

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 25, 2013  
PROJECT ANALYST: Bernetta Thorne-Williams  
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10140-13/ University of North Carolina Hospitals at Chapel Hill/  
Develop eighth vascular interventional radiology procedure room and  
acquire vascular interventional unit to operate at the existing hospital/  
Orange 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 University of North Carolina Hospitals at Chapel Hill proposes to develop an additional vascular interventional radiology (VIR) procedure room and purchase one additional unit of vascular interventional (angiography equipment) for a total of eight VIR rooms upon project completion. The addition of the proposed VIR procedure room would require the relocation of the Wound/Healing/Podiatry Clinic and the HyperBaric Oxygen therapy chamber rooms from their current location on the second floor to the first floor. The project does not require new construction or expansions of the existing facility. The applicant does not purpose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2013 State Medical Facilities Plan (2013 SMFP). However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is applicable to this review.

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need*

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*application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

In Section III.2, pages 41-42, the applicant states:

*"UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan for the VIR project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. ...*

...

*The facility renovation plans and specifications for the project shall be researched and developed by the project architect, with input from facility engineering and administration, to include specific design features to ensure improved energy efficiency and water conservation.*

*UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan that is specific to the project and will address the following systems and features:*

- 1. Lighting Systems – Lighting systems will be renovated, added and upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The changes to the lighting systems shall not adversely affect patient or resident health, safety or infection control.*
- 2. Water Systems – Water systems, hand wash facilities, and toilets will be modified, added and upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency ...*

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3. *Heating, Ventilation, and Air-conditioning (HVAC) Systems – HVAC systems will be renovated, added and upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency ...*
4. *Minor Equipment such as ice machines will be evaluated prior to purchase and implementation based on energy efficiency and water conservation. ...*
5. *Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as UNCH administration.”*

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and 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

The University of North Carolina Hospitals at Chapel Hill proposes to develop an additional vascular interventional radiology procedure room and purchase VIR equipment for a total of eight VIR rooms upon project completion. The addition of the proposed VIR procedure room would require the relocation of the Wound/Healing/Podiatry Clinic and the HyperBaric Oxygen therapy chamber rooms within the clinic from their current location on the second floor to the first floor. The project does not require new construction or expansions of the existing facility.

Population to be Served

In Section III.4(a), pages 43-45, the applicant identifies the population it served, as of June 30, 2012 (Fiscal Year 2012). As North Carolina’s only state-owned, tertiary care referral center, UNC Hospital provided care to residents residing in counties throughout North Carolina with the majority of that care being provided to residents of Orange County. The 2013 SMFP identifies the acute care and vascular interventional radiology service area of UNC Hospitals at Chapel Hill as Orange County. The table below summarizes the historical percentage of patient origin, based on the project analyst’s recalculation of the number of cases/patients served at the acute care facility, as reported on page 44 of the application.

County of	Number of	% Of Patients
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<b>Residence</b>	<b>Patients</b>	<b>All Services</b>
Orange	163,121	24.3%
Wake	90,712	13.5%
Durham	67,182	10.0%
Alamance	64,045	9.5%
Chatham	45,289	6.7%
<b>Sub Total</b>	<b>430,349</b>	<b>64.0%</b>
All Other NC Counties*	229,373	34.2%
Other Counties Outside of NC	11,842	1.8%
International	42	0.06%
<b>Total</b>	<b>671,606</b>	<b>100.0%</b>

\*All other counties include the remaining counties in North Carolina

As illustrated in the above table, Orange, Wake, Durham, Alamance and Chatham Counties represent 64.0% of the patient origin at UNC at Chapel Hill, 34.2% of its patient origin comes from other counties within North Carolina and 1.8% of those patients served at UNC reside in other States.

In Section III.4(b), pages 45-46, the applicant identifies the VIR population it served, as of June 30, 2012 (Fiscal Year 2012). The applicant states that it provided VIR services to patients in 82 of North Carolina's 100 countries. The table below illustrates the five counties with the highest historical percentage of patient origin, as reported on page 46 of the application.

<b>County of Residence</b>	<b>% Of Patients Receiving VIR Services</b>
Wake	13.5%
Orange	10.5%
Alamance	7.2%
Cumberland	5.7%
Chatham	5.4%
<b>Total</b>	<b>42.3%</b>

In Section III.5(c), pages 48-50, the applicant provides the projected patient origin for VIR services for the first two years following completion of the proposed project. An additional 2.8% of those patients who received VIR services at UNC Hospitals at Chapel Hill resided in other States with 54.9% of the VIR population origin residing in other counties throughout North Carolina. The table below illustrates the five counties projected to have the highest patient origin.

