ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: January 20, 2012

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8758-11/ Charlotte Radiology, P.A. / Acquire second mammography unit at the Monroe Breast Center and designation as a diagnostic center / Union County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Charlotte Radiology, P.A. proposes to acquire a second mammography unit at the Monroe Breast Center and obtain designation as a diagnostic center. The Monroe Breast Center is located in the Union Medical Office Building, 1550 Faulk Street, Suite 1200 in Monroe.

The applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2011 State Medical Facilities Plan (2011 SMFP). There are no policies in the 2011 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

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

C

The applicant, Charlotte Radiology, P.A. proposes to acquire a second mammography unit at the Monroe Breast Center and obtain designation as a diagnostic center. The Monroe Breast Center is located in the Union Medical Office Building, 1550 Faulk Street, Suite 1200 in Monroe.

Designation as a Diagnostic Center

In Section II.1, page 18, the applicant lists current diagnostic equipment, in Section VIII.2, page 62, the applicant lists the proposed equipment with costs and in Exhibit E, provides the manufacturer's quote and specifications for the proposed diagnostic equipment:

Equipment Description	Quantity	Equipment Costs
Mammography	1	$239,000
Ultrasound	2	$46,000
Physician Workstation	2	$120,000
Bone Density	1	$78,000
Subtotal		**$483,000**
*CT Scanner & associated components (mammography)	1	$510,000
*Image Checker & Software	1	$65,000

*proposed new equipment

The total capital costs for the new digital mammography CT scanner and associated components are $575,000. The proposed new equipment plus the equipment currently in use at the Monroe Breast Diagnostic Center costs more than 10,000 each. This includes the multiple components of the diagnostic systems.

In Section II, pages 17-18, the applicant states:

> "*The acquisition of $575,000 for the proposed digital mammography equipment and related components, elevates the value of Charlotte Radiology's diagnostic equipment at Monroe Breast Center to more than $500,000; therefore, it is necessary for Charlotte Radiology to apply for designation as a diagnostic center. Under NCGS 131E-176(7a), a 'diagnostic center' is a 'free standing facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which costs $10,000 or more exceeds $500,000.* ...
>
> *As shown in the table above, the total cost of the existing diagnostic equipment at Charlotte Radiology's Monroe Breast Center is $483,000. Therefore, the purchase of the proposed digital mammography equipment, quoted to cost $575,000 will qualify the site as a diagnostic center and require the State's approval to obtain such designation.* ..."

Population to be Served

In Section III, pages 31-37, the applicant discusses its service area population, service area breast cancer incidence rates, concern for the capacity and projects utilization at the Monroe Breast Center.

"*Service Area Population*

Based on patient origin data for the Monroe Breast Centers, Charlotte Radiology determined that Union County represents the primary service area for mammography services. This section provides a discussion of the population growth statistics in Union County, focusing primarily on the female population that is over the age of 45 which represents the portion of the population who most frequently will utilize this service.

...

Since breast cancer risk is primarily in women age 40 and older, population statistics for the female population over the age of 45 are important in order to project future utilization and need. The following table provides an illustration of the 2000 and 2010 total female population and female population over age 45 in Union County. Statewide data is included as a basis for comparison."

Historical Growth – Female Population				
	2000	2010	% Increase	CAGR
Union 45+	20,035	36,944	84.4%	8.4%
NC 45+	1,516,462	1,933,545	27.5%	2.8%
Union Total	61,921	101,926	64.6%	6.5%
NC Total	4,106,618	4,889,991	19.1%	1.9%

Source: North Carolina Office of State Budget and Management

"*As the above table demonstrates, the Union County female population is increasing at a rate that is significantly greater than the statewide female population growth rate. The data also shows that the growth of its female population over the age of 45 is also occurring at a much faster pace. Similar to nearly every region in the United States, the populations of Union County and North Carolina are aging, resulting in a larger percentage of the population being over the age of 50. The growth trend in the female population over age 45 appears to be following the same pattern. Therefore, it is not surprising that the growth rate in this population segment, the subgroup almost exclusively utilizing mammography scanners, is growing at a faster rate than the population as a whole and the entire female population. While the Monroe Breast Center serves women under the age of 45, Charlotte Radiology believes that this population cohort captures a significant portion of its patient population and therefore the growth rate in this population is a relevant statistic.*

The population statistics discussed above support a continued pattern of utilization that is similar to that currently experienced at the Monroe Breast Center. The following section provides an overview of the breast cancer statistics for this region, which lend further support to the proposed project.

