

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 16, 2015

Findings Date: October 16, 2015

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: P-11050-15

Facility: Wayne Memorial Hospital

FID #: 933535

County: Wayne

Applicant: Wayne Memorial Hospital, Inc.

Project: Expand and renovate space at its main hospital campus related to the provision of surgical and endoscopy services which involves a change of scope for Project ID#P-7554-09 (add one operating room) and developing two new hybrid operating rooms

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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 applicant, Wayne Memorial Hospital, Inc. (WMH) proposes to expand and renovate space at its main hospital campus related to the provision of surgical and gastrointestinal (GI) endoscopy services. This proposal also involves a change of scope for Project ID#P-7554-09 (add one operating room) and the acquisition of two angiographic endovascular

imaging systems to develop two hybrid operating rooms (ORs) in renovated OR space and new construction on the ground floor of WMH.

### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to the review of this application.

### **Policies**

There is one policy on page 39 in the 2015 SMFP that is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities. 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 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.”*

The proposed capital expenditure for this project is greater than \$2 million. The applicant addresses Policy GEN-4 in Section III.2, pages 77-78, and Section XI.7, pages 137-138. On page 77, the applicant states,

*“WMH is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. ...”*

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation to meet the requirements for Policy GEN-4. See Condition #3 in Criterion (4).

**Conclusion**

In summary, the application is consistent with Policy GEN-4, and therefore is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to expand and renovate space at its main hospital campus related to the provision of surgical and GI endoscopy services. WMH submitted this proposal to overcome age-related facility deficiencies and to increase the efficiency of surgery services. This proposal involves a change of scope for Project I.D.# P-7554-09 (add one operating room) and the acquisition of two angiographic endovascular imaging systems to develop two hybrid ORs in renovated OR space and new construction on the ground floor of WMH.

WMH currently has 12 ORs in its OR inventory. A listing of WMH’s ORs by type is illustrated below in the table:

<b>WMH 2015 Operating Room Inventory*</b>	
<b>Type</b>	<b>Number</b>
Dedicated Open Heart Surgery	0
Dedicated C-Section	1
Other Dedicated Inpatient Surgery	0
Dedicated Ambulatory Surgery	0
Shared - Inpatient/Ambulatory Surgery	12
<b>Total Surgical ORs</b>	<b>13</b>
*Source: 2015 Hospital License Renewal Application	

In Section II.1(a), pages 23-25, the applicant states that the proposed angiographic endovascular imaging equipment is designed for imaging in the operating room environment. The applicant further states:

*“The proposed system is the first multi-axis system based on robotic technology that can be positioned in various configurations desired by surgeons. ... The system enables image-guided surgery without the limitations of conventional systems in the operating room environment and reduces interference with anesthesia equipment. Further, the system enables the performance of pre-operative diagnostics and post-operative evaluation with immediate results. In addition, ergonomically designed controls streamline workflow and help staff function more efficiently. ...”*

In addition, the applicant states that the proposed equipment will take faster images that result in better image quality and greater patient comfort and will also reduce radiation exposure for the patient, staff and physician. In summary, the applicant states, on page 25, *“The system’s advanced imaging capabilities enhance the decision making of clinicians and facilitate faster and more effective procedures.”*

### **Population to be Served**

On page 60, the 2015 SMFP defines the service area for operating rooms as the operating room planning area in which the operating room is located with the exception of any multi-county planning areas. Thus, in this application, the planning area is Wayne County. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a) and (b), pages 81-82, the applicant provides the current patient origin by county of residence for general acute care admissions, ORs and GI endoscopy rooms for FFY 2014, as shown in the following table:

<b>WMH General Acute Care, OR and GI Endoscopy Patient Origin FFY2014</b>			
<b>County</b>	<b>Acute Care</b>	<b>OR</b>	<b>GI Endoscopy</b>
Wayne	83.7%	78.2%	86.0%
Lenoir	5.4%	7.2%	3.6%
Johnston	2.8%	5.0%	2.7%
Duplin	2.7%	3.2%	2.8%
Sampson	2.7%	2.5%	2.2%
Other*	0.8%	3.8%	2.7%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

\*Other includes additional counties in NC and other states as listed in Section III.4, pages 81-82. Note: totals may not foot due to rounding.