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County of Residence	% of patients receiving VIR Services	
	Project Yr 1 (10/1/14-9/30/15)	Project Yr 2 (10/1/15-9/30/16)
Wake	13.49%	13.49%
Orange	10.46%	10.46%
Alamance	7.18%	7.18%
Cumberland	5.73%	5.73%
Chatham	5.42%	5.42%
<b>Total</b>	<b>42.28</b>	<b>42.28%</b>

As illustrated in the table above, the applicant projects that 42.8% of its VIR patient’s origin will come from Wake, Orange, Alamance, Cumberland, and Chatham Counties. An additional 2.77% of its patient origin is projected to come from residence residing outside of North Carolina with 54.9% of its VIR population origin residing in other counties throughout North Carolina. The applicant states that its VIR patient origin for the proposed project will remain consistent with its historical (FY2012) VIR patient origin.

The applicant adequately identifies the population it proposes to serve.

**Need Analysis**

In Section II.1(a), page 14, the applicant discusses the relocation of other services to accommodate the proposed eighth vascular interventional procedure room. The applicant states:

*“The addition of the proposed VIR procedure room involves relocations of existing services with no new construction or expansions. This option allows the new VIR procedure room to be developed in close proximity to the seven existing VIR rooms. ... The proposed new VIR room will utilize space that will be vacated by the relocation of the HyperBaric Oxygen therapy chamber rooms that are within the Wound/Healing/Podiatry Clinic. The scope of the VIR renovations will encompass one exam room and one workroom in an adjoining clinic that are seldom used and will not need to be replaced. ...*

*[T]he Wound/Healing/Podiatry Clinic and HyperBaric Oxygen therapy chambers [will be moved] from the current 2<sup>nd</sup> floor location to the 1<sup>st</sup> floor. This 1<sup>st</sup> floor space is currently occupied by office space of the Inpatient Physical Therapy which is relocating to another space that is already being vacated for a different, unrelated service (formerly Medical Records, which has already relocated off-site). ...”*

In Section III.1, page 30, the applicant states the need for the proposed eighth VIR room and unit is based on the following 4 factors:

- *“The growth and aging of the population of Orange County and North Carolina is expected to increase demand for healthcare services, including VIR procedures.*
- *High utilization of the seven existing VIR procedure rooms causes scheduling difficulties.*
- *Expansion of UNC Hospitals’ acute care capacity will increase inpatient and outpatient utilization as the hospital can accept additional transfer request from other facilities.*
- *Physician recruitment will increase utilization within the VIR Section.*

### Population Growth

In Section III.1, pages 30-31, the applicant states the population for the Health Service Area IV (HSA) is projected to increase by 7.54 percent or 184,667 persons between 2013 and 2018. On page 31, the applicant provides a population projection table for the 13 counties that comprise HSA IV which illustrates a consistent growth in population. The table further illustrates a projected population growth for Orange County of 7 percent or 9,808 persons from 2013-2018. The applicant further states on page 31, that the need for VIR services in Orange County will be greater as the population continues to age. The Orange County population of age 65+ is projected to increase from 15,434 persons in 2013 to 20,172 persons in 2018 which is a 30.7 percent increase in the 65+ age group.

In Section III.1, pages 31-33, the applicant states:

*“UNC Hospitals utilizes minimally-invasive image-guided procedures to diagnose and treat diseases in nearly every organ system. Many conditions that once required surgery can now be treated non-surgically by interventional radiologists. By minimizing the physical trauma to the patient, peripheral interventions can reduce infection rates and hospital stays. ...*

*As the population ages the prevalence of vascular disorders, stroke, cancer and end stage renal disease increases. The five leading causes of death among North Carolinians age 65 and older during 2007 were, in order, heart disease, cancer, stroke, chronic respiratory disease and Alzheimer’s Disease. ...*

...

*As the state’s population continues to grow older, the number of North Carolinians suffering from strokes will likely increase; as the number of stroke survivors increases, demand for VIR procedures is also likely to grow.*

*... The UNC Hospitals Stroke Center is a multidisciplinary program that incorporates state-of-the art approaches in caring for patients with stroke or other cerebrovascular disorders. ...*

*The Stroke Center's multidisciplinary care approach utilizes the expertise of Stroke and Neurocritical Care neurologists and other physicians and staff with specialty training in the treatment of stroke and other TIA ... . The Stroke Team is available 24/7 and coordinates acute treatments, such as intravenous thrombolysis and interventional procedures. VIR procedures are often performed very soon after a patient is admitted in order to expedite the diagnosis and treatment of strokes.*

*Another patient population that has a high utilization of VIR procedures is patients with end stage renal disease who have need for dialysis. End stage renal disease prevalence has increased at a dramatic rate:*

- *At the end of 2009, more than 871,000 people were being treated for ESRD.*
- *...*
- *...*
- *ESRD patients often require vascular access procedures that include arteriovenous (AV) fistula, an AV graft, or a catheter and other dialysis access.*

*UNC Hospitals' VIR procedure rooms are often utilized to perform renal intervention, ablation of kidney masses, dialysis access maintenance, and central venous access."*

In Section III.1, pages 33-35, the applicant states:

*"Increased future demand for VIR procedures is based on the need to provide timely access for a wide range of high acuity patients that are routinely admitted to UNC Hospitals. UNC Hospitals provides ... depth and continuity of acute and rehabilitative services as a Level 1 Trauma Center, an academic medical facility, and the main teaching hospital for the University of North Carolina School of Medicine. ...*

*...*

*Over the past several years the beds available to accommodate a specific patient's needs were often full, making it difficult to accept all transfer requests. Since UNC Hospitals is a quaternary referral hospital, trauma center, and provider of specialty care for complex diseases affecting patients from all areas of North Carolina, this problem is of great concern. ... In October 2012, 23 additional acute care beds became licensed. This boost in acute care admissions further strengthened by increasing the number of ICU beds in proportion to medical surgical beds. As the mix of ICU beds increases, UNC Hospitals will be positioned to accept more transfers of high acuity patients (stroke, trauma, brain and spinal cord injury, and burns) from other hospitals; the ongoing increases in UNC*

*acute care capacity will generate higher demand for VIR procedures to provide timely and appropriate patient care.”*

Utilization of Existing Equipment

In Section III.1, page 35, the applicant states as a result of the changing of CPT codes for VIR procedures it is difficult to compare the historical number of procedures performed at UNC Hospitals with projected procedures in the future. Therefore, the applicant based its projected utilization on historical VIR cases which is the same number as VIR patients. On pages 35-36, the applicant states:

*“The seven existing VIR procedure rooms (excluding OR 22 and the c-arm procedure room at Meadowmont) are currently operating at high utilization due to the tremendous depth of the types of vascular procedures that are needed by both inpatients and outpatients. Also the VIR equipment and procedure rooms are intensively utilized for teaching medical students and residents. ...*

	<b>FY11</b>	<b>FY12</b>	<b>YTD FY13 (10 months)</b>	<b>FY13 Annualized</b>
<i>VIR Main Cases (7 Units Angiography Equipment)</i>	7,693	7,992	6,761	8,113

*Source: UNC Hospitals records (Fiscal years are July 1<sup>st</sup> to June 30<sup>th</sup>)  
 FY2013 is based on 10 months’ of actual data that is annualized.*

*The studies most frequently performed in the Vascular Interventional Radiology Section at UNC Hospitals include: abdominal aortogram, aorto-femoral angiogram, arch aortogram, renal angiogram, pulmonary angiogram, visceral angiogram, neuro angiogram, venous catheter placement, drainage catheter placement, tumor ablation, vessel embolism, angioplasty, etc. The Vascular Interventional Radiology Section’s radiologist treat aneurysms, arteriovenous malformations, internal bleeding, blood clots (using clot dissolving thrombolytic therapy), vena cava filter insertions, chemoembolizations, renal hypertension, infections and abscesses, urinary tract obstructions, and other conditions without using surgery. Additional VIR capacity is needed to respond to the growth in demand and provide timely patient access.*

*In 2011, UNC Hospitals’ Center for Heart & Vascular Care at Meadowmont began operation with some types of low complexity outpatient interventional vascular procedures that are performed with a portable C-arm unit instead of a more advanced fixed angiography equipment that is utilized in the seven VIR angiography procedure rooms at UNC Hospitals.*



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*Even with this shift of hundreds of low complexity vascular cases per year to Meadowmont ... the remaining number of cases at the seven VIR procedure rooms has seen continued growth. In addition, the types of cases that are performed in these seven VIR procedure rooms include high complexity cases with multiple procedures.”*

In Section III.1, page 36, the applicant demonstrates that the seven current VIR angiography units and procedure rooms are operating at nearly full capacity, as illustrated in the table below.

***Historical and Current Year***

	<b>FY12</b>	<i>FY 2013 Annualized</i>
<b><i>VIR Cases</i></b>	7,992	8,113
<b><i>VIR Case Hours (Cases x 2.6 hrs)</i></b>	19,980	20,283
<b><i># VIR Rooms</i></b>	7	7
<b><i>Annual Hours Capacity</i></b>	21,242	21,242
<b><i>Capacity Calculation</i></b>	94.06%	95.49%
<b><i>(Total Case Hours / Annual Available Hours)</i></b>		

The applicant provides its assumptions for the above calculations on page 36. The applicant states:

*“VIR cases are based on UNC Hospitals records for the 7 VIR rooms and excludes cases performed in OR 22 and Meadowmont because those rooms have different uses and / or types of equipment. The total cases seen in the above table include on-call VIR cases.*

*VIR case hours is based on the current average of 2.5 hours per case.*

*Annual hours of operation for the current seven VIR rooms is 21,242 hrs [sic] is based on staffed availability hours for scheduled procedures.*

*On-call staff provide all required procedures beyond the Monday – Friday hours including urgent and emergent services such as those required by stroke patients. These services are available 24 hours per day to meet emergent patient needs and must be available on-site to accommodate critical inpatients.”*

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Projected Utilization

In Section IV.1(d), page 52, the applicant provides historical and projected vascular intervention radiology utilization projections by fiscal years (July 1 – June 30), for the proposed project, as illustrated in the tables below.

