



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director, Division of Health Service Regulation

April 25, 2019

Gary S. Qualls  
430 Davis Drive, Suite 400  
Morrisville, NC 27560

**No Review**

**Record #:** 2920  
**Facility Name:** Carolinas Medical Center  
**FID #:** 943070  
**Business Name:** The Charlotte-Mecklenburg Hospital Authority  
**Business #:** 1770  
**Project Description:** Utilize existing electrophysiology unit at CMC-Main as cardiac catheterization equipment and dispose of previously utilized cardiac catheterization equipment at CMC-Mercy  
**County:** Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION  
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603  
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704  
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Please do not hesitate to contact this office if you have any questions.

Sincerely,



Julie M. Faenza  
Project Analyst



Martha J. Frisone, Chief  
Healthcare Planning and Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR

April 18, 2019

Gary S. Qualls  
Gary.qualls@klgates.com

T +1 919 466 1182  
F +1 919 516 2072



**Via Hand Delivery**

Martha Frisone  
Chief  
Department of Health and Human Services  
Division of Health Service Regulation  
Healthcare Planning and Certificate of Need  
Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Re: No Review Request for Cardiac Cath Equipment Swap Within CMC's Licensed Campuses

Dear Ms. Frisone:

My client, The Charlotte-Mecklenburg Hospital Authority ("CMHA"), d/b/a Carolinas Medical Center ("CMC") requests a no review determination that the relocation of cardiac catheterization ("cath") CON rights within CMC's licensed hospital does not require a CON.

Specifically, CMC has nine (9) Cardiac Cath Equipment<sup>1</sup> Units in its licensed hospital. Eight (8) of those Units are currently on the CMC Campus and one (1) Unit is on the CMC-Mercy Campus. Historically, CMC operated eight (8) Cardiac Cath Equipment Units on its license and Atrium Health University City (f/k/a CHS University) operated one (1) Cardiac Cath Equipment Unit on its license. However, by a September 29, 2017 Material Compliance Approval (attached as Exhibit 1), the Agency approved CMHA's request to relocate the University City Cardiac Cath Equipment Unit to CMC. CMHA has recently implemented that relocation. Therefore, CMC now operates nine (9) Cardiac Cath Equipment Units under its license.

CMC wants to house all nine Cardiac Cath Equipment Units on the CMC Campus. To do so, CMC proposes to cease using the one Unit on the CMC-Mercy Campus and start using an electrophysiology ("EP") unit as a Cardiac Cath Equipment Unit in its stead (the "Equipment Swap"). The existing CMC-Mercy Campus Cardiac Cath Equipment Unit will be disposed of.

<sup>1</sup> The term "Cardiac Cath Equipment," as used in this letter, is the equipment regulated by N.C. Gen. Stat. § 131E-176(16)(f)(3) and defined in N.C. Gen. Stat. § 131E-176(16)(2f).



We ask that the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) determine that this intra-hospital “Equipment Swap” is non-reviewable because it does not constitute a new institutional health service under N.C. Gen. Stat. § 131E-176(16).

Under North Carolina law, a CON is required only prior to offering or developing a “new institutional health service.” “New institutional health service[s]” include a variety of services and activities, including the acquisition of cardiac cath equipment. See N.C. Gen. Stat. § 131E-176(16)(f1)(3). However, CMHA is not acquiring Cardiac Cath Equipment here. Rather, CMHA is simply shifting which piece of existing equipment within the same licensed hospital will be used as Cardiac Cath Equipment, as regulated by Section 131E-176(16)(f1)(3) and defined in Section 131E-176(16)(2f).

The attached floor plans show where the seven (7) Adult Cardiac Cath Units on the CMC Campus will be housed. CMC has two (2) Pediatric Cardiac Cath Equipment Units that are not located in the same area of the building as the Adult Cardiac Cath Equipment Units. Because the Pediatric Cardiac Cath Equipment Units are not being affected by the Equipment Swap, the attached floor plans do not show these two (2) Pediatric Cardiac Cath Equipment Units.