The applicant states, in Section III.5(a), page 82:

*“WMH projects that Wayne County will remain the primary service area for its operating room and GI endoscopy room patients while Duplin, Sampson, Lenoir, and Johnston counties will comprise the secondary service area. Wayne County accounts for 78 and 86 percent, respectively, of operating room and GI Endoscopy room patients in the most recent full fiscal year (FFY 2014) whereas Duplin, Sampson, Lenoir, and Johnston counties together accounted for approximately 18 percent and 11 percent of patients, respectively.”*

The applicant provides projected patient origin by county of residence for the proposed project for the first two full years of operation following completion of the project in Section III.5(c), page 84, as illustrated below:

<b>WMH Projected Patient Origin OR and GI Endoscopy Project Years 1 &amp; 2</b>		
<b>County</b>	<b>Projected OR Patient Origin (PY 1 &amp; 2)</b>	<b>Projected GI Endoscopy Patient Origin (PY 1 &amp; 2)</b>
Wayne	78.2%	86.0%
Lenoir	7.2%	3.6%
Johnston	5.0%	2.7%
Duplin	3.2%	2.8%
Sampson	2.5%	2.2%
Other*	3.8%	2.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>
*Other includes additional counties in North Carolina and other states as listed in Section III.5(c), page 84. Note: totals may not foot due to rounding.		

In Section III.5(d), page 85, the applicant states that its projected patient origin is based on its historical data and no changes in patient origin are anticipated as a result of this project.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section III.1(a), page 49, the applicant states that WMH has been in its current facility since 1970 and although the facility has been well maintained, it is now significantly aged and has been forced to accommodate multiple services of a size and scope that were not foreseen when WMH moved into this facility 45 years ago. The applicant further states,

*“As a result, the primary need for this project is to remedy age-related facility deficiencies and renovate and expand the existing facility to enable the hospital to*

*continue to provide and support ... patient care both now and in the future, particularly as it relates to surgical and endoscopy services.*

*... the project proposes to add approximately 39,773 square feet to the existing facility and to renovate approximately 49,397 square feet of existing space. As shown on the proposed line drawings, included in Exhibit 5, the proposed project includes the following departments: operating rooms, operating room support space, endoscopy, post-anesthesia care unit (PACU), pre/post holding, pre-admission testing, patient intake, patient registration, outpatient laboratory, and staff/administrative space. Please note that the two service components included in the proposed project are surgery services and endoscopy services. The remainder of the proposed renovation involves ancillary and support services related to the provision of surgical and endoscopy services.”*

On pages 50-75, the applicant discusses the need to renovate and expand space for surgical and endoscopy services as summarized below:

- Replacement of WMH’s 12 ORs (includes one dedicated C-Section room) is driven by changing technology and standards of practice since the ORs were first constructed.
- Expected increase in surgical demand due to an aging population, inpatient to outpatient surgery shift and an increased prevalence of chronic conditions.
- The size of the existing ORs thus rendering them inadequate to meet the spatial demands of surgical and anesthesia equipment, staff and surgeons. On page 53, the applicant states that two of the larger ORs will house the fluoroscopy equipment to function as hybrid ORs. One of the larger ORs will house the existing daVinci robot. The fourth larger OR will provide WMH with the flexibility to add other equipment that requires larger space (if necessary in the future).
- The two proposed hybrid ORs will eliminate the need to move patients from the OR for imaging services and will allow all imaging services to be performed in the OR. The proposed imaging system has state of the art imaging capabilities which will enhance physicians’ decision making and facilitate efficiency and effectiveness of procedures; benefitting both the patients and the physicians.
- Relocation of existing GI endoscopy services into renovated space to allow immediate proximity to surgical services will allow for increased efficiencies in staffing and operational flow. Furthermore, anesthesiologists will be able to efficiently cover both surgical and GI endoscopy cases. Currently ERCP (endoscopic retrograde cholangiopancreatography) patients, who typically require anesthesia are transported to the GI endoscopy department to receive anesthesia and then transported back to the radiology department for the actual procedure, which is not ideal for patients.