	<b>Prior Full FY 2011</b>	<b>Last Full FY 2012</b>	<b>Current Full FY 2013 (10 months)</b>	<b>Interim FY 2014</b>
# of Units /Rooms	7	7	7	7
# of Cases	7,992	8,113	6,761*	8,519
# of Procedures (cases x 2.91)	22,771	23,177	24,215	24,799

\*FY2013 data reflects data based on 10 months of actual data that was annualized as reported in Section III.1, pages 35 and 53 of the application.

	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>
# of Units /Rooms	7 / 8	8	8	8
# of Cases	8,774	9,038	9,309	9,558
# of Procedures (cases x 2.91)	25,541	26,310	27,099	27,911

The applicant’s assumptions and methodology used to project utilization are provided in Section IV, pages 52-57, which are condensed and described as follows:

*“VIR cases performed in the 7 procedure rooms in FY 2012 totaled 7,992, which was a 3.9 percent increase over the previous year’s volumes. FY 2013 is projected to total 8,113 VI cases based on 10 months’ annualized data for a 1.5 percent annual increase. The 2013 year-to-date volume for the 7 VIR procedure rooms has been somewhat constrained due to VIR room # 4 being taken out of service from September 2012 through February 2013 for equipment replacement.*

*The methodology and assumptions for future years’ projections are based on the most recent annualized VIR cases and utilization statics for FY 2013.*

*In FY 2014, UNC Hospitals conservatively projects 5 percent annual growth in total VIR cases based on the addition of Dr. Ari Isaacson to the existing VIR facility (6 physicians) beginning in July 2013.*

*For FY 2015, FY 2016 and FY 2017, UNC Hospitals projects 3 percent annual growth based on the addition of previously approved inpatient acute care beds, which will increase capacity and allows for the acceptance of additional patient transfers plus the*

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*growth in demand for outpatient VIR procedures due to population growth and continued expansion of referral relationships. ...*

On page 53, the applicant provides a table which illustrates with the projected 3% growth rate in VIR procedures by FY 2014, UNC Hospitals' 7 VIR rooms will have 21,298 cases hours [8,519 cases x 2.5 hours (average time per procedure) = 21,297.5]. The applicant states on page 36 that the annual hours of capacity for the seven VIR procedure rooms is 21,242 hours which is based on "staffed availability hours for scheduled procedures." Based on this capacity the seven VIR procedure rooms would be operating at 100.3% capacity by FY 2014. The applicant provides its assumptions and methodology for UNC Hospitals VIR procedure rooms in Section IV.2, page 56, as summarized in the table below.

<b># of Existing VIR Rooms</b>	<b>Days / Hours of Operation</b>	<b>Weekly Available Hours</b>	<b>Totals</b>
5	Monday – Friday 7:30 a.m. – 6:00 p.m. 5 days per week	M-F 237.5 [9.5 hrs x 5 days = 47.5 x 5 rooms = 237.5]	M-F 237.5
2	Monday – Friday 7:30 a.m. – 6:00 p.m. 5 days per week + Saturday & Sunday 7:00 a.m. – 7:00 p.m.	[2 rooms x 7 days = 14 x 9.5hrs = 133] + [11.5 hrs x 2 days = 23 x 2 rooms = 46] [133+ 46 = 179]	Sat-Sun 179
<b>Total Weekly Hours for 7 VIR Rooms</b>			4,165
<b># of Weeks operational per year</b>			x 51
<b>Annual staffed hours for 7 VIR Rooms</b>			21,241.5
<b>Averaged hours per room (21,241.5 hrs / 7 rooms = 3,034.5)</b>			3,035
<b>VIR Cases Average 2.5 hrs</b>			2.5
<b>Annual Capacity of Cases per VIR Room 1,214</b>			1,214
<b>VIR Cases average 3.37 procedures</b>			3.37
<b>Annual capacity of VIR procedures per room (1,214 cases per room x 3.37 average # of procedures per case = 4,091.18)</b>			4,091

The following table illustrates the projected utilization for the proposed 8<sup>th</sup> VIR procedure room and equipment as reported by the applicant on page 56.

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# of Proposed VIR Room	Days / Hours of Operation	Weekly Available Hours	Totals
1	Monday – Friday 7:30 a.m. – 6:00 p.m. 5 days per week	M-F 237.5 [9.5 hrs x 5 days = 47.5	M-F 47.5
<b>Total Weekly Hours for 1 VIR Room</b>			47.5
<b># of Weeks operational per year</b>			x 51
<b>Annual staffed hours for 1 VIR Room</b>			2,422.5
<b>Annual staff hours available for the existing 7 VIR procedure rooms</b>			21,242
<b>Total projected hours for 8 VIR procedure rooms (21,242 existing 7 rooms + 2,422.5 proposed room = 23,664.5)</b>			23,665
<b>Average annual hours per VIR room (23,665 hrs / 8 rooms = 2,958.06)</b>			2,958
<b>VIR Cases Average 2.5 hrs</b>			2.5
<b>Annual Capacity of Cases per VIR Room 1,183</b>			1,183
<b>VIR Cases average 3.37 procedures</b>			3.37
<b>Annual capacity of VIR procedures per room (1,183 cases per room x 3.37 average # of procedures per case = 3,986.71)</b>			3,987

The applicant states on page 57, that based on the historical utilization and the projected 3 percent growth rate, with eight VIR procedure rooms, UNC is projected to reach 99.1% capacity by project year 3 (2017), as illustrated in the table below.

