</sup> floor of the existing surgical department at Albemarle Hospital.

Population to be Served

In Section III.4, page 53, the applicant provides current patient origin for acute care services provided at Albemarle Hospital during FY 2011 as illustrated in the table below.

County of Residence	# of Patients	% of Patients
Pasquotank	69,294	51.9%
Perquimans	15,674	11.7%
Dare	12,825	9.6%
Camden	10,647	8.0%
Currituck	10,036	7.5%
Gates	6,322	4.7%
Chowan	3,393	2.5%
Other (<1% each)	5,304	4.0%
<b>Total</b>	<b>133,495</b>	<b>100.0%</b>

In Section III.5(c-d), pages 56-58, the applicant projects patient origin for the da Vinci Surgical System for the two years following completion of the proposed project, as shown in the table below.

**Projected Patient Origin for Hysterectomy Cases  
1<sup>st</sup> and 2<sup>nd</sup> Year of Operation—Fiscal Years 2014-2015**

County of Residence	# of Patients	% of Patients	# of Patients	% of Patients
	FY 1 2014	FY 1 2014	FY 2 2015	FY 2 2015
Pasquotank	28	48.4%	33	48.4%
Perquimans	7	13.0%	9	13.0%
Dare	4	7.4%	5	7.4%
Camden	6	9.7%	7	9.7%
Currituck	6	10.2%	7	10.2%
Gates	2	4.1%	3	4.1%
Chowan	2	4.2%	3	4.2%
Other (<1% each)	2	3.0%	2	3.0%
<b>Total</b>	<b>57</b>	<b>100.0%</b>	<b>68 [69]</b>	<b>100.0%</b>

The applicant states,

*“Albemarle Hospital is an existing provider of gynecologic services with an established patient base. The applicant projects its historical gynecologic patient origin, see Table III.8, will remain constant through the second year of operation.”*

The project analyst notes that Albemarle Hospital is the only acute care hospital in Pasquotank County and has been in operation in the service area for 98 years. No new hospitals are approved for the service area that could alter or impact the historical patient origin.

The applicant adequately identified the population to be served.

### Need for the da Vinci Surgical System

In Section III.1, pages 43-50, the applicant describes the need for the da Vinci Surgical System:

*“The need that necessitates the inclusion of each of the proposed project services discussed in II.1(a) includes:*

- *The clinical need for the services proposed;*
- *The need to maintain state-of-the-art capability in surgery at Albemarle Hospital; and*
- *The need based on the sustained population of the service area.*

### Clinical Need for Hysterectomy

In Section III.1(a), pages 43-45, the applicant states:

*“In the United States, from 1998-2005, a gynecological condition was the principal reason for inpatient hospitalization for more than 6 million women.<sup>4</sup> These gynecological conditions, including uterine leiomyoma, endometriosis, menstrual disorders, genital prolapse, benign cysts of the ovary, and pelvic inflammatory disease, affect quality of life and are important contributors to inpatient hospitalizations among reproductive-age and midlife women.*

*From 2000 through 2004 alone, nearly 3.1 million US women received a hysterectomy for treatment of gynecological conditions during an inpatient hospitalization.<sup>5</sup>*

---

<sup>4</sup> M.K. Whiteman, E. Kuklina, D.J. Jamieson et al., “Inpatient hospitalization for gynecologic disorders in the United States,” *American Journal of Obstetrics & Gynecology*, 202, 6 (2010): 541.e1-6, [Summary article only;] <http://download.journals.elsevierhealth.com/pdfs/journals/0002-9378/PIIS000293780902256X.main-abr.pdf?jid=ylob>

<sup>5</sup> M.K. Whiteman, S.D. Hillis, D.J. Jamieson et al., “Inpatient hysterectomy surveillance in the United States, 2000-2004,” *American Journal of Obstetrics & Gynecology*, 198, 1 (2008): 34.e1-7, [Summary article only;] <http://download.journals.elsevierhealth.com/pdfs/journals/0002-9378/PIIS0002937807006795.main-abr.pdf?jid=ylob>

...

*Of the hysterectomies performed from 2000 through 2004, 67.9 percent were performed abdominally and 32.1 percent vaginally.<sup>6</sup> Postoperative infection rates, lengths of stay, and accrued patient costs are all higher for open abdominal hysterectomies than laparoscopic or vaginal.<sup>7</sup> Thus, the need for minimally invasive hysterectomy procedures, such as laparoscopic and vaginal hysterectomy, is crucial.”*

### Need to Maintain State-of-the-Art Capability in Surgery at Albemarle Hospital

The US Food and Drug Administration approved use of the da Vinci Surgical System for laparoscopic surgery in 2000. Today, the da Vinci Surgery System is used in a range of surgical specialties: urology, gynecology, general surgery, cardiothoracic surgery and some pediatric and training functions. In Section III.1, page 45, the applicant explains why the hospital has not considered the adoption of robotic surgery until now.