Service Area Breast Cancer Incidence Rates

Union County's current and projected breast cancer incidence rates are slightly higher than those experienced throughout North Carolina and nationwide. According to the North Carolina Center for Health Statistics, breast cancer is second only to lung cancer as the leading cause of cancer related deaths in women, thus mirroring the national trend. Between 2001 and 2009, breast cancer has represented between 15 and 17 percent of all diagnosed cancer cases in Union County and in North Carolina.

With respect to incidence rates, the general trend indicates a stabilizing/slightly decreasing trend in incidence rates and a decline in breast cancer mortality rates in Union County. The following tables illustrate estimated breast cancer cases as well as estimated breast cancer incidence and mortality rates."

Breast Cancer Cases						
Region	*Union County*		*NC*		*US*	
Year	*Cases*	*% Total*	*Cases*	*% Total*	*Cases*	*% Total*
2001	*80*	*15.7%*	*5,095*	*15.3%*	*192,200*	*15.2%*
2003	*90*	*16.1%*	*6,345*	*15.8%*	*203,500*	*15.8%*
2005	*95*	*16.5%*	*6,335*	*15.9%*	*211,240*	*15.4%*
2007	*95*	*15.1%*	*6,155*	*15.1%*	*178,480*	*12.4%*
2009	*146*	*17.1%*	*7,781*	*16.8%*	*192,370*	*13.0%*

Source: North Carolina Center for Health Statistics

Breast Cancer Incidence Rates per 100,000		
Region	2001-2005	2004-2008
Union County	104.7	103.7
North Carolina	121.7	123.3

Source: North Carolina Center for Health Statistics

Breast Cancer Mortality Rate		
Region	2001-2005	2004-2008
Union County	24.1	23.5
North Carolina	25.6	25.7

Source: North Carolina Center for Health Statistics

"As demonstrated above, Union County trends are similar to trends across North Carolina and the nation. Breast cancer in Union County represents a slightly larger percentage of the total cases in the County than in North Carolina whereas the incidence and mortality rates are slightly lower. However, the overall trends are comparable. ... Cancer incidence rates, coupled with the population growth and aging trends discussed above help support the need for Charlotte Radiology to expand its existing mammography capacity with the proposed acquisition of a second digital mammography scanner.

Capacity Concerns

Since 2001, the Monroe Breast Center has provided screening mammography services. In 2007, Charlotte Radiology replaced its analog equipment at this location with one digital unit. The Monroe Breast Center began providing digital services to its diagnostic patients in November 2008. Currently, no other providers in the primary or secondary service areas offer digital diagnostic services.

Over the last four years, the number of screening exams completed at the Monroe Breast Center has increased at an average annual rate of 3.1%. This growth rate would have been much higher if the Center did not reduce its screening capacity in order to perform diagnostic mammograms. Prior to offering diagnostic services, the annual growth of screening exams averaged 6%. Diagnostic services have seen a larger increase as the number of diagnostic mammograms has increased at an average annual rate of 9.3%. In 2010, the Monroe Breast Center operated at 98.6% of capacity for screening services and 96.3% of capacity for diagnostic services (See Section IV.2). Based on the first 8 months of volumes in 2011, the Center is expected to complete over 6,600 screening exams and 2200 diagnostic exams by the end of this year, both numbers of which will exceed the capacity of the Center. Already the Center is facing operational issues and has seen its backlogs grow over the last year. Through the first eight months of 2011, the Center has had an average 8.4 business day backlog for diagnostic services. This type of delay causes significant emotional distress to women who have a suspected problem and can become a significant source of patient dissatisfaction. The backlog for screening services has averaged 6.8 business days and some women will decide to forego getting their screening exam because services aren't readily available. Charlotte Radiology feels that backlogs for diagnostic and screening services should be less than 5 days but lacks adequate equipment at the Monroe Breast Center to meet and exceed this target."

Also in Section III, page 34, the applicant discusses the changes it has made in scheduling the equipment and patients in the interest to better serve its patients. The applicant also discusses the impact of the increasing volumes of patients due to aging of the population and health reform on its ability to meet the needs of patients requiring screening and diagnostic mammograms. Due to its current capacity limitations, the applicant states it will not be able to accommodate the growing need for mammography services without the proposed equipment.