#### **Current Locations of Cardiac Cath Units on CMC License**

The current locations of CMC’s licensed Cardiac Cath Equipment Units are as follows:

- One (1) Adult Cardiac Cath Equipment Unit is located on CMC Main, Level 4 (Exhibit 2 Floor Plan).
- Five (5) Adult Cardiac Cath Equipment Units are located on CMC Main, Level 6 (Exhibit 3 Floor Plan).
- Two (2) Pediatric Cardiac Cath Equipment Units are located on CMC Main, Level 6 (Not on Floor Plan).
- One (1) Cardiac Cath Equipment Unit is currently located on the CMC Mercy Campus.





Martha Frisone  
Chief  
April 18, 2019  
Page 3

**Proposed Locations of Cardiac Cath Units on CMC License**

After the Equipment Swap, the proposed locations of CMC's licensed Cardiac Cath Equipment Units are as follows:

- One (1) Adult Cardiac Cath Equipment Unit is located on CMC Main, Level 4 (Exhibit 1 Floor Plan).
- Six (6) Adult Cardiac Cath Equipment Units are **to be** located on CMC Main, Level 6 (Exhibit 4 Floor Plan).
- Two (2) Pediatric Cardiac Cath Equipment Units are located on CMC Main, Level 6 (Not on Floor Plan).
- **No** Cardiac Cath Units will be located on the CMC Mercy Campus. See Disposition Letter attached as Exhibit 5.

Given that the Equipment Swap does not trigger any "new institutional health service" categories, please confirm that the Equipment Swap is not CON reviewable because it does not constitute a new institutional health service.

If you require additional information, please feel free to contact me at the above number. Thank you in advance for your review of this request.

Sincerely,



Gary S. Qualls





**Exhibits**

1. Material Compliance Approval to Relocate University City Cardiac Cath Equipment Unit to CMC
2. Floor Plan showing One (1) Adult Cardiac Cath Unit located on CMC Main, Level 4
3. Floor Plan showing Five (5) Adult Cardiac Cath Units located on CMC Main, Level 6
4. Floor Plan showing Six (6) Adult Cardiac Cath Units to be located on CMC Main, Level 6
5. Equipment Disposition Letter









DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

September 29, 2017

Gary S. Qualls  
K&L Gates  
430 Davis Drive, Suite 400  
Morrisville, NC 27560

**Material Compliance Approval**

Project ID #: F-6384-01  
Facility: Carolinas HealthCare System (CHS) University  
Project Description: Change site of one unit of cardiac catheterization equipment from CHS University to Carolinas Medical Center (CMC)  
County: Mecklenburg  
FID #: 923516

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of September 7, 2017 is in material compliance with representations made in the application. This change includes changing the site of one unit of cardiac catheterization equipment from CHS University to CMC where it will be located in Cardiology Room 8. The EP unit located in that room will become a cardiac catheterization unit. Upon completion, CHS University will have zero cardiac catheterization units and CMC will have nine cardiac catheterization units on its license. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

*Gloria C. Hale*

Gloria C. Hale  
Project Analyst

*Martha J. Frisone*

Martha J. Frisone  
Chief, Healthcare Planning and  
Certificate of Need Section

cc: Construction Section, DHSR  
Acute and Home Care, Licensure and Certification Section, DHSR  
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**