*“To date, the hospital has refrained from adopting robotic surgery. Before embracing the technology, Albemarle Hospital needed other, larger institutions to determine that the technology would endure. The hospital also needed training programs to mature to a level that could be adopted by a small community hospital.”*

The applicant states that by not offering robotic surgery, patients have migrated to other facilities as they elect to seek institutions that offer the robotic option. The applicant has now realized that robotic surgery has become commonly accepted. Migration of patients to other facilities currently providing robotic surgery decreases the volume of laparoscopic procedures being performed at Albemarle Hospital, thereby reducing the surgeons’ proficiency and affecting the quality of care being provided to the patient. Thus, Albemarle Hospital needs to offer the robotic option to assure that its surgeons have the volume necessary to maintain their craft and to meet patient requests.

### The Need Based on the Sustained Population of the Service Area

In Section III.1, pages 46-47, the applicant states:

*“Hysterectomy rates are highest among women aged 41-50 years old, but can be medically necessary for women of any age. The most recent research published by the Centers for Disease Control and Prevention reported a hysterectomy rate of 5.4 procedures per 1,000 females in the United States. Based on historical*

---

<sup>6</sup> Whiteman et al., (2008): 34.e1-7. Women Gynecology and Childbirth Associates, PC. <http://www.wgcaobgyn.com/about-da-vinci-hysterectomy> accessed June 8, 2012

<sup>7</sup> L. Warren, J.A. Ladapo, B.J. Borah et al., “Open abdominal versus laparoscopic and vaginal hysterectomy: analysis of a large United States payer measuring quality and cost of care,” *Journal of Minimally Invasive Gynecology*, 16, 5 (2009): 581-8, [Abstract only]; [http://www.jmig.org/article/S1553-4650\(09\)00339-2/abstract](http://www.jmig.org/article/S1553-4650(09)00339-2/abstract)

patient origin, the applicant proposes to serve Pasquotank, Perquimans, Currituck, Camden, Chowan, Gates and Dare Counties. The North Carolina Office of State Budget and Management (NCOSBM) estimate places the number of females in the seven county service area at 75,107 in 2012.

According to the NCOSBM, the number of females in the seven county area grew between 2000 and 2010 at a compound annual rate of 1.58 percent.

**Table III.1 Service Area Female Population, 2000 through 2010**

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	CAGR
<b>Total</b>	64,604	65,401	67,047	68,665	70,643	72,438	73,883	74,959	75,457	75,543	75,585	1.58%

Source: NCOSBM

After peaking in 2010, the female population is projected to marginally decrease at a compound annual rate of 0.17 percent per year from 2010 through 2016, the third year of the proposed project.

**Table III.2 Projected Service Area Female Population, 2010 through 2016**

	2010	2011	2012	2013	2014	2015	2016	CAGR
<b>Total</b>	75,585	75,546	75,107	74,999	74,919	74,868	74,830	-0.17%

Source: NCOSBM

As the female population of the service area continues to age, the need for gynecologic procedures, including hysterectomies will continue to increase into the near future.

In Section IV.1, page 62, the applicant provides projected utilization for the proposed da Vinci Surgical System for the first three years following project completion, as illustrated in the table below. Albemarle Hospital does not currently have a da Vinci Surgical System.

	Fiscal Year 1 10/1/13 – 9/30/14	Fiscal Year 2 10/1/14 – 9/30/15	Fiscal Year 3 10/1/15 – 9/30/16
Inpatient	16	19	21
Observation/Outpatient	41	49	52
<b>Total</b>	<b>57</b>	<b>68</b>	<b>73</b>

The applicant provides the assumptions and methodology used to project utilization in Section IV.1, pages 62-67, which are summarized below.

*“Methodology*

*Step 1: Determine the need for hysterectomy cases in the service area through 2016.  
See Table III.6*

*Assume that it is reasonable to apply state demographer annual population estimates to the Albemarle Hospital fiscal year.*

*Step 2: Determine the number of hysterectomy cases performed at Albemarle Hospital,*

fiscal years 2010 through 2012, that meet criteria for da Vinci Surgical System.

**Table IV.4 Hysterectomy Cases at Albemarle Hospital that Meet da Vinci Criteria, Fiscal Year 2010 through Fiscal Year 2012**

<b>Fiscal Year</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
	<i>a</i>	<i>b</i>	<i>c</i>
<b>Cases</b>	125	147	130

*a* Full year, Albemarle Hospital database

*b* Full year, Albemarle Hospital database

*c* Annualized using first half of fiscal year (65 cases x 2 = 130)

Candidate hysterectomy cases are described by ICD-9 codes in Table IV.5

**Table IV.5 ICD-9 Codes for Historic Albemarle Hysterectomy Data**

<b>Hysterectomy Procedure</b>	<b>ICD-9 Code</b>
Laparoscopic Abdominal	68.31, 68.41, 68.61
Laparoscopic Vaginal	68.51, 68.71
Open Abdominal	68.39, 68.49

Intuitive Surgical's estimating models for the da Vinci Surgical System use all but one of the procedures in Table IV.5, ICD-9 code 68.49. Pennsylvania Department of Health, March 2012, newsletter, included in Exhibit 48, notes that code 68.49 is also a candidate for da Vinci robotic assistance. Albemarle Hospital included this code as well.