In Section III.5(a), page 40, the applicant states:

> "*The primary service area for the Monroe Breast Center is Union County. The secondary service area is Anson County. This determination is based on the NC patient origin data (III.4) which shows that over 93% of the NC patients receiving mammography services at the Monroe Breast Center reside in these two counties.*"

In Section III.5(d), page 41, the applicant states its projected patient origin:

> "*Projected patient origin for each service at Charlotte Radiology's Monroe Breast Center is based on that experienced in 2010. Charlotte Radiology does not contemplate any significant change in patient origin during the project years. Charlotte Radiology assumes that one procedure equals one patient.*"

In Section III.5(c), page 41, the applicant provides projected patient origin by service type (i.e., screening and diagnostic mammography) during the first and second operating years, as illustrated in the following tables:

Monroe Digital Screening Mammography				
County	Year 1 Patients	Year 1 Patient %	Year 2 Patients	Year 2 Patient %
Union	6,108	81.1%	6,505	81.1%
Anson	979	13.0%	1,041	13.0%
*Other	444	5.9%	473	5.9%
Total	7,531	100.0%	8,021	100.0%

**Other includes all NC counties except Bertie, Hyde, Martin, Northhampton, Perqulman* [sic], *Tyrell and Washington.*

Monroe Diagnostic Mammography				
County	Year 1 Patients	Year 1 Patient %	Year 2 Patients	Year 2 Patient %
Union	2,045	79.9%	2,177	79.9%
Anson	343	13.4%	365	13.4%
*Other	171	6.7%	183	6.7%
Total	2,599	100.0%	2,725	100.0%

**Other includes all NC counties except Bertie, Hyde, Martin, Northhampton, Perqulman* [sic], *Tyrell and Washington.*

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III, pages 23-37, the applicant states that the need for the proposal is based on the following:

"*Breast Cancer Data*

Although breast cancer can occur in men, it is a disease overwhelmingly affecting the female population. The median age for a woman diagnosed with breast cancer is 61.[1] *However, 52 percent of breast cancers occur in women between the ages of 35 and 54.*[2] *Breast cancer is second only to non-melanoma skin cancer as the most frequently occurring cancer in women.*[3] *Further, breast cancer is second only to lung cancer for cancer related mortality in women. In the United States, 28 percent of all projected cancer cases and 22.8 percent of all projected cancer related deaths in women are breast cancer related.*[4]

The 1980s and 1990s marked an increase in breast cancer incident rates, although this is at least somewhat attributable to increased screening and detection. Incidence rates began to stabilize beginning 2001 and are currently showing insignificant signs of decline."

On page 24, the applicant includes a graph depicting rates of new cases of the most common cancers and states:

"*As the graph portrays, breast cancer incident rates rose significantly from 1980 to 1987, before stabilizing from 1987 – 1998. Since 1998, the graph shows that incidence rates have declined through 2007. While encouraging, researchers and other experts in the field have no explanation for the relative stabilization in breast cancer incidence. Stabilizing incidence rates coupled with population growth support the conclusion that utilization rates will continue on an upward trend.*

As with other types of cancer, individual breast cancer risk is dictated by a combination of genetic, behavioral, and environmental risk factors. Current estimates indicate that one in eight women will develop breast cancer during her lifetime. The primary risk factor for developing breast cancer, aside from being female, is age. According to the National Cancer Institute, 80 percent of all breast cancer cases are found in women over the age of 50. Other risk factors exist outside of age and gender and include: (1) genetics (specifically, BRCA1 and BRCA2 genes); (2) lifestyle and behavioral factors (including obesity, diet, and alcohol consumption) and elevated estrogen levels (attributed to hormone replacement therapy, birth control pills, and age at first pregnancy). Despite current knowledge about the disease, much of the information as to what causes breast cancer in some women and not in others is still unknown. Therefore, it appears likely that the incident rates will experience significant decline in the near future. However, while incidence rates are showing no significant sign of decline, mortality rates for breast cancer have been on the decline since 1990."

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[1] *National Cancer Institute, Surveillance Epidemiology and End Results*
[2] *National Cancer Institute, Surveillance Epidemiology and End Results*
[3] *Centers for Disease Control, Cancer Among Women*
[4] *Centers for Disease Control, Cancer Among Women*

On page 26, the applicant includes a graph depicting death rates for the top five most common female breast cancers, and explains:

> "*The decline in breast cancer mortality rates has been attributed to improved treatment modalities as well as advances in screening and detection. As the following section illustrates, early detection plays an extremely important role in prognosis for a breast cancer patient. According to the National Cancer Institute, mammography is one of two commonly used tests by healthcare providers to screen for breast cancer.*
>
> *Mammography and Early Detection*
>
> *As with other cancers, one of the greatest weapons in the fight for survival from breast cancer is early detection. Mammography screening has been found to be a very effective tool as it can detect tumors that are too small to feel during a physical breast exam.*[5] *According to the Susan G. Komen Foundation, mammography can find 85 to 90 percent of breast cancers in women over the age of 50. It is clear that early detection will have a positive impact on survival rates. According to cancer statistics provided by the National Cancer Institute, detection at Stage 1 (confined to primary site) is associated with a 5-year survival rate of 98.6 percent. Detection in Stage 2 (after the cancer has spread to lymph nodes) results in a drop in the 5-year survival rate to 83.8 percent. Once the cancer has metastasized (Stage 3), the 5-year survival rate is only 23.4%. This data alone illustrates the importance of effective screening tools, as well as encouraging women to get regular screenings.*
>
> *Mammography, in its modern form, came into existence in 1969. Advances in technology, however, render the current machines very different from those used even fifteen years ago. The mammogram is a dedicated X-ray that uses lower energy X-rays than those used in a standard X-ray machine, therefore decreasing the amount of ionizing radiation exposure to the patient. Screening mammograms have been found to significantly increase the chance for successful treatment, if breast cancer is found, and for survival.*
>
> *... the increased breast cancer incidence rates in the 1980s are at least in part attributable to the increased use of mammography and other screening techniques. In addition, a significant decrease in mortality rates has been achieved through the increased utilization of mammogram across all groups of women. It is estimated that breast cancer screening for women ages 50 to 69 lowers breast cancer mortality risk by 30 percent and for women in their 40s, by 17 percent.*[6] *Despite these findings, there has been a recent decline in women over the age of 40 obtaining routine mammograms. The following graph provides an illustration o the utilization of mammography screening from 1987 to 2005.*"

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[5] National Cancer Institute, Summary Document: Breast Cancer Screening
[6] National Cancer Institute, Cancer Trends Progress Report 2009

On page 28, the applicant provides a chart depicting the percentage of women aged 40 and older having mammography 1987-2005.

> " *... mammography screening utilization has increased significantly over the last eighteen years. This increase has impacted survival rates among women diagnosed with breast cancer. Advances in technology, such as digital mammography, can help further increase early detection rates and decrease breast cancer related mortality rates.*"

In Section III, page 42, the applicant discusses meeting the identified need and states the following about digital mammography.

> "*The Monroe Breast Center is the only provider in the primary and secondary service area that provides digital mammography services for diagnostic patients. Digital mammography for screening patients is also not available in the secondary service area.*"

The applicant discusses the benefits of digital mammography in Section II, pages 14-18 and in Section III, pages 29-31. Such benefits include:

- Improves the detection and diagnosis of breast cancer; including improved quality of biopsy and decreased mortality rates
- Improves accuracy in certain groups including women under 50, women with dense/thick breasts, pre-menopausal and peri-menopausal women
- Increases patient throughput as the time necessary to read the scans is decreased; also decreases the need for call backs and re-scanning

Projected Utilization

In Section III, pages 35-36, the applicant provides projected utilization for the Monroe Breast Center for the first three years of the proposed project.

Monroe Breast Center Projected Screening and Diagnostic Mammograms			
Fiscal Year	2013	2014	2015
Projected Screening	7,513	8,021	8,542
Projected Diagnostic	2,559	2,725	2,902

Summary

In Section III, pages 36-37, the applicant summarizes the need for the proposed diagnostic center designation and the additional digital mammography unit, and states that the need is demonstrated by addressing the following factors:

- "*Stabilizing breast cancer incidence rates*
- *Role of mammography in decreasing breast cancer mortality*

- *Service area population statistics*
- *Benefits of digital mammography*
- *Diagnostic imaging utilization (historical, current, and projected)*

While immense strides have been made in the fight against breast cancer, a cure is unlikely in the near future. Therefore, the most powerful weapon is early detection made possible by imaging modalities such as mammography. Digital mammography is more effective at improving the detection capabilities compared to traditional analog mammography. The relevant service area population, Union County female population over the age of 45, has experienced growth exceeding that experienced in other population sub-groups. Since routine mammography screening for women in this age group is strongly recommended by medical professionals as well as national organizations such as the National Cancer Institute, Centers for Disease Control and Prevention, and the American Cancer Society, Charlotte Radiology believes that most women in this subgroup will receive a screening mammography scan everyone one to two years. Therefore, it is reasonable to assume that utilization will increase and will continue to support screening and diagnostic mammography services at Charlotte Radiology's Monroe Breast Center."

The applicant adequately demonstrates the need to acquire the proposed second digital mammography unit and for the proposed diagnostic center designation in Monroe. Consequently, the application is conforming to this criterion.