- Current age-related deficiencies also include inadequate storage space for equipment and supplies, temperature and humidity control, and structural problems which lead to ceiling leaks, cracked floors and walls.
- Difficulty in meeting the standards of the Centers for Medicare and Medicaid Service (CMS), The Joint Commission (JC), and fire code standards, as the current ORs are deficient in having adequate electrical circuits, panels and outlets.
- Relocation/renovation for consolidation of ancillary and support services to include patient intake, registration, pre-admission testing, and outpatient laboratory to make it easier for staff and patients to navigate the area.

The applicant adequately demonstrates the need for renovation and expansion of the existing OR, GI endoscopy space and respective ancillary and support services space.

Projected Utilization

In Section III, page 64 and Section IV, pages 88-89, the applicant provides historical and projected utilization. Historical utilization from the two full fiscal years prior to submission of the application and projected utilization from pages 88-89 are shown in the following table.

<b>WMH ORs &amp; GI Endoscopy Historical and Projected Utilization</b>					
	<b>Prior Full FY FFY2013</b>	<b>Last Full FY FFY2014</b>	<b>1<sup>st</sup> Full FY FFY2019</b>	<b>2<sup>nd</sup> Full FY FFY2020</b>	<b>3<sup>rd</sup> Full FY FFY2021</b>
<b>Operating Rooms</b>					
# Shared ORs	12	12	13	13	13
# IP Surgical Cases	2,588	2,654	3,317	3,487	3,505
# OP Surgical Cases	7,184	7,112	8,027	8,271	8,314
<b>Total Surgical Cases</b>	<b>9,772</b>	<b>9,766</b>	<b>11,344</b>	<b>11,758</b>	<b>11,819</b>
<b>GI Endoscopy Rooms</b>					
# Rooms	3	3	3	3	3
# IP Procedures	1,405	1,414	1,109	1,115	1,121
# OP Procedures	2,138	2,182	2,672	2,686	2,700
<b>Total GI Procedures</b>	<b>3,543</b>	<b>3,596</b>	<b>3,781</b>	<b>3,801</b>	<b>3,821</b>
Excludes dedicated C-Section room.					

In Section III.1(b), pages 61-75, the applicant provides the assumptions and methodology used to project utilization, summarized below.

### Population Growth

- The applicant provides projected population data for Wayne County from 2015-2021 (Source: NC Office of State Budget and Management, see Exhibit 18).
- Wayne County is projected to experience population growth at a compound annual growth rate (CAGR) of 0.53% annually from 2015-2021.
- The CAGR for the 65 and older population of Wayne County is projected to grow by 2.73% annually for the same time period.
- The applicant states that according to the National Center for Health Statistics (NCHS), older segments of the population utilize healthcare services at a higher rate than younger segments, thus for these residents, improved access will support the expected higher utilization of this population group.

### Surgical Services

- WMH currently operates 12 ORs (including one dedicated C-Section room) and was previously approved to develop a 13<sup>th</sup> OR by way of Project I.D. #P-7554-06 and a subsequent Declaratory Ruling (See Exhibit 6).
- The applicant provides historical OR utilization for FFY 2008 through FFY 2015 (annualized) for the existing ORs, excluding the dedicated C-Section room.
- The applicant states that the decline in surgical volume in the operating rooms is due to the loss of several surgeons from the WMH medical staff.
- Projected utilization (excluding the dedicated C-Section room) for surgical services is based on historical OR utilization, the need methodology for ORs in Chapter 6 of the 2015 SMFP, planned physician recruitment and Wayne County population growth.
- Given these factors, WMH expects that its FFY 2015 surgical volume, prior to impact of future physician recruitment, will increase at the Wayne County CAGR stated above, through year 2021.

### Hybrid Operating Rooms

- A portion of WMH's surgical volume is currently being performed in the radiology department and is not included in WMH's reported OR volume on its LRA.



- At project completion, the OR appropriate cases historically performed in the radiology department will shift to the two hybrid ORs along with any additional cases appropriate to be performed there.
- The applicant analyzed the historical annual volume of hybrid OR appropriate cases performed in the radiology department and the mix of inpatient and outpatient cases.
- The applicant states that these cases are expected to grow over time at a rate equivalent to the population growth rate for the county, 0.53% annually.