**Step 3:** Determine the proportion of service area hysterectomy cases represented by Albemarle Hospital's candidate hysterectomy cases, for the last three fiscal years (Market Share).

**Table IV.6 Albemarle Hospital Market Share of Service Area Hysterectomy Cases, Fiscal Year 2010 through Fiscal Year 2012**

	<b>Fiscal Year</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>a</b>	<b>Service Area Hysterectomy Cases Needed</b>	343	335	326
<b>b</b>	<b>Albemarle Hospital Hysterectomy</b>	125	147	130
<b>c</b>	<b>Albemarle Hospital Market Share</b>	36%	44%	40%

Source:

*a* – Table III.6

*b* – Table IV.4

*c* –  $b / a$

**Step 4:** Calculate the average Market Share of service area hysterectomy cases represented by Albemarle Hospital's candidate hysterectomy cases for the last three fiscal years. ( $(36 + 44 + 40) / 3 = 40$ )

Step 5: Project Market Share of candidate hysterectomy cases for Albemarle Hospital through fiscal year 2016.

**Table IV.7 Projected Albemarle Hospital Market Share of da Vinci Candidate Hysterectomy Cases, Fiscal Year 2013 through Fiscal Year 2016**

<b>Fiscal Year</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Market Share</b>	40%	41%	41%	41%

*Assumption:*

- a. Albemarle Hospital market share will continue at the recent 3-year average until the da Vinci Surgical System is introduced.
- b. The availability of robotic surgical option will increase Albemarle Hospital hysterectomy market share by one percent. More patients will remain in the service area for the robotic procedure.
- c. Forty-one (41) percent is a reasonable market share; it is less than the 2011 market share peak of 44 percent of service area hysterectomy cases.

Step 6: Project da Vinci candidate hysterectomy cases for da Vinci Surgical System at Albemarle Hospital through fiscal year 2016.

**Table IV.8 Projected Candidate Hysterectomy Cases at Albemarle Hospital, Fiscal Year 2013 through Fiscal Year 2016**

	<b>Fiscal Year</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>a</b>	<b>Service Area Hysterectomy Cases Needed</b>	318	310	302	295
<b>b</b>	<b>Albemarle Hospital Market Share for Candidate Cases Only</b>	40%	41%	41%	41%
<b>c</b>	<b>Albemarle Hospital Candidate Hysterectomy Cases</b>	127	127	124	121

Source: a – Table III.6

b – Table IV.7

c – a \* b

Step 7: Determine an incremental adoption rate for use of da Vinci Surgical System for hysterectomy cases for each of the first three years.

**Table IV.9 Percent of Candidate Albemarle Hospital Hysterectomy Cases Using the da Vinci Surgical System**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
<b>Percent of Candidate Hysterectomy Cases Using da Vinci</b>	45%	55%	60%

*Assumption:*

- a. Proportion of cases using the da Vinci Surgical System will increase gradually as surgeons acclimate to the system and become proficient in robotic hysterectomies.
- b. Surgeons will act in accordance with letters of support in Exhibit 31.
- c. This is conservative; surgeons at Albemarle Hospital have communicated to administration that all of their cases involving these gynecology ICD-9 codes could be done with robotic surgery.

*Step 8: Project the number of hysterectomy cases at Albemarle Hospital that will use the da Vinci Surgical System through 2016*

**Table IV.10 Projected Hysterectomy Cases at Albemarle Hospital Using da Vinci Surgical System 2014 through 2016**

<i>Fiscal Year</i>	<i>2014</i>	<i>2015</i>	<i>2016</i>
<i>Albemarle Hospital Candidate Hysterectomy Cases</i>	127	124	121
<i>Percent of Candidate Hysterectomy Using da Vinci</i>	45%	55%	60%
<i>Number of Hysterectomy Cases Using da Vinci</i>	57	68	73

Source: a – Table IV.8

b – Table IV.9

c – a \* b

In Exhibit 31, the applicant provides letters of support from physicians expecting to refer patients to Albemarle Hospital for robotic surgery and/or perform robotic surgery themselves. In fact, the supporting physicians report they expect to perform 54-68 gynecologic robotic surgeries per month.