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

NA

(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 37-38, the applicant describes the alternatives it considered, including maintaining status quo, purchasing an analog mammography unit and purchasing a second digital mammography unit. The applicant adequately demonstrates that the proposal is the least costly or most effective alternative. Therefore, the application is conforming to this criterion, and is subject to the following conditions:

1. **Charlotte Radiology, PA – Monroe Breast Center shall materially comply with all representations made in its certificate of need application, except as amended by the conditions of approval.**
2. **Charlotte Radiology, PA – Monroe Breast Center 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 this application and which would otherwise require a certificate of need.**
3. **Charlotte Radiology, PA – Monroe Breast Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, pages 62-64, the applicant projects the total capital costs for the digital mammography equipment will be $575,000; which includes the mammography unit and digital image checker. In Section VIII, page 64, the applicant anticipates that the project will be financed via a conventional loan with SunTrust Bank. Exhibit L contains a letter dated October 13, 2011 from the First Vice President of SunTrust Bank, which states in part:

> *"On behalf of SunTrust Bank ('Bank'), I am pleased to make available to Charlotte Radiology, P.A. ('Borrower'), a loan commitment to acquire digital mammography equipment for the breast center located at 1550 Faulk St. in Monroe, NC. Our commitment is subject to the following terms and conditions:*
>
> ...
>
> *Amount:* *Up to $575,000 but not to exceed 100% of the purchase price of the equipment including shipping, tax and installation. ..."*

In Section IX, page 67, the applicant states there are no start-up or initial operating expenses associated with this project.

Exhibit M contains the financial statements for Charlotte Radiology, which show that as of December 31, 2010, Charlotte Radiology had cash & cash equivalents of $910,477, total assets of $10,991,569, and total net assets (total assets less total liabilities) of $635,200.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Exhibit N, Form D, the applicant provides projected average charges for the proposed diagnostic center in Monroe, which the applicant states are based on Fiscal Year (FY) 2010 actual revenue allocation. The following chart depicts the projected average charge for the first three fiscal years of the project:

Monroe Breast Center - Average Charge		
FY 2013	FY 2014	FY 2015
$267.00	$258.00	$250.00

Exhibit N contains the projected financial report for the proposed project. The following table derived from Forms B & C, illustrates projected revenues and expenses for the project during each of the first three project operating years.

Revenue, Expenses & Income for FY 2013-FY2015			
	FY 2013	FY 2014	FY 2015
Gross Revenue	$2,480,469	$2,554,883	$2,631530
Net Revenue	$1,783,129	$1,836,623	$1,891,721
Total Expenses	$822,405	$826,122	$844,474
Net Income	$960,724	$1,010,500	$1,047,248

As shown in the above table, in the third project year (FY 2015) the applicant projects revenues will exceed expenses by $1,047,248. The applicant provides assumptions for the ProForma in Exhibit N, pages 1 of 1 and 2 of 2.

Revenues and expenses projected by the applicant seem reasonable. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

C

Charlotte Radiology, P.A. proposes to acquire a second mammography unit at the Monroe Breast Center and obtain designation as a diagnostic center. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination methodology in the 2011 SMFP.

See Criteria (1) and (3) for discussion of methodology and need projections. The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing services, and 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 II, pages 17 and 19, the applicant states:

> *"Charlotte Radiology's hours of operation at the Monroe Breast Center are 7:30am to 5:00pm. Screening mammography services are available 4 days a week, Monday, Wednesday, Thursday, and Friday. Diagnostic services are available Monday, Tuesday, Wednesday and Thursday. Both services are periodically offered on Saturday."*

In Section VII.1(b), page 58, the applicant provides the projected staffing during the second operation year, as shown in the following table:

Monroe Breast Center Staffing FY 2	
Position	Projected FTEs Year 2
Site Coordinator	1.0
Front Desk /Clerical	2.0
Radiology Technologists	2.0
Total	5.0

On page 59, the applicant states that an additional radiology technologist will be hired for the project for a total of 2.0 FTEs. The applicant states that physicians employed by Charlotte Radiology will not be used at the Monroe Breast Center; but continue to provide support as currently done. On page 59, the applicant states the following about the availability of required personnel:

> *"Charlotte Radiology historically has had not problems filling vacancies using typical recruitment efforts. In addition, Charlotte Radiology provides a training program for X-ray technologists to assist them with obtaining their mammography technologist certification. Filling the new technologist position should not pose a problem due to past recruitment successes and the availability of a robust training program."*

On pages 48 and 61, the applicant states that Dr. Matthew Gromet, J.D., M.D. is the Medical Director for the Monroe Breast Center and is a board certified radiologist. Exhibit I contains the list and curriculum vitas of Charlotte Radiology physicians who will work at the Monroe Breast Center.