### GI Endoscopy Services

- WMH currently operates three GI endoscopy procedure rooms.
- The applicant provides historical GI endoscopy procedure utilization for the last two full operating years (2013 and 2014) by both inpatient and outpatient cases in Section IV.1, page 88.
- Projected utilization for GI endoscopy services is based on historical utilization and Wayne County population growth.
- Given these factors, WMH expects that its GI endoscopy volume will increase at the Wayne County CAGR previously stated above, through year 2021.

Projected utilization is based on reasonable and adequately supported assumptions.

### Access

In Section VI.2, page 101, the applicant states it will provide services to all persons in need of medical care including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons, including the medically indigent. In Section VI.14(b), page 109, the applicant projects that 61.8% of patients to be served will be Medicare beneficiaries and 12.2% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. 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 78-80, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – the applicant states that this alternative was not chosen because it would not remedy age-related facility deficiencies, increase the efficiency of surgical and GI endoscopy services or enhance quality of care.
- 2) Separately Develop One New Operating Room (Project I.D.# P-7554-09) and Renovate Existing Space - the applicant states that this alternative was not chosen because the existing surgical department does not have adequate space to develop an additional OR. Further, this alternative would not alleviate age-related deficiencies in the current surgical department.
- 3) New Construction, Renovation of Existing Space and Acquisition of New Equipment - the applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative because age-related deficiencies will be corrected that currently have a negative impact on the efficiency of the operation of its surgical and GI endoscopy services. The proposed project will give WMH adequate space and adequate state of the art technology to enhance patient care as well as physician and staff satisfaction.

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

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

1. **Wayne Memorial Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
  2. **Wayne Memorial Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
  3. **Wayne Memorial Hospital, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
  4. **Wayne Memorial Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the of the certificate of need**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to expand and renovate space at its main hospital campus related to the provision of surgical and GI endoscopy services. WMH submitted this proposal to overcome age-related facility deficiencies and to increase the efficiency of surgery services. This proposal involves a change of scope for Project I.D.# P-7554-09 (add one operating room) and the acquisition of two angiographic endovascular imaging systems to develop two hybrid ORs in renovated OR space and new construction on the ground floor of WMH.

**Capital and Working Capital Costs**

In Section VIII.2, pages 123-124, the applicant projects that the capital cost will be as follows:

Site Costs	\$683,400
Construction / Renovation Costs	\$20,975,031
Miscellaneous Costs	\$12,754,802
<b>Total</b>	<b>\$34,413,233</b>

In Section IX, page 128, the applicant projects no working capital costs (start-up costs and initial operating costs) as the project is proposed for existing services and no new services are proposed.

**Availability of Funds**

In Section VIII.1, page 121, the applicant states that the capital costs of the project will be financed with accumulated reserves and bond financing. In Exhibit 25, the applicant provides documentation of the availability of funds for the proposed project, which states: “... Bond financing will cover \$30.0 million of the capital cost and WMH’s accumulated reserves will cover up to \$5.0 million.” The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three project years for both surgical and endoscopy services, as illustrated in the tables below.

<b>Surgical Services</b>	<b>Project Year 1 2019</b>	<b>Project Year 2 2020</b>	<b>Project Year 3 2021</b>
Projected # of procedures	11,344	11,757	11,819
Projected Average Charge (Gross Patient Revenue / Projected # of procedures)	\$14,689	\$15,130	\$15,584
Gross Patient Revenue	\$166,630,731	\$177,883,617	\$184,183,913
Deductions from Gross Patient Revenue	\$99,076,283	\$105,767,091	\$109,513,158
Net Patient Revenue	\$67,554,447	\$72,116,526	\$74,670,755
Total Expenses	\$45,268,780	\$47,467,892	\$48,971,378
Net Income	\$22,285,667	\$24,648,634	\$25,699,377