*Step 9: Determine the mix of inpatient and observation (outpatient) hysterectomy cases in fiscal year 2011.*

**Table IV.11 Ratio of Inpatient / Observation da Vinci Candidate Hysterectomy Cases at Albemarle Hospital in 2011**

	<i>Fiscal Year 2011</i>	<i>Percent of Cases</i>
<i>Inpatient</i>	42	29%
<i>Observation / Outpatient</i>	105	71%
<b><i>Total</i></b>	<b>147</b>	<b>100%</b>

Source: Albemarle Hospital Internal Data

*Assumption:*

According to current coding and care practice, hysterectomy cases are placed in observation status if a stay may be 48 hours or less. These are treated and billed as “Outpatient” cases.

*Step 10: Project the mix of inpatient and observation (outpatient) da Vinci candidate hysterectomy cases at Albemarle Hospital through fiscal year 2016.*



**Table IV.12 Projected Ratio of Inpatient / Observation da Vinci Candidate Hysterectomy Cases at Albemarle Hospital, Fiscal Year 2013 through Fiscal Year 2016**

<b>Fiscal Year</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Inpatient</b>	29%	29%	29%	29%
<b>Observation / Outpatient</b>	71%	71%	71%	71%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

*Assumption: Inpatient and observation mix will remain constant through 2016.*

*Step 11: Project the number of inpatient and observation hysterectomy cases that will use the da Vinci Surgical System at Albemarle Hospital through fiscal year 2016.”*

**Table IV.13 Projected Albemarle Hospital Inpatient Hysterectomy Cases Using the da Vinci Surgical System Fiscal Year 2014 through Fiscal Year 2016**

<b>Fiscal Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Albemarle Hospital da Vinci Hysterectomy Cases</b>	57	68	73
<b>Inpatient Ratio</b>	29%	29%	29%
<b>Outpatient Ratio</b>	71%	71%	71%
<b>Inpatient da Vinci Hysterectomy Cases</b>	<b>16</b>	<b>19</b>	<b>21</b>
<b>Outpatient da Vinci Hysterectomy Cases</b>	<b>41</b>	<b>49</b>	<b>52</b>

As shown in the tables above, in the third operating year, the applicant projects that the proposed da Vinci System will perform 73 hysterectomy cases. As more surgeons complete training on the da Vinci Surgical System, it will be used for other surgeries. Projected utilization is based on reasonable and supported assumptions regarding: 1) the number of surgical cases currently performed on residents of the service area at Albemarle Hospital that would be appropriate for use of the da Vinci Surgical System; and 2) the number of residents of the service area currently traveling outside the service area who are expected to shift to Albemarle Hospital once the da Vinci Surgical System is available. There is no da Vinci Surgical System physically located in the proposed service area.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population to be served has for the proposed da Vinci Surgical System. 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 52-53, the applicant discusses the alternatives to the proposed project that were considered prior to submission of this application and the basis for selection of the proposed project. The first alternative the applicant considered was maintaining the status quo; however, this alternative was not deemed to be an effective alternative because it would mean that Albemarle Hospital would continue to offer surgical services only in the traditional open or laparoscopic form. This alternative would result in a reduction of procedure volumes as patients would choose to seek care at robotic centers; a reduction in procedural volume would also reduce the surgeon's ability to sustain proficiency necessary to maintain their skill and limit Albemarle Hospital's ability to compete equally with other hospitals for the better qualified surgeons. The second alternative the applicant considered was to lease the robotic equipment, however, this alternative was not deemed to be an effective alternative because of the higher cost to lease the equipment. Alternative three, was deemed to be the most effective alternative which is to purchase the da Vinci Surgical System as proposed in this CON application. Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and the *Criteria and Standards for Major Medical Equipment 10A NCAC 14C .3100*. The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming with this criterion and approved subject to the following conditions.

1. **Albemarle Hospital Authority shall materially comply with all representations made in its certificate of need application and in the supplemental information requested by the Certificate of Need Section. In those instances where representations conflict, Albemarle Hospital Authority shall materially comply with the last-made representation.**
2. **Albemarle Hospital Authority 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 or that would otherwise require a certificate of need.**
3. **Albemarle Hospital Authority 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, page 105, the applicant projects the total capital cost for the project will be \$1,085,000, comprised as follows:

Equipment Cost	\$ 1,020,000
Contingency	<u>\$ 65,000</u>
Total	\$ 1,085,000

In Section VIII.3, page 106, the applicant states that the capital cost will be financed with the accumulated reserves of Albemarle Hospital Authority. In Section IX, page 110, the applicant states there will be \$30,000 in start up or initial operating expenses.