WWW.NCDHHS.GOV

TELEPHONE: 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



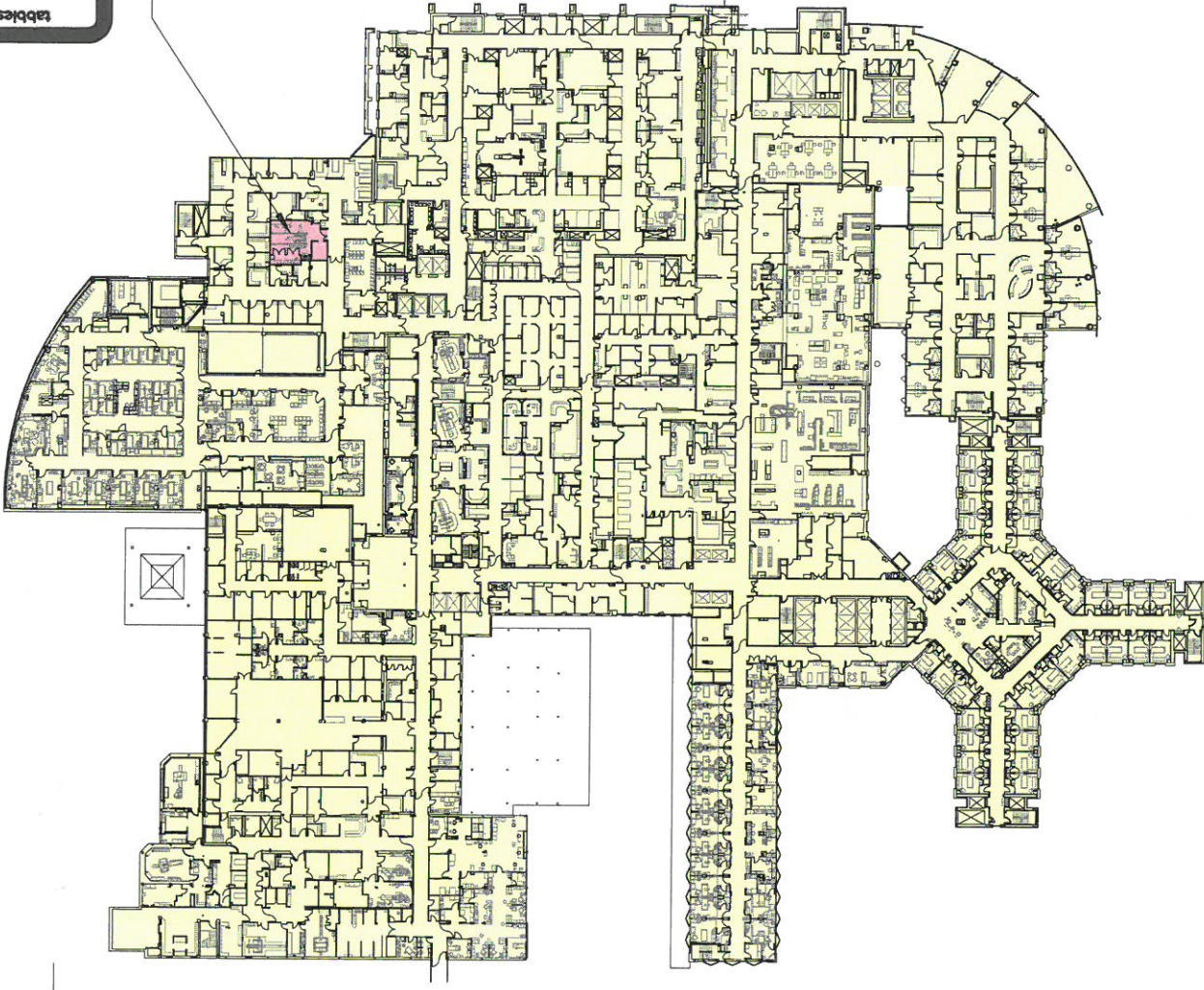








ROOM #8-CARDIAC  
CATH



CON Color Legend

- CATH LABS, OR, ENDO, MRI, SPECIAL PROCEDURE, PET, LINEAR ACC & OTHER
- EXISTING BUILDING

# OVERALL PLAN - LEVEL 04 - CURRENT

## Cath Labs





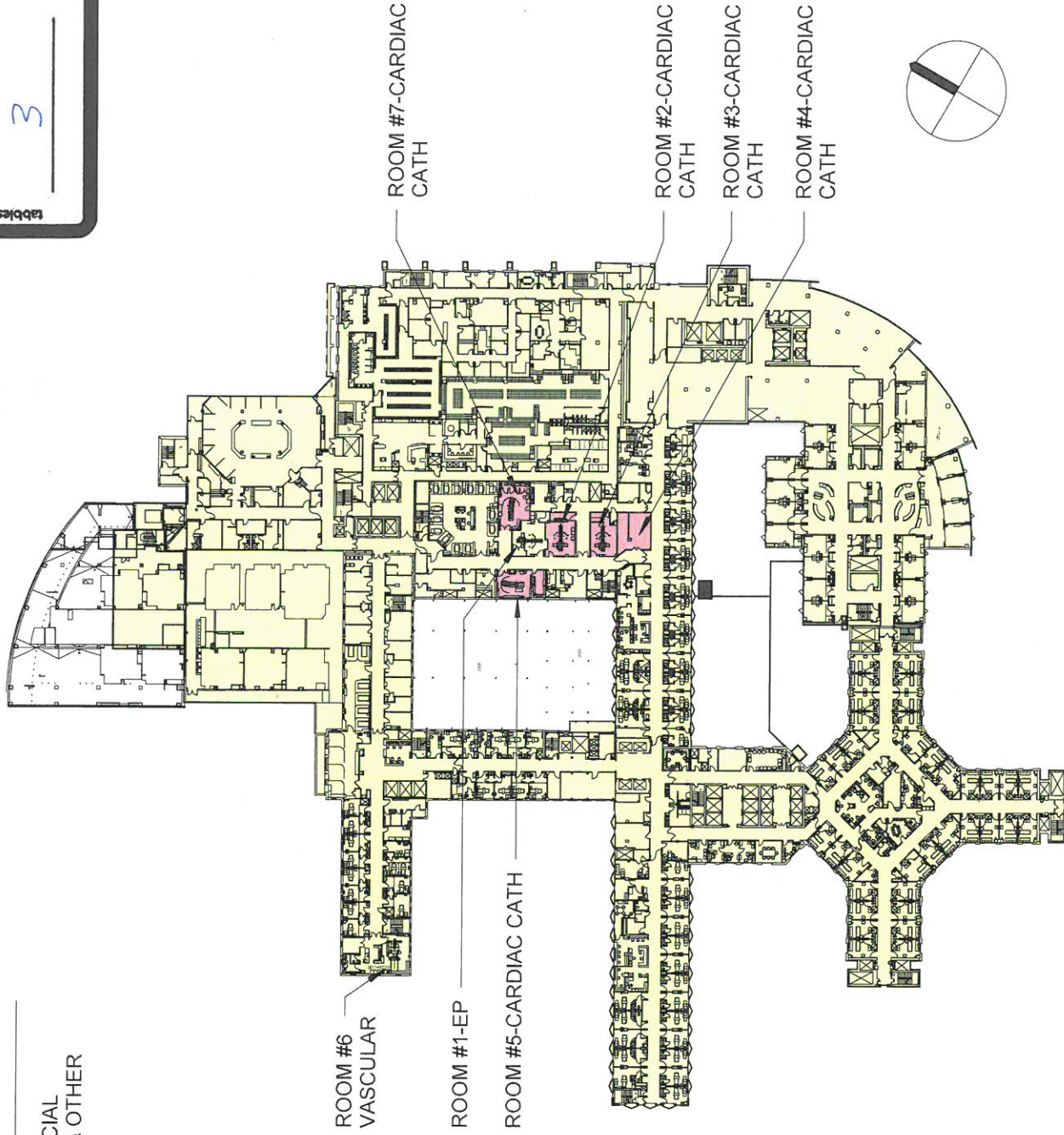






CON Color Legend