The applicant demonstrates the availability of adequate health manpower and management personnel for the provision of the proposed screening and diagnostic mammography 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, page 19, the applicant states:

> "*Charlotte Radiology already has in place the ancillary and support departments needed to provide screening and diagnostic mammography services at the Monroe Breast Center. These departments will be unaffected by this project and will maintain the same organizational structure following the approval of the application. Please see Exhibit C for a copy of Charlotte Radiology's organizational chart.*"

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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

C

In Section VI.2 (a-f), page 52, the applicant states:

> "*Charlotte Radiology provides access to care to all patients regardless of age, race, national or ethnic origin, disability, sex, income, or immediate ability to pay. Patients are admitted and services are rendered in compliance with: (1) Title VI of Civil Rights Act of 1963; (2) Section 504 of Rehabilitation Act of 1973; (3) The Age discrimination* [sic] *Act of 1975; (4) Americans with Disabilities Act.*"

In Section VI.12 and 13, page 56, the applicant provides the current (January 1-December 31, 2010) payor mix for the Monroe Breast Center mammography services. The applicant states that the projected payor mix is expected to be the same as the current payor mix after project completion.

Monroe Breast Center Mammography Services FY January 1-December 31, 2010			
Current Procedures as Percent of Total Utilization		Current Revenue as Percent of Total Revenue	
Blue Cross	35.3%	Blue Cross	35.4%
Medicare	31.4%	Medicare	31.5%
Commercial Insurance/Managed Care	29.6%	Commercial Insurance/Managed Care	29.6%
Medicaid	2.5%	Medicaid	2.4%
Self-Pay/Indigent/Charity	1.2%	Self-Pay/Indigent/Charity	1.1%
Total	100.0%	Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table were obtained on January 10, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)**
Union County	11.0%	3.4%	18.0%
Statewide	17.0%	6.7%	19.7%

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

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage 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. However, as of January 10, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Charlotte Radiology Monroe Breast Center. 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

In Section VI.10(a), page 55, the applicant states:

> "*Not Applicable. No civil rights equal access complaints have been filed against Charlotte Radiology in the past five years.*"

In Section VI.11(a), page 56, the applicant states:

> "*Charlotte Radiology has no public obligations to provide uncompensated care, community service, or access to minorities and handicapped persons.*"

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 V1.13, page 56, the applicant provides the future payor mix as depicted in the chart on page 17 of these findings. In Section V1.14, page 57 of the application, the applicant states:

> "*Charlotte Radiology expects its payor mix at the Monroe Breast Center to remain the same following completion of the proposed project.*"

The applicant projects that 33.9% percent of the diagnostic center patients will have some or all of their services paid for by Medicare or Medicaid; while 65% will be paid for by Blue Cross and other commercial insurance/managed care. It is estimated that another 1.1% of services will be self-pay/indigent/charity. The applicant demonstrates that it will provide adequate access to medically underserved populations. 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 55, the applicant states,

"Due to the nature of the proposed project as an outpatient service, Charlotte Radiology expects to operate primarily on a scheduled and non-emergent basis through physician referrals, as it currently does."

Further, in Section VI.9(b), page 55, the applicant states that historically it has received referrals from local healthcare systems and the health department.

The information the applicant provides 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(a-c), page 47, the applicant discusses how it meets the clinical needs of health professional training programs in the area. The applicant states in part that it trains students from schools such as Stanly Community College and Rowan-Cabarrus Technical School. Charlotte Radiology also provides mammography specialty training to registered X-ray technologists to assist them with obtaining their mammography technologist certification. Charlotte Radiology states that it has provided training to twenty technologists and is currently training six new students. The application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates that the proposal is needed and that it is a cost-effective alternative to meet the demonstrated need [see Criteria (1), (3), (4) (5) and (12) for additional discussion];

- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Charlotte Radiology Monroe Breast Center states that the facility is accredited by the FDA and the American College of Radiology. The applicant also states that the facility will continue to comply with all applicable federal, state and county laws, including building codes and safety regulations. The information provided by the applicant is reasonable and credible. 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

Charlotte Radiology is proposing to develop a new diagnostic center in Monroe by acquiring one additional digital mammography unit. The application is conforming to all applicable Criteria and Standards for Diagnostic Centers, promulgated in 10A NCAC 14C .1800. The specific criteria are discussed below.