<b>GI Endoscopy Services</b>	<b>Project Year 1 2019</b>	<b>Project Year 2 2020</b>	<b>Project Year 3 2021</b>
Projected # of procedures	3,781	3,801	3,821
Projected Average Charge (Gross Patient Revenue / Projected # of procedures)	\$2,395	\$2,467	\$2,541
Gross Patient Revenue	\$9,056,699	\$9,377,470	\$9,709,602
Deductions from Gross Patient Revenue	\$5,214,754	\$5,399,450	\$5,590,688
Net Patient Revenue	\$3,841,945	\$3,978,019	\$4,118,913
Total Expenses	\$2,567,538	\$2,639,979	\$2,714,742
Net Income	\$1,274,407	\$1,338,041	\$1,404,171

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The assumptions used by the applicant in preparation

of the pro forma financial statements are reasonable, including projected utilization, and costs and charges. See Financials, pages 150-153, for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 expand and renovate space at its main hospital campus related to the provision of surgical and GI endoscopy services. WMH submitted this proposal to overcome age-related facility deficiencies and to increase the efficiency of surgery services. This proposal involves a change of scope for Project I.D.# P-7554-09 (add one operating room) and the acquisition of two angiographic endovascular imaging systems to develop two hybrid ORs in renovated OR space and new construction on the ground floor of WMH.

On page 60, the 2015 SMFP defines the service area for operating rooms as the operating room planning area in which the operating room is located with the exception of any multi-county planning areas. Thus, in this application, the planning area is Wayne County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved facilities with operating rooms located in Wayne County.

Facility	# ORs	Utilization during the Last Full Year Cases (Inpatient & Outpatient)	# Hours	Utilization Rate*
Wayne Memorial Hospital (Excluding 1 C-Section Room)	12	9,772	18,630	82.9%
*Utilization rate based on 2015 SMFP, Chapter 6, Operating Rooms, pages 59-63. Formula: # OR hours/capacity (1872) x # ORs				

As shown in the table above, Wayne Memorial Hospital, currently licensed for 12 ORs, is the only licensed facility and provider of surgical services in the county.

There are two licensed providers of GI endoscopy services in Wayne County – WMH and Goldsboro Endoscopy Center. The following table illustrates GI endoscopy utilization in both facilities.

Facility	# Endoscopy Rooms	Utilization during the Last Full Year Procedures (Inpatient & Outpatient)
Wayne Memorial Hospital	*3	3,543
Goldsboro Endoscopy Center	4	3,533
Source: 2015 SMFP - Procedure data for 10.01.2012 – 9.30.2013. *Per WMH, had been inadvertently reporting 2 rooms when actually has 3 rooms.		

In Section III.6(b), pages 85-86, the applicant states, “*The proposed project is in response to a need that is internal at WMH and its patients. Therefore, other providers cannot meet this need to serve patients that are seeking care at WMH. ...*

*... Further, based on the utilization data shown in Exhibit 19, WMH has fewer endoscopy rooms than Goldsboro Endoscopy Center ... and is still performing nearly as many procedures as Goldsboro Endoscopy Center, demonstrating that patient demand supports the proposed project.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing and approved ORs or GI endoscopy rooms. 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, pages 111-114, the applicant provides current and proposed staffing, as shown below in the table.

Position	Number of Full-Time Equivalent (FTE) Positions	
	Current	Project Year 2
<b>Surgical Services</b>		
Administrators	3.5	4.0
Registered Nurses	69.1	99.7
Nursing Aides, Orderlies or Attendants	12.1	17.5
Surgical Technicians	22.0	32.0
Radiologic Technologists/Technicians	0.0	5.0
Licensed Pharmacists	0.0	1.0
Pharmacy Technicians	0.0	1.0
Non-health professionals/technical	32.5	40.0
<b>Total Surgical Services</b>	<b>139.2</b>	<b>200.2</b>
<b>GI Endoscopy</b>		
Administrators	0.5	1.0
Registered Nurses	7.6	11.4
Nursing Aides, Orderlies or Attendants	3.0	5.0
Non-health professionals/technical	1.0	0.0
<b>Total Endoscopy Services</b>	<b>12.1</b>	<b>17.4</b>
<b>Total Surgical &amp; Endoscopy Services</b>	<b>151.3</b>	<b>217.6</b>