In a letter dated June 4, 2012, Vice President of Finance for Albemarle Hospital Authority states, “As Vice President of Finance, I have the authority to obligate up to \$1,800,000 of Albemarle Hospital Authority’s accumulated reserves for the capital cost and working capital requirements of the da Vinci Surgery System project.” Exhibit 44 contains audited financial statements for Albemarle Hospital Authority which documents the applicant had total net assets (total assets less total liabilities) of \$63,467,837 and cash and cash equivalents of \$2,216,116 as of September 30, 2011. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In both the Statement of Revenues and Expenses for the entire facility (Form B) and in the Statement of Revenues and Expenses for Surgical Services, including the da Vinci Surgical System (Form C) the applicant projects positive net income from operations in each of the first three years following project completion, with the exception of FFY 2014 in Form C. In the Statement of Revenues and Expenses for just the da Vinci Surgical System service component (Form C), the applicant projects positive net income in the second and third year following project completion. The projected costs and revenues are based on reasonable assumptions, including projected utilization. See Criterion (3) for discussion of projected utilization, which is hereby incorporated as if fully set forth herein. Therefore, the applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues and the application is conforming with 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

Albemarle Hospital Authority proposes to acquire one da Vinci Si Surgical System to be located on the 2<sup>nd</sup> floor of the existing surgical department at Albemarle Hospital. Albemarle Hospital does not currently have a da Vinci Si Surgical System, nor is there a da Vinci Si Surgical System in the service area (Pasquotank, Perquimans, Dare, Camden, Currituck, Gates and Chowan Counties). The patients to be served will be the same as the patients currently served in the existing location. No new services will be offered. Albemarle Hospital adequately demonstrates it is more cost effective to acquire the da Vinci Si Surgical System in order to maintain state of the art capability in surgery at Albemarle Hospital, provide a needed service to patients who have been migrating to other facilities in order to receive robotic laparoscopic surgery, increase laparoscopic procedural volumes at Albemarle Hospital to improve physician proficiency, allow Albemarle Hospital the ability to compete equally with other hospitals for the better qualified surgeons, and meet the clinical training needs of health professional training programs in the area. The applicant adequately demonstrates the need to acquire the da Vinci Si Surgical System. Projected utilization is based on reasonable, credible, and supported assumptions. See Criterion (3) for a description of the methodologies used to project utilization. The discussion in Criterion (3) regarding projected utilization 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, page 94, the applicant provides projected staffing of the proposed da Vinci Surgical System. The applicant projects it will hire a 0.082 FTE RN position, a 0.314 FTE Floor RN position, a 0.163 Technician position and 1.180 FTE Surgery Support Staff position for a total of 1.74 FTE positions for the proposed project. In Section VII.6, page 98, the applicant describes its experience in the recruitment and retention of staff. In Section VII.8, page 99, the applicant identifies the Chief of Medical Officer at Albemarle Hospital and the Medical Director for the proposed da Vinci Surgical Program at Albemarle Hospital. Exhibit 31 contains a letter from the Chief of Staff at Albemarle Hospital. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and the application is conforming with 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 25 and Exhibit 7, the applicant states all necessary ancillary and support services are already available at Albemarle Hospital. In Section VI.9, page 86, the applicant states that the hospital has transfer agreements with existing health care providers. Exhibit 30 contains an example of one of these transfer agreements. In Exhibits 31, 33 and 35, the applicant provides letters from physicians, board members and management and members of the community supporting the proposal to acquire a da Vinci Surgical System. The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming with 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

NA

- (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

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 2010 and CY 2009, respectively. The data in the table were obtained on September 13, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	<b>Total # of Medicaid Eligible as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2008-09 % Uninsured (Estimate by Sheps Center)</b>
Pasquotank County	19.0%	8.4%	21.1%
Perquimans	19.0%	8.6%	21.1%
Dare	11.0%	4.0%	20.8%
Camden	11.0%	4.8%	17.6%
Currituck	11.0%	4.6%	20.2%
Gates	15.0%	7.0%	20.8%
Chowan	23.0%	10.7%	20.8%
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 services proposed in the application.

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 48.6% for those age 20 and younger (Pasquotank County percentage was 30.0% for those age 20 and younger) and 31.6% for those age 21 and older (Pasquotank County percentage was 25.4% 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. Furthermore, OSBM's website does not include information on the number of handicapped persons.

In Section VI.2(a-f), page 78, the applicant states,

*“Albemarle Hospital provides access to its services to all persons regardless of race, sex, religious beliefs, national origin, social status, age, or ability to pay.”*

In Sections VI.12 and VI.13, page 88, the applicant provides the current payor mix for the entire facility and the existing gynecology surgery program (service component) for FY 2011 at Albemarle Hospital, as shown below.