10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall use the Acute Care Facility/Medical Equipment application form.

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

(b) An applicant shall also provide the following additional information:

(1) the number, type, cost, condition, useful life and depreciation schedule of all medical diagnostic equipment that either is proposed to be acquired or is currently owned or operated by the applicant, and will be part of the diagnostic center following completion of the project;

-C- The applicant provides the information required by this Rule in Section II, page 18 and in Section VII.2, page 62, Section X, page 76, and in additional information requested by the Agency. The applicant states: "*Charlotte Radiology uses the 150 percent declining balance method of depreciation. The equipment is depreciated over a 5 year period and is assumed to have no salvage or book value at the end of its depreciable life.*" See the following table:

Proposed Equipment Description	**Number**	**Existing/ New**	**Year Expected Purchase**	**Condition**	**Purchase Cost --- Remaining Book Value**	**Depreciation Life**
Selenia Base Unit & Image Checker	1	Existing	8/2007	Excellent	$239,000 --- $24,737	5 years
Hologic Securview	1	Existing	8/2007	Excellent	$60,000 --- $6,210	5 years
Hologic Securview	1	Existing	12/2008	Excellent	$60,000 --- $14,994	5 years
Siemens Antares US	1	Existing	12/2008	Excellent	$21,000 --- $5,248	5 years
Siemens Antares US	1	Existing	12/2008	Excellent	$23,150 --- $5,786	5 years
GE Lunar Prodigy	1	Existing	10/2006	Excellent	*$57,900 --- $0	5 years
Total Initial Cost					**$461,050**	
Selenia Dimensions 2D System (mammo-graphy unit)	1	New	**2012	New	$510,000	5 years
Digital Image Checker	1	New	**2012	New	$65,000	5 years

*Purchase amount corrected in information requested by the Agency. **See proposed Development Schedule, Section X, page 76.

(2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;

-NA- In additional information requested by the Agency, the applicant states that no additional equipment is necessary.

(3) the maximum number of procedures that each piece of medical diagnostic equipment in the diagnostic center is capable of performing and the assumptions used to project capacity;

-C- In Section IV, page 46, the applicant provides the maximum number of procedures for each type of equipment and the assumptions. See the following table:

	Procedures Per Day	Number of Units	Annual Capacity Per Unit	Total Service Capacity
Current Capacity				
Screening	50	1	6,300	6,300
Diagnostic	17	1	2,142	2,142
Future Capacity				
Screening	64	2	4,032	8,064
Diagnostic	28	2	1,764	3,528

(4) a list of all existing and approved health service facilities that operate or have been approved to operate medical diagnostic equipment and diagnostic suites by type and location in the proposed medical diagnostic equipment service area;

-C- In Section III, pages 41-42, the applicant lists the following facilities as providing mammography exams: CMC Union, CMC Anson County Hospital, Presbyterian Imaging & Breast Center-Union, and at its own facility, Charlotte Radiology Monroe Breast Center. However, the applicant states that Presbyterian data is not available and that outpatient centers are not required to report such data. The following table identifies hospitals located in the proposed service area and the data reported in their 2010 License Renewal Application. Charlotte Radiology Monroe Breast Center data is internally generated data.

Providers in the Service Area	Mammography Exams
CMC-Union	0
CMC-Anson County Hospital	40
Presbyterian Imaging & Breast Center-Union	NA
Charlotte Radiology Monroe Breast Center	6,213

(5) the hours of operation of the proposed diagnostic center and each proposed diagnostic service;

-C- The hours of operation of each diagnostic service at the proposed diagnostic center are provided in Section II, pages 17 and 19.

(6) the patient origin by percentage by county of residence for each diagnostic service provided by the applicant in the 12 month period immediately preceding the submittal of the application;

-C- In Section III, pages 39-41, the applicant provides patient origin by percentage by county of residence for each service proposed. The assumptions and data supporting the methodology are also included in Section III, pages 39-41.

(7) the projected patient origin by percentage by county of residence for each service proposed, and all the assumptions and data supporting the methodology used for the projections;

-C- Section III, pages 39-41, the applicant provides patient origin by percentage by county of residence for each service proposed. The assumptions and data supporting the methodology are also included in Section III, pages 39-41.

(8) drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and

-C- Exhibit O includes a drawing of the proposed diagnostic center that identifies a distinct area for each of the proposed services.

(9) a three year capital budget.

-C- The applicant provides the three year capital budget in additional information requested by the Agency.