In Section VII.6, pages 116-117, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 21 contains copies of letters from Dr. Robert Ottavianti, Chairman of the Department of Surgery and Dr. Stewart Futch, Chairman of the Department of GI Endoscopy expressing their interests in serving as the Medical Directors for the proposed surgical and GI endoscopy services, respectively. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, pages 30-31, the applicant describes the necessary ancillary and support services and explains how they will be provided. Exhibit 9 contains a copy of a letter from William Paugh, the President and Chief Executive Officer stating that WMH has the necessary ancillary and support services in place to support the proposed project. Exhibit 29 contains copies of letters from other health care providers and the community expressing

support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

The applicant proposes to renovate 49,397 square feet of existing space and construct 39,773 square feet of new space related to the provision of surgical and GI endoscopy services on the ground floor of the main hospital campus. Exhibit 24 contains a letter from an architect that estimates that architectural fees, site preparation costs, and construction costs will total \$21,636,531.00, which corresponds with the projected capital



cost provided by the applicant in Section VIII, page 123. In Section XI, pages 137-138, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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.12-13, page 108, the applicant provides the payor mix during FFY2014, as illustrated in the table below.

	Percentage of Total	Percentage of Total	Percentage of Total
	<b>Entire Facility</b>	<b>Surgery</b>	<b>GI Endoscopy</b>
Self-Pay / Indigent / Charity	9.2%	6.8%	6.7%
Medicare/Medicare Managed Care	61.8%	46.0%	53.8%
Medicaid	12.2%	16.4%	7.7%
TriCare/Managed Care/Commercial	16.8%	30.9%	31.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

In Section VI.2, page 85, the applicant states: “*WMH provides access to care to all patients ... WMH does not discriminate based on age, race, national or ethnic origin, disability, sex, income, or ability to pay. ...*” Exhibit 22 contains WMH’s admissions, credit and collections policy.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was

not available. The following counties comprise the projected counties of residence for the patients to be served by Wayne Memorial Hospital.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Wayne County	20.2%	8.3%	20.3%
Duplin County	20.3%	7.6%	24.6%
Johnston County	17.5%	6.7%	20.0%
Lenoir County	24.6%	11.0%	21.1%
Sampson County	25.4%	10.1%	24.0%
Statewide	16.5%	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 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 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, handicapped persons or women utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at Wayne Memorial 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 107, the applicant states: “*WMH has no obligation to provide uncompensated care. ... the hospital provides, without obligation, ... charity care.*”

In Section VI.10, page 107, the applicant states that it is not aware of any civil rights equal access complaints being filed against its facilities or programs in North Carolina within the past 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 VI.15(a), pages 109-110, the applicant provides the projected payor mix during Project Year 2, as shown in the following table.

	Percentage of Total	Percentage of Total	Percentage of Total
	Entire Facility	Surgery	GI Endoscopy
Self-Pay / Indigent / Charity	9.2%	6.8%	6.7%
Medicare/Medicare Managed Care	61.8%	46.0%	53.8%
Medicaid	12.2%	16.4%	7.7%
TriCare/Managed Care/Commercial	16.8%	30.9%	31.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

On page 110, the applicant states the projected payor mix is based on its historical experience and expects no changes from the current payor mix. The applicant demonstrates 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), page 106, the applicant states that persons will have access to the proposed services through referrals from physicians with admitting privileges at WMH and through emergency department admissions. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1(a), page 91, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs. See Exhibit 29 for a letter of support from the president of Wayne Community College stating that allied health and health science students have the benefit of clinical experiences at WMH. The information provided is reasonable and adequately supports a determination that 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

The applicant proposes to expand and renovate space at its main hospital campus related to the provision of surgical and GI endoscopy services. WMH submitted this proposal to overcome age-related facility deficiencies and to increase the efficiency of surgery services. This proposal involves a change of scope for Project I.D.# P-7554-09 (add one operating room) and the acquisition of two angiographic endovascular imaging systems to develop two hybrid ORs in renovated OR space and new construction on the ground floor of WMH.

On page 60, the 2015 SMFP defines the service area for operating rooms as the operating room planning area in which the operating room is located with the exception of any multi-county planning areas. Thus, in this application, the planning area is Wayne County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved facilities with operating rooms located in Wayne County.