<i>Entire Facility – Last Full Fiscal Year As a Percent of Gross Charges 10/1/2010 through 9/30/2011</i>	
<i>Self Pay / Indigent / Charity</i>	<i>7%</i>
<i>Medicare/Medicare Managed Care</i>	<i>52%</i>
<i>Medicaid</i>	<i>13%</i>
<i>NC BCBS</i>	<i>13%</i>
<i>Managed Care</i>	<i>8%</i>
<i>Other (Commercial Insurance)</i>	<i>7%</i>
<b><i>Total</i></b>	<b><i>100%</i></b>

<i>Service Component – Last Full Fiscal Year As a Percent of Gross Charges 10/1/2010 through 9/30/2011</i>	
<i>Self Pay / Indigent / Charity</i>	<i>6%</i>
<i>Medicare/Medicare Managed Care</i>	<i>16%</i>
<i>Medicaid</i>	<i>15%</i>
<i>NC BCBS</i>	<i>30%</i>
<i>Managed Care</i>	<i>25%</i>
<i>Other (Commercial Insurance)</i>	<i>8%</i>
<b><i>Total</i></b>	<b><i>100%</i></b>

The applicant demonstrates that medically underserved populations currently have adequate access to services offered at Albemarle Hospital. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 87, the applicant states,

*“Albemarle Hospital fulfilled the Hill-Burton requirements regarding the provision of uncompensated care in 1992.”*

In Section VI.10, page 87, the applicant states there have been no civil rights complaints filed against Albemarle Hospital in the past 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.14 and VI.15, pages 89 and 90, the applicant provides the projected payor mix for the entire facility and the service component in the second operating year (FY 2015) following project completion, as shown in the following table.



<b>Entire Facility – 2nd Full Fiscal Year As a Percent of Gross Charges 10/1/2014 through 9/30/2015</b>	
<i>Self Pay / Indigent / Charity</i>	7%
<i>Medicare/Medicare Managed Care</i>	52%
<i>Medicaid</i>	13%
<i>NC BCBS</i>	13%
<i>Managed Care</i>	8%
<i>Other (Commercial Insurance)</i>	7%
<b>Total</b>	<b>100%</b>

<b>Service Component – 2nd Full Fiscal Year As a Percent of Gross Charges 10/1/2014 through 9/30/2015</b>	
<i>Self Pay / Indigent / Charity</i>	6%
<i>Medicare/Medicare Managed Care</i>	16%
<i>Medicaid</i>	15%
<i>NC BCBS</i>	30%
<i>Managed Care</i>	25%
<i>Other (Commercial Insurance)</i>	8%
<b>Total</b>	<b>100%</b>

In Section VI.2, page 78, the applicant states, “*Albemarle Hospital provides access to its services to all persons regardless of race, sex, religious beliefs, national origin, social status, age, or ability to pay.*” Exhibit 38 contains Albemarle Hospital’s Charity and Indigent Care Policy which describes how the facility plans to ensure access to its services by indigent and other medically underserved persons. The applicant demonstrates it will provide adequate access to medically underserved groups. 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 86, the applicant states that all patients will have access to Albemarle Hospital through physician referrals and other healthcare providers throughout the proposed service area. Specific hospitals and healthcare facilities include Sentara Norfolk General Hospital, Pitt County Memorial Hospital, The Outer Banks Hospital, Guardian Care of Elizabeth City, North Carolina Baptist Hospital, Chowan Hospital, and the Neonatal Network for Virginia and North Carolina. In Section VI.9(c), page 86, the applicant states that Albemarle Hospital has already established positive working relationships with each of these agencies. Exhibit 30 includes two sample agreements with these agencies (Sentara Norfolk General Hospital and Pitt County Memorial Hospital). The information provided in Section VI.9 is reasonable and credible. 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

See Section V.1, page 69, the applicant states,

*“Albemarle Hospital has an affiliation with College of the Albemarle to provide clinical practice and observational experiences for students in health science programs. Although initially the program was designated for nursing students only, it has since grown to include the disciplines of surgical technology, medial assisting, phlebotomy and medical lab technology.*

*...Albemarle Hospital intends to train College of the Albemarle students as operating room technicians using the da Vinci Surgical System.”*

Exhibit 29 contains a copy of a letter from Sharon Tanner, Albemarle Hospital Authority President, verifying the intention to train College of the Albemarle students using the system. Exhibit 6 contains a copy of the training agreement with College of Albemarle. The applicant adequately demonstrates that it 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

See Section V.7, pages 75-76, in which Albemarle Hospital discusses how the proposed project will foster competition by promoting cost-effectiveness, quality and access to robotic surgery. 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 include a positive impact on cost-effectiveness, quality and access to acute care services in Pasquotank County and surrounding counties (Perquimans, Currituck, Camden, Chowan, Gates and Dare). The following conclusions are based on a review of the information in Sections II, III, V, VI and VII and the Pro Formas:

- ◆ The applicant adequately demonstrates the need to acquire a da Vinci Si Surgical System and that it is a cost-effective alternative;
- ◆ The applicant proposes to provide quality services; and states:

*“As discussed in previous sections, the benefits of robotic surgery are numerous. Most important is the reduced frequency of invasive procedures, and related reduction in patient blood loss and length of stay in the acute care facility. Enhanced surgical precision should also enhance patient outcomes. Giving patients local access to state-of-the-art medical technology in their community is ideal. Hospitals that once attracted patients away from the service area based on a perceived technological advantage will have to find other ways to draw for patients from the Albemarle Hospital community.”*

- ◆ The applicant proposes to provide adequate access to medically underserved populations.