(c) An applicant proposing to establish a new mobile diagnostic program shall also provide the following information:

(1) the number, type and cost of all proposed mobile medical diagnostic equipment including the cost of the transporting equipment;
(2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;
(3) the number and type of all existing and approved mobile diagnostic equipment in the proposed mobile diagnostic center service area;
(4) the maximum number of procedures that each proposed piece of medical diagnostic equipment is capable of performing and the assumptions used to project capacity;
(5) the name, address and hours of service at each host facility that is proposed to be served by the mobile diagnostic program; and
(6) copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the mobile diagnostic program.

-NA- The applicant does not propose to acquire mobile medical diagnostic equipment.

(d) An applicant shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration or will be operated or used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.

-C- The applicant provided copies of certificates of accreditation from the FDA and the American College of Radiology in additional information requested by the Agency. In Section II, page 20 of the application, the applicant states:
"*The Monroe Breast Center is accredited by the FDA and the American College of Radiology.*"

(e) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

(1) the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project; and

-C- In additional information required by the Agency the applicant provides the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project.

(2) the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following completion of the project; and

-C- In additional information required by the Agency the applicant provides the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following completion of the project.

(3) the projected number and type of diagnostic procedures proposed to be provided by CPT code or ICD-9-CM procedure code for each of the first twelve calendar quarters following completion of the project.

-C- In additional information required by the Agency, the applicant provides the projected number of patients to be served by CPT code for the first twelve calendar quarter following completion of the project.

10A NCAC 14C .1804 PERFORMANCE STANDARDS

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

(1) documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;

-C- The applicant states: "*the applicant does not have access to volume information for all the existing providers of digital mammography services in the primary and secondary service areas and cannot determine if the existing providers are operating at 80% capacity. What information that is available is found in Section II.6(b) (page 42 of the application). It should be noted that there are no providers in Anson County providing digital mammography services. In addition, Charlotte Radiology is the only provider in Union County providing digital diagnostic mammography services.*"

(2) documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;

-C- The applicant provides capacity information that supports utilization at 80% of the maximum number of procedures by the fourth quarter of the third year of operation. See Section III, page 36 and Section IV page 46.

Charlotte Radiology Monroe Breast Center – Project Year 3 (FY2015)						
Equipment	**# of Units**	**Projected # of Exams**	**Annual Capacity per Unit**	**Total Capacity for Facility**	**80% of Capacity for Facility**	**Utilization Rate**
Screening	2	8,542	4,032	8,064	6,451	106%
Diagnostic	2	2,902	1,764	3,528	2,822	82%

*Calculated by project analyst based on "80% Capacity of Total # of Units" provided by applicant.

(3) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and

-C- In Section II, pages 9-13, specifically pages 12-13, the applicant provides information about Charlotte Radiology's experience. In Section III, pages 23-33 and 35-37, the applicant provides epidemiological information about breast cancer, screening and diagnostic mammograms.

(4) all the assumptions and data supporting the methodologies used for the projections in this Rule.

-C- The applicant provides all assumptions and data supporting the methodologies used for the projections in this Rule in Sections III.1 & III.5 (pages 23-43) and IV.1 and IV.2 (pages 44-46). See Criterion (3).

10A NCAC 14C .1805 SUPPORT SERVICES
An applicant shall provide documentation showing the proximity of the proposed diagnostic center to the following services:

(1) emergency services;

(2) support services;
(3) ancillary services; and
(4) public transportation.

-C- In Section II, page 19, the applicant provides information about emergency, support and ancillary services. Public Transportation is addressed in additional information requested by the Agency. The applicant states, "*The city of Monroe does not provide public transportation services. However, the Monroe Breast Center is located on Hwy 74 and is easily accessible to patients living in Union and Anson Counties.*"

10A NCAC 14C .1806 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall identify the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff that are projected to be involved in providing each of the proposed diagnostic services.

-C- In Section VII.1(a and b), page 58, Section VII.8, page 61 and Exhibit I, the applicant identifies the number of staff listed in the Rule projected to be involved in providing the proposed diagnostic services.

(b) An applicant proposing to provide ionizing and nonionizing radiation procedures shall demonstrate that a physician, licensed to practice medicine in North Carolina shall be available to perform and supervise all radiation procedures and shall document the qualifications of this physician to perform radiation procedures.

-NA- The applicant states that Charlotte Radiology Monroe Breast Center will not perform ionizing and nonionizing radiation procedures.

(c) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.

-C- The applicant provides information about continuing education in Section VII.4, page 59 and in Exhibit K.