Facility	# ORs	Utilization during the Last Full Year Cases (Inpatient & Outpatient)	# Hours	Utilization Rate*
Wayne Memorial Hospital (Excluding 1 C-Section Room)	12	9,772	18,630	82.9%
*Utilization rate based on 2015 SMFP, Chapter 6, Operating Rooms, pages 59-63. Formula: # OR hours/capacity (1872) x # ORs				

As shown in the table above, Wayne Memorial Hospital, currently licensed for 12 ORs, is the only licensed facility and provider of surgical services in the county and utilizes 83% of its OR capacity.

There are two providers of endoscopy services in Wayne County – WMH and Goldsboro Endoscopy Center. The following table illustrates utilization for GI endoscopy services in Wayne County. As the table shows, WMH performed approximately as many procedures in three GI endoscopy rooms as Goldsboro Endoscopy Center performed using four rooms.

Facility	# Endoscopy Rooms	Utilization during the Last Full Year Procedures (Inpatient & Outpatient)
Wayne Memorial Hospital	*3	3,543
Goldsboro Endoscopy Center	4	3,533
Source: 2015 SMFP - Procedure data for 10.01.2012 – 9.30.2013. *Per WMH, had been inadvertently reporting 2 rooms when actually has 3 rooms.		

In Section III.6(b), pages 85-86, the applicant states, “*The proposed project is in response to a need that is internal at WMH and its patients. Therefore, other providers cannot meet this need to serve patients that are seeking care at WMH. ...*

*... Further, based on the utilization data shown in Exhibit 19, WMH has fewer endoscopy rooms than Goldsboro Endoscopy Center ... and is still performing nearly as many procedures as Goldsboro Endoscopy Center, demonstrating that patient demand supports the proposed project.”*

In Section V.7, pages 96-99, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states, "... *The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area ...*" The applicant further states that the project will maximize healthcare value by renovating existing space, constructing new space and acquiring medical equipment all in one project; promote safety and quality by creating appropriately sized ORs to meet best practices and more efficient usage; and promote equitable access by continuing to serve all persons in need of medical care.

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

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes 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 for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

In Section I.12(c), page 11, the applicant states that it nor its parent company Wayne Health Corporation, currently owns, leases, or manages any other hospital in North Carolina or other states. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred at Wayne Memorial Hospital,

Inc. (the applicant) within the eighteen months immediately preceding submission of the application through the date of this decision. The problems were corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Wayne Memorial Hospital, the applicant provides sufficient evidence that quality care has been provided in the past and adequately demonstrates that there is no pattern of substandard quality of care. Therefore, the application is conforming to this criterion.

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

C

The application is conforming to all applicable Criteria and Standards for 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- WMH 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 41, the applicant defines the service area for the proposed angiographic endovascular imaging equipment in the hybrid ORs based on historical patient origin for

WMH's surgical services. The applicant states that Wayne County will be its primary service area, and that Duplin, Johnston, Lenoir, and Sampson counties will comprise its secondary service area. In Section III.5(a), page 82, the applicant states that it expects Wayne County to account for nearly 78% of its OR patients and 86% of GI endoscopy patients, while its secondary service area counties will account for approximately 18% of OR patients and 11% of GI endoscopy patients.

- (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 I.12(e), pages 12-16, the applicant describes its experience in providing care to the patients to be served using the proposed equipment. The applicant states on pages 12-13, that through its acute care facility it provides a variety of services including neurosurgery, medical and invasive cardiology and vascular surgery. In Section II.1, page 19, the applicant states, *“With this project WMH does not propose any new services that it is not currently offering, but believes the proposed project will enable it to improve the delivery of those services it currently offers.”*
- (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- See Exhibit 14 for documentation that 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- Exhibit 5 contains line drawings for all areas listed above as (1)-(6).
- (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 manufacturer's standards for the type of major medical equipment to be installed.*



- C- The applicant provides a letter in Exhibit 9 signed by the President of WMH, dated June 15, 2015, stating that the proposed project will be developed in accordance with federal, state and local building codes and standards.