*“Not all patients who prefer a robotic procedure will have the monetary means to travel to another community to receive one. Additionally, some patients may not feel comfortable receiving care in a different state or unfamiliar city, away from family and friends. Should this application be approved, patients who would have elected not to travel for a robotic procedure because of monetary considerations or a preference to remain near their homes and families would now have access to the most current technology.”*

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

Albemarle Hospital is accredited by the Joint Commission and certified by CMS for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred at Albemarle Hospital 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

Albemarle Hospital proposes to acquire a da Vinci Surgical System. Therefore, the Criteria and Standards for Major Medical Equipment, promulgated in 10A NCAC 14C .3100, are applicable to this review. The application is conforming to all applicable Criteria and Standards for Major Medical Equipment. The specific criteria are discussed below.

### **SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT**

#### ***10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT***

*(a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.*

-C- The applicant used the Acute Care Facility/ Medical Equipment application form.

*(b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.*

-C- In Section II.8, page 33, the applicant states the proposed service area includes Camden, Chowan, Currituck, Dare, Gates, Pasquotank and Perquimans Counties.

*(c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.*

-C- In Section II.8, page 33, the applicant states that Albemarle Hospital is proposing to use the da Vinci Surgical System for hysterectomies and provides historical hysterectomy cases from 2010 through 2012.

*(d) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.*

-C- In Exhibits 22 and 23, the applicant provides a statement from the company which produces the da Vinci Surgical System (Intuitive Surgical) and a letter from the Director of Surgical Services for Albemarle Hospital: both state that the da Vinci Surgical System has been approved by the U.S. Food and Drug Administration for the proposed clinical uses.

*(e) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:*

- (1) receiving/registering area;*
- (2) waiting area;*
- (3) pre-procedure area;*
- (4) procedure area or rooms;*
- (5) post-procedure areas, including observation areas; and*
- (6) administrative and support areas.*

-C- In Exhibit 24, the applicant provides a floor plan of the existing surgical department at Albemarle Hospital, which identifies the areas required by this rule.

*(f) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacture's standards for the type of major medical equipment to be installed.*

-C- In Exhibit 25, the applicant provides a letter dated May 30, 2012 from the Maintenance Director at Albemarle Hospital, which states “*Albemarle Hospital, and the surgical services department, shall continue to meet or exceed all applicable federal, state and local building codes and manufacture’s standards necessary to operate the da Vinci Surgery System.*”

#### **10A NCAC 14C .3104 NEED FOR SERVICES**

*(a) An applicant proposing to acquire major medical equipment shall provide the following information:*

- (1) the number of patients who will use the service, classified by diagnosis;*

-C- In a letter dated September 21, 2012, the applicant provides the projected number of patients who will undergo surgery performed with the proposed da Vinci Surgical System, classified by diagnosis, during the first three years following project completion.

**Forecast of Patients by Diagnosis**

<b>ICD-9</b>	<b>Description</b>	<b>Percent</b>	<b>Year 01</b>	<b>Year 02</b>	<b>Year 03</b>
218.9	Uterine Leiomyoma Nos	35.3%	20	24	26
626.2	Excessive Menstruation	18.8%	11	13	14
617.0	Endometriosis of uterus	7.1%	4	5	5
620.1	Corpus Luteum Cyst	3.5%	2	2	3
625.3	Dysmenorrhea	3.5%	2	2	3
618.04	Rectocele	2.4%	1	2	2
618.4	Uterovaginal Prolapse Nos	2.4%	1	2	2
621.0	Polyp Of Corpus Uteri	2.4%	1	2	2
621.8	Disorders Of Uterus Nec	2.4%	1	2	2
218.2	Subserous Leiomyoma	1.2%	1	1	1
219.0	Benign Neo Cervix Uteri	1.2%	1	1	1
219.1	Benign neoplasm of corpus uteri	1.2%	1	1	1
219.9	Benign Neo Uterus Nos	1.2%	1	1	1
233.1	Ca In Situ Cervix Uteri	1.2%	1	1	1
256.4	Polycystic Ovaries	1.2%	1	1	1
617.3	Pelv Perit Endometriosis	1.2%	1	1	1
618.01	Cystocele, Midline	1.2%	1	1	1
618.09	Oth Prolapse Of Vag Walls Wo Mention Of Uterine Prolapse	1.2%	1	1	1
618.1	Uterine Prolapse	1.2%	1	1	1
620.2	Ovarian Cyst Nec/Nos	1.2%	1	1	1
620.8	Noninfl Dis Ova/Adnx Nec	1.2%	1	1	1
621.2	Hypertrophy Of Uterus	1.2%	1	1	1
621.32	Complex Endometrial Hyperplasia Without Atypia	1.2%	1	1	1
621.33	Endometrial Hyperplasia With Atypia	1.2%	1	1	1
622.11	Mild Dysplasia Of Cervix	1.2%	1	1	1
625.9	Fem Genital Symptoms Nos	1.2%	1	1	1
154.0	Malignant neoplasm of rectosigmoid junction	1.2%	1	1	1
789.03	Abdominal Pain, Right Lower Quadrant	1.2%	1	1	1
	<b>Grand Total</b>	<b>100.0%</b>	<b>57</b>	<b>68</b>	<b>73</b>

(2) *the number of patients who will use the service, classified by county of residence;*

-C- The applicant provides the number of patients who will use the service, classified by county of residence, in Section III.5, pages 56-57 for the 1<sup>st</sup> and 2<sup>nd</sup> year of operation.