	<b>PY 1 10/1/14 – 9/30/15</b>	<b>PY 2 10/1/15 – 9/30/16</b>	<b>PY 3 10/1/16 – 9/30/17</b>
# of Units /Rooms	8	8	8
# of Cases	8,837	9,103	9,376
# of Procedures (cases x 2.91)	25,726	27,525	27,294
Annual Capacity Cases	9,464	9,464	9,464
Capacity Percentage	93.4%	96.2%	99.1%

The applicant adequately demonstrated the need to develop an eighth vascular interventional radiology room and to acquire an eighth vascular interventional unit to “*expand capacity and patient access and treatment choices.*” The applicant also adequately demonstrated the need to relocate the Wound Care and Hyperbaric Chambers from the second floor to the first floor to accommodate the renovation of the existing space for the additional vascular interventional

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radiology procedure room. Furthermore, the applicant adequately demonstrates the need for the proposal for all of the following reasons:

- 1) The applicant does not propose any new construction or expansion of the existing facility;
- 2) University of North Carolina Hospitals at Chapel Hill is one of five academic medical center teaching hospitals in North Carolina and the only state-owned teaching hospital in North Carolina; and
- 3) the addition of an eighth vascular interventional procedure room will maximize efficiency for patients requiring inpatient and outpatient vascular interventional procedures.

**Access**

In Section VI.2, page 63, the applicant states:

*“UNC Hospitals has traditionally provided services to a wide variety of patient groups. Listed below is a table providing utilization percentages for UNC Hospitals as a whole and the applicable service components during FY 2012:*

**Medically Underserved  
 FY12 as of 3/14/13**

	<i>Low Income</i>	<i>Racial &amp; Ethnic Minorities</i>	<i>Women</i>	<i>Elderly</i>	<i>Other Underserved</i>
<b>Total Hospital</b>	17.4%	36.7%	59.2%	22.3%	10.3%
<b>VIR Main</b>	19.1%	40.4%	51.2%	26.7%	5.5%

*Low Income = Medicaid and ½ of Medicaid Pending  
 Other Underserved = Self Pay and ½ of Medicaid Pending”*

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. 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.

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- (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 42-43, the applicant describes several alternatives considered which include the following:

- 1) Maintain Status Quo – UNC considered maintaining the status quo, however, the applicant concluded this option was impractical based on the high utilization of the existing equipment and rooms.
- 2) Alternative Location / Configuration within VIR Department – UNC facilities staff and architects evaluated alternative locations within the VIR department. However, this alternative was rejected as it would have required more comprehensive and costly renovations.
- 3) Potential Alternative Location for Ancillary Service Relocation – UNC continues to evaluate an alternative relocation for the Wound Care and Hyperbaric Chambers to an existing hospital-owned space at Meadowmont in Chapel Hill. The applicant notes that should UNC Hospitals at Chapel Hill elect to pursue this alternative the total capital costs for the relocation would be comparable to the proposed relocation within the hospital and the applicant would provide the CON Section with an appropriate and timely request.
- 4) Relocation / Expansion of the Entire Vascular Interventional Service – UNC briefly considered relocating its entire VIR service and adding the eighth procedure; however, this alternative was rejected as the project would have been too costly and would have not been implemented for years due to having to relocate other departments, thus resulting in the delay of needed additional vascular interventional radiology equipment and procedure room.
- 5) Develop the Project as Proposed – the applicant concluded developing the project as proposed held the best combination of being a timely and cost effective alternative. Thus, the applicant concluded that this was UNC's least costly and most effective alternative to meet the growing need for vascular interventional radiology services.

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

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need to expand its vascular interventional services. The application is conforming to this criterion and approved subject to the following conditions.