**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 Exhibit 15, pages 412-413, the applicant provides a table depicting the projected utilization of hybrid OR cases by diagnosis, for project years one through three. WMH projects 1,065 cases in FFY19, 1,222 cases in FFY 2020 and 1,229 cases in 2021.

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

- C- In Section II, page 43, the applicant states that it, “... *projected cases (patients) by county for the two proposed hybrid operating rooms based on WMH’s FFY 2014 experience.*” On page 44, the applicant provides the projected number of patients by county of origin who will use the hybrid ORs for the first three full years of operation, illustrated as follows:

<b>WMH - Projected Patient Origin by County for Hybrid ORs</b>				
<b>County</b>	<b>% of Total</b>	<b>Projected Patients</b>		
		<b>FFY 2019</b>	<b>FFY 2020</b>	<b>FFY 2021</b>
Wayne	78.5%	836	960	965
Sampson	6.9%	74	85	85
Duplin	5.0%	53	61	61
Lenoir	4.5%	47	54	55
Johnston	1.8%	20	22	23
Other*	3.3%	35	40	40
<b>Total</b>	<b>100.0%</b>	<b>1,065</b>	<b>1,222</b>	<b>1,229</b>

\*Other includes Beaufort, Greene, Harnett & Moore counties & other states. Totals may not foot due to computer rounding.

(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- The applicant states in Section II, page 44, “*Per the 2015 SMFP, the estimated time that an operating room is utilized per case is equal to 3.0 hours and 1.5 hours for inpatient and ambulatory cases, respectively. These assumptions result in the 2,340 maximum operating hours per year, per OR (capacity).*”

(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, page 45, the applicant provides the following projected quarterly utilization for

the proposed hybrid OR during the first three project years:

<b>WMH Hybrid OR Projected Quarterly Utilization</b>				
<b>Quarter</b>	<b>Quarterly Distribution</b>	<b>FFY 2016</b>	<b>FFY 2017</b>	<b>FFY 2018</b>
First	25%	266	306	307
Second	25%	266	306	307
Third	25%	266	306	307
Fourth	25%	266	306	307
<b>Total</b>	<b>100%</b>	<b>1,064</b>	<b>1,222</b>	<b>1,299</b>
Totals may not foot due to computer rounding.				

(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 to project utilization of the proposed hybrid ORs in Section III.1(b), pages 61-75.

(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 45, the applicant states, “*WMH is not proposing to acquire new major medical technology 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- In Section II, page 46, the applicant states that since it is an existing acute care hospital, it already has all necessary ancillary and support services in place. It further states, “*This infrastructure, as well as existing ancillary and support staff, will be sufficient to support the fluoroscopy imaging equipment proposed in this application.*” The applicant provides a letter

from the President of WMH in Exhibit 9 that documents the availability of ancillary and support services for the proposed project.

#### **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- The applicant discusses its staffing for the proposed project in Section VII.1(b) and VII.2(b), and provides a letter from the President of WMH in Exhibit 9 which states that WMH is committed to employing trained and qualified staff and that this will not change with the proposed project. In addition, the equipment quote from the vendor, provided in Exhibit 7, includes online, classroom, and onsite training sessions.
- (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 Section II, page 47, the applicant refers to Exhibit 9, which contains a letter from the President of WMH that indicates the facility will employ appropriately trained and qualified staff for the proposed project, and states, “...in accordance with 10A NCAC 14C .3106(b), this practice will not change following the development of the proposed project. Further, ... physicians who will use the proposed equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with the same or similar medical equipment.” In addition, the applicant includes the physicians’ curricula vitae in Exhibit 16.
- (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 Section II, pages 47-48, the applicant discusses the training policy in place at WMH hospital. The applicant states, “Exhibit 17 includes a policy specific to staff education, orientation and training including basic life support training. WMH requires all clinical staff ... to undergo basic life support training under the direction of the American Heart Association. ...”

*... Exhibit 12 contains a copy of several operating room safety guidelines related to the provision of quality care.*

*In regard to training for the proposed fluoroscopy equipment, as part of the equipment cost, the vendor will provide three phases of specific training to optimize system hardware and software, clinical workflow and operating safety. ...”*