**Projected Patient Origin for Hysterectomy Cases  
1<sup>st</sup> and 2<sup>nd</sup> Year of Operation—Fiscal Years 2014-2015**

<b>County of Residence</b>	<b># of Patients FY 1 2014</b>	<b>% of Patients FY 1 2014</b>	<b># of Patients FY 2 2015</b>	<b>% of Patients FY 2 2015</b>
Pasquotank	28	48.4%	33	48.4%
Perquimans	7	13.0%	9	13.0%
Dare	4	7.4%	5	7.4%
Camden	6	9.7%	7	9.7%
Currituck	6	10.2%	7	10.2%
Gates	2	4.1%	3	4.1%
Chowan	2	4.2%	3	4.2%
Other (<1% each)	2	3.0%	2	3.0%
<b>Total</b>	<b>57</b>	<b>100.0%</b>	<b>68 [69]</b>	<b>100.0%</b>

(3) *documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;*

-NA- In Section II.8, page 36, the applicant states that “*Albemarle Hospital does not have a comparable piece of equipment.*”

(4) *quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and*

-C- In Section II.8, page 37, the applicant provides projected quarterly utilization of the proposed da Vinci Surgical System for the first three operating years. Albemarle Hospital does not have an existing da Vinci Surgical System.

**Projected Quarterly da Vinci Surgical System  
Hysterectomy Cases  
Fiscal Years 2014 through 2016**

<b>QTR.</b>	<b>Cases</b>
Oct-Dec	14
Jan-Mar	14
Apr-Jun	14
July-Sep	15
<b>TOTAL Yr. 1 (FY 2014)</b>	<b>57</b>
Oct-Dec	16
Jan-Mar	17
Apr-Jun	17
Jul-Sep	18
<b>TOTAL Yr. 2 (FY 2015)</b>	<b>68</b>
Oct-Dec	17
Jan-Mar	18
Apr-Jun	18
Jul-Sep	19
<b>TOTAL Yr. 3 (2016)</b>	<b>73</b>

(5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*

-C- The assumptions and data supporting the methodology used for the projections in this rule are provided in Section III.8, pages 38-39.

*(b) An applicant proposing to acquire new major medical technology shall provide the following information:*

- (1) the number of patients who will use the service, classified by diagnosis;*
- (2) the number of patients who will use the service, classified by county of residence;*
- (3) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;*
- (4) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;*
- (5) documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and*
- (6) all the assumptions and data supporting the methodology used for the projections in this Rule.*

-NA- Albemarle Hospital is not proposing to acquire new major medical technology as defined in 10A NCAC 14C .3102(4).

#### **10A NCAC 14C .3105 SUPPORT SERVICES**

*An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.*

-C- In Section II.2, page 25, the applicant identifies all necessary ancillary and support services and states “*All required ancillary and support services are currently available through Albemarle Hospital and / or Vidant Health and will be provided to the da Vinci Surgery Program.*” Exhibit 7 contains letters from Albemarle Hospital Authority’s President documenting the availability of these services.

#### **10A NCAC 14C .3106 STAFFING AND STAFF TRAINING**

*(a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:*

- (1) trained and qualified clinical staff shall be employed, and*
- (2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.*



- C- In Exhibit 23, the applicant provides a letter from Albemarle Hospital Authority’s Director of Surgical Services which documents that both trained and qualified clinical staff and trained and qualified technical staff and support personnel shall be employed to operate the proposed da Vinci Surgical System.

*(b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.*

- C- In Exhibit 23, the applicant provides a letter from Albemarle Hospital Authority’s Director of Surgical Services which documents that physicians who will use the equipment will have had relevant residency training, formal continuing medical education courses and prior on-the-job experience with the proposed da Vinci Surgical System.

*(c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:*

- (1) certification in cardiopulmonary resuscitation and basic cardiac life support; and*
- (2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.*

- C- In Exhibit 23, the applicant provides a letter from Albemarle Hospital Authority’s Director of Surgical Services which documents that training will be provided to the staff who will operate the proposed da Vinci Surgical System in cardiopulmonary resuscitation and basic cardiac life support. The letter also documents that an organized program of staff education and training integral to the operation of the proposed da Vinci Surgical System and designed to ensure improvement in technique and the proper training of new personnel will be provided.