- 1. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in its certificate of need application.**
  - 2. University of North Carolina Hospitals at Chapel Hill 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 which would otherwise require a certificate of need.**
  - 3. University of North Carolina Hospitals at Chapel Hill shall acquire no more than one angiography imaging equipment system to operate in the eighth vascular intervention radiology procedure room in the existing hospital.**
  - 4. University of North Carolina Hospitals at Chapel Hill shall submit a plan of energy efficiency and water conservation to the Construction Section, DHSR, that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation.**
  - 5. Prior to issuance of the certificate of need, University of North Carolina Hospitals at Chapel Hill shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 79, the applicant states that the total capital cost of the project will be \$5,983,544, including \$2,584,000 for construction contract costs, \$2,380,544 for movable equipment costs, \$136,000 for furniture costs, \$497,000 for architect and engineering costs, and \$386,000 for contingency costs. In Section IX, page 84, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. In Section VIII.3, page 80, the applicant states that the project will be funded through UNC at Chapel Hill owner's equity. Exhibit 24 contains a June 10, 2013 letter signed by the Executive Vice President and CFO for UNC Hospitals, which states:

*"This letter is to confirm the availability of funding in excess of \$5,983,544 specifically for use for the capital costs associated with the development of the above referenced project. ..."*

Exhibit 25 of the application contains the audited financial statements for UNC at Chapel Hill for the year ending June 30, 2012. As of June 30, 2012, UNC had \$144,227,747 in cash and

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cash equivalents and \$1,187,798,914 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In pro forma financial statements for UNC's vascular interventional radiology services (Form C), the applicant projects revenues will exceed expenses in each of the first three operating years for its vascular services, as shown in the table below:

**UNC Hospitals Vascular Services**

	FY 2016	FY 2017	FY 2018
Total Net Revenue	\$21,108,655	\$22,828,667	\$24,688,508
Total Expenses	\$16,618,018	\$17,242,034	\$17,894,069
Net Income	\$4,490,637	\$5,586,633	\$6,794,439

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and 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

The applicant proposes to acquire an eighth vascular interventional unit (angiography equipment) and to develop an eighth vascular interventional radiology procedure room. The vascular interventional unit and procedure room will be located on the second floor, in space vacated by the relocation of Wound/Healing/Podiatry Clinic and the HyperBaric Oxygen, near existing VIR services. The applicant proposes to relocate the Wound/Healing/Podiatry Clinic and the HyperBaric Oxygen therapy chamber rooms to the first floor. The project does not require new construction or expansions of the existing facility.

The applicant does not propose to acquire any new beds or to offer any new services. As stated in Criterion (3), despite the applicant's shift of patients to Meadowmont where low complexity vascular interventional procedures can be performed on the less costly portable C-arm equipment, the utilization in the seven VIR rooms continues to increase. The applicant adequately demonstrates the need for all components of its proposal. See Criterion (3) for the discussion regarding the need for the proposal which is incorporated hereby as if fully set forth herein.

The applicant currently provides VIR services in Orange County. Utilization of the existing seven VIR rooms operated at over 94% capacity in FY2012. Currently, the VIR rooms are operating at over 80% capacity [6,761 cases x 2.5 hours (average time per procedure) =



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16,902 / 21,242 (average hours of capacity for the seven VIR procedure rooms) = 79.56). This is based on FY13 actual data for 10 months (annualized), as reported in Section III.1, pages 35 and 53 of the application. With the addition of the 8<sup>th</sup> vascular interventional unit, UNC at Chapel Hill is projected to exceed 90% capacity by the end of Project Year 1.

The applicant adequately demonstrates the project will not result in the unnecessary duplication of existing or approved acute care services in the Orange County service area. Consequently, 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) and (b), pages 72-73, the applicant provides the current and projected staffing during the second full fiscal year for the eighth vascular interventional procedure room, as illustrated in the table below.

	CURRENT FTES	PROJECTED FTES FY 2017
Imaging Nursing Mgr	0.4	0.4
Clinical Nurse (RN)	16.5	17.6
VIR Program Director	0.1	0.1
VIR Supervisor	1.0	1.0
VI Techs	18.5	19.6
Health Unit Clerk	3.5	3.5
<b>Grand Total</b>	<b>40.0</b>	<b>42.2</b>

As illustrated in the above table, the applicant projects to add 2.2 full-time equivalent (FTE) (1.1 vascular interventional technologists and 1.1 clinical nurses) positions by the second full fiscal year following completion of the proposed project. Furthermore, in Section VII.3(a), page 73, the applicant states:

*“The staffing for VIR services will be increased by 2.02 additional FTEs. ... The current levels for the other existing budgeted VIR staff positions is sufficient to provide schedule services for all of the VIR procedure rooms including on-call coverage.”*

In Section VII.6(a) and (b), pages 74-75, the applicant provides UNC’s recruitment and staff retention plan. In Section VII.8(a), page 76, the applicant states Dr. Matthew Mauro serves as the Chairman of the Department of Radiology and the Professor of Surgery at the UNC Hospitals at Chapel Hill School of Medicine and Dr. Charles Burke is the Associate Professor of Radiology, Division Chief and Fellowship Program Director for VIR services. See Exhibit 2 for copies of the physician’s curricula vitae. The applicant demonstrated the availability of adequate health

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manpower and management personnel to provide the proposed services, and 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

The applicant currently provides vascular services and the necessary ancillary and support services are currently available. In Section II.2(a), page 15, the applicant states:

*“The proposed project is for the expansion of an existing service with the addition of one VIR procedure room and equipment and includes the relocation of existing hyperbaric chambers and clinic services. All ancillary and support services are currently available. No additional staff is needed for the ancillary and support services.”*

See Exhibit 6 of the application for a copy of a letter from Dr. Brian P. Goldstein attesting to the availability of ancillary and support services. Exhibit 3 contains letters of support from physicians for the proposed additional vascular interventional unit and procedure room. 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 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

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(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 and VI.13, pages 63-64, the applicant provides the payor mix during FY 2012 for the entire hospital and the vascular services department, as illustrated in the table below:

UNC Hospital FY 2012 (7/1/11-6/30/12) Patient Days/Procedures as a % of Total Utilization		
	Entire Facility	Vascular Services
Self Pay / Indigent / Charity	5.3%	5.5 %
Medicare/Medicare Managed Care	30.4%	42.9%
Medicaid	31.3%	19.1%
Commercial Insurance	1.1%	0.8 %
Managed Care)	26.2%	26.6%

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Other	5.8%	5.1%
Total	100.0%	100.0%

In Section VI.2, page 63, the applicant states:

*“As North Carolina’s only state-owned comprehensive, full service hospital-based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance.*

*The facility is designed in accordance with the latest State of North Carolina and Federal guidelines for handicapped accessibility. ... ”*

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.

	<b>Total # of Medicaid Eligibles as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Orange County	9.0%	3.5%	18.9%
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 peripheral vascular services proposed in this 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 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 applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at UNC Hospitals at Chapel Hill. 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, pages 69-70, the applicant states:

*“UNC Hospitals has long since satisfied its “free care” obligation under the Hill-Burton Act. UNC Hospitals provides care to all persons based only on their need for care and without regard to minority status, handicap/disability, or ability to pay.”*

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See Exhibit 22 for a copy of the applicants' Policy and Procedure regarding UNC's admission and discharge policies.

In Section VI.10 (a), page 69, the applicant states that no Office of Civil Rights complaints have been filed against UNC Hospitals in last five years. Therefore, 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(a) and (b), page 71, the applicant provides the projected payor mix for the second full fiscal year of operations for the entire hospital and the vascular services department for the proposed second year of service (July 1, 2015 – June 30, 2016), as illustrated in the table below:

UNC Hospital Projected Utilization Patient Days/Procedures as a % of Total Utilization		
	Entire Facility	Vascular Services
Self Pay / Indigent / Charity	5.3%	5.5 %
Medicare/Medicare Managed Care	30.4%	42.9%
Medicaid	31.3%	19.1%
Commercial Insurance	1.1%	0.8 %
Managed Care)	26.2%	26.6%
Other	5.8%	5.1%
Total	100.0%	100.0%

On page 71, the applicant states the projected payor percentages are based on FY 2012 actual percentages with no change in payor mix percentages projected.

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services. 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(a), pages 66-67, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity 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 58, the applicant states UNC Hospitals has established relationships with area health professional training programs. As the only state-owned hospital in North Carolina, UNC Hospitals' VIR program is used for medical rotation for medical residents and fellows as well as multiple health professional training programs. Exhibit 15 contains copies of UNC's training program affiliation agreements. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity 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

The applicant operates the only state-owned academic medical center in North Carolina and is the only acute care hospital in the Orange County service area. UNC is the only provider of inpatient and outpatient vascular interventional services in the applicant's service area. The applicant proposes to develop an additional VIR procedure room and purchase VIR equipment for a total of eight VIR rooms upon project completion. The addition of the proposed VIR procedure room would require the relocation of the Wound/Healing/Podiatry Clinic and the HyperBaric Oxygen therapy chamber.

In Section V.7, pages 61-62, 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. The applicant states

*“UNC Hospitals is an existing provider of VIR procedures. This project is designed to enhance the provision of timely, quality patient care, and to assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research and community service. The project will foster competition by promoting improved patient access and advance cost effectiveness and quality of VIR services.*

...”

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 purchase additional vascular interventional equipment, develop an eighth VIR procedure room and relocate existing services and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that UNC Hospitals at Chapel Hill has and will continue to provide quality services; and
- ◆ The applicant demonstrates that UNC Hospitals at Chapel Hill has and 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

The University of North Carolina Hospitals at Chapel Hill is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Licensure and Certification Section, Division of Health Service Regulation, 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 with all applicable Criteria and Standards for Major Medical Equipment, promulgated in 10A NCAC 14C .3100. 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- UNC 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, page 20, the applicant defined the service area for the proposed service as Orange County, as defined in the 2013 SMFP. However, the applicant also states the service area includes most of North Carolina.
- (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, page 20, the applicant describes its experience in providing VIR services as being extensive.
- (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

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institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.

- C- See Exhibit 13 for a letter that documents the proposed equipment is approved for use by the U.S. Food and Drug Administration.
  
- (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 Section II, page 21, the applicant states, *“Please see the facility plans in Exhibit 5. The above listed spaces are labeled.”*
  
- (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- Exhibit 15 contains a letter dated June 11, 2013 from the President of UNC Hospitals which documents that the VIR procedure room will 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.

**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- See Exhibit 4 for the number of patients projected to use the VIR services, classified by diagnosis for the first three years of operations for the proposed equipment. The applicant states in Section II, page 21, that UNC assumes the percentages of patients by diagnosis that receive VIR procedures in the future will remain consistent with the actual percentages for UNC Hospitals at Chapel Hill VIR services in FY2012.
  - (2) the number of patients who will use the service, classified by county of residence;

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- C- In Section II, pages 21-22, the applicant provides the number of patients who will use the service, by classification and county for the first two years of operations for the proposed VIR procedure room. The applicant assumes that patient origin percentages in the future will remain consistent with the actual percentages of UNC Hospitals at Chapel Hill VIR services in FY2012. The counties that are projected to have a 4% or higher patient origin are illustrated in the table below:

<i>County</i>	<i>Project Yr 1 2016</i>		<i>Project Yr 2 2017</i>	
	<i>Cases</i>	<i>% of Total</i>	<i>Cases</i>	<i>% of Total</i>
<i>Alamance</i>	635	7.18%	654	7.18%
<i>Chatham</i>	479	5.42%	505	5.42%
<i>Cumberland</i>	506	5.73%	533	5.73%
<i>Durham</i>	389	4.40%	409	4.40%
<i>Lee</i>	352	3.98%	363	3.98%
<i>Orange</i>	924	10.46%	952	10.46%
<i>Wake</i>	1,192	13.49%	1,228	13.49%
<b><i>Total</i></b>	<b>4,477</b>	<b>50.66%</b>	<b>4,644</b>	<b>50.66%</b>

The applicant further states on page 22, that 2.77% of the total percentage of patients who receive VIR services come from areas outside of North Carolina with the other counties in North Carolina representing 46.57% of the total percentage of patients receiving VIR services at UNC Hospitals at Chapel Hill.

- (3) documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;
- C- In Section II, page 23, the applicant provides the maximum number of procedures that existing equipment used for similar procedures in the facility is capable of performing. The applicant states, *“The seven existing VIR procedure rooms have an annual capacity of 1214 cases per procedure room. Each VIR case currently averages 2.91 procedures per case. Therefore the annual capacity is 4091 procedures per VIR room.”*
- (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, pages 23-25, the applicant provides the following quarterly projected utilization for the proposed equipment for the first three years following completion of the proposed project, as summarized in the table below:

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Description	Projected Patients		
	FY 15	FY 16	FY 17
# of VIR Units	7*/8	8	8
Quarter 1 (July-Sept):			
• Cases	2,106	2,169	2,234
• Procedures	6,130	6,314	6,504
Quarter 2 (Oct-Dec):			
• Cases	2,281	2,350	2,420
• Procedures	6,641	6,841	7,046
Quarter 3 (Jan-Mar):			
• Cases	2,106	2,169	2,234
• Procedures	6,130	6,314	6,504
Quarter 4 (Apr-June):			
• Cases	2,281	2,350	2,420
• Procedures	6,641	6,841	7,046
<b>Total Cases</b>	<b>8,774</b>	<b>9,038</b>	<b>9,309</b>
<b>Total Procedures</b>	<b>25,541</b>	<b>26,310</b>	<b>27,099</b>
<b>Annual Projected Capacity</b>	<b>93%</b>	<b>95.5%</b>	<b>98.3%</b>

\*First quarter of FY2015 is the only quarter projected to have 7 units of VIR equipment. All other quarters are projected to have 8 units.

- (5) all the assumptions and data supporting the methodology used for the projections in this Rule.
- C- The applicant provides the assumptions and methodology used in Section IV, pages 52-57.
- (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- In Section II, page 28, the applicant states UNC Hospitals at Chapel Hill does not propose to acquire new major medical equipment as defined by 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- See Exhibit 6 for documentation that UNC Hospitals at Chapel Hill currently and will continue to provide all ancillary and support services that are required to support the VIR procedure rooms.

**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

-C- See Section VII, pages 72-77 and Exhibit 16 for documentation of the clinical staff job qualifications and training. See Exhibit 10 for job position summaries, training requirements and mandatory classes/training. Exhibit 2 contains the curriculum vita for the physicians.

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

-C- See Section VII, pages 72-77 and Exhibit 10 for documentation concerning the trained technical staff and support personnel qualifications. As the only acute care provider of inpatient and outpatient VIR services in Orange County, UNC Hospitals at Chapel Hill currently has the necessary trained staff and support personal currently in place.

(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.

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- C- Exhibit 2 contains the curricula vitae for the physicians that will have medical oversight of the proposed VIR procedure room and equipment. See Exhibit 14 for physician credentialing information.
  
- (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- See Exhibit 10 for documentation of the clinical staff job qualifications and training including CPR and basic cardiac life support and training requirements.