- CATH LABS, OR, ENDO, MRI, SPECIAL PROCEDURE, PET, LINEAR ACC & OTHER
- EXISTING BUILDING



# OVERALL PLAN - LEVEL 06 - CURRENT

## Cath Labs







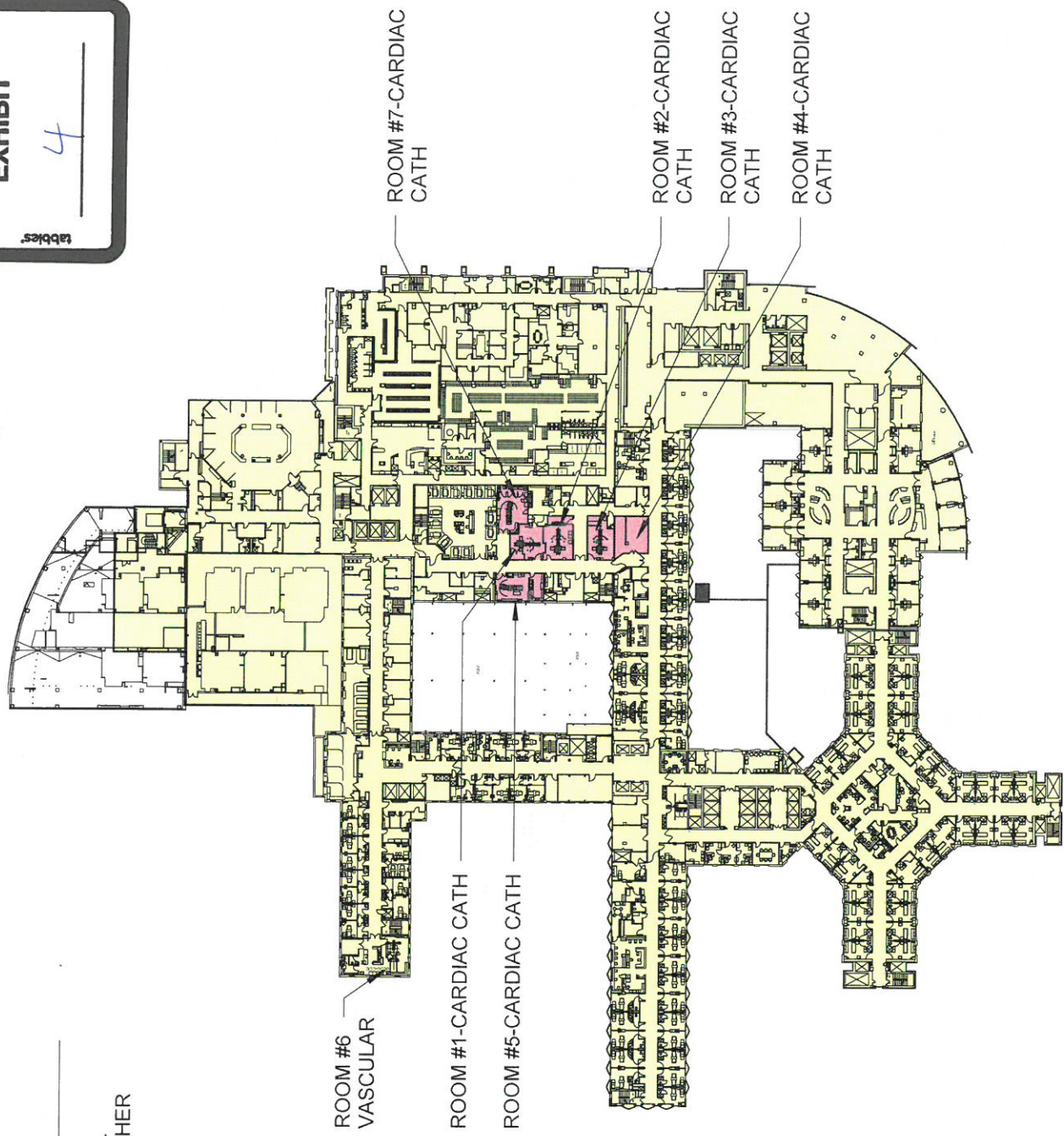




EXHIBIT  
4

CON Color Legend

- CATH LABS, OR, ENDO, MRI, SPECIAL PROCEDURE, PET, LINEAR ACC & OTHER
- EXISTING BUILDING



# OVERALL PLAN - LEVEL 06 - PROPOSED

## Cath Labs

Atrium Health

03/05/2019

Carolinas Medical Center - Main



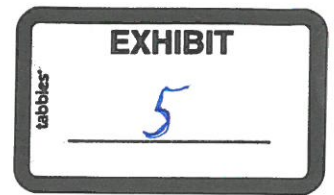






# PHILIPS

Memo



Philips Medical Systems Nederland B.V., Refurbished Systems Best

To Whom it may concern

Copy Sreedar Handeth, Guido Stomp, Peter v/d/ Linden, Martin Raaimakers, Kimberly Bates, Daniel Abu Manneh

From Mathijn Ungerer      Quality Assurance RS      Tel: +316 27 122 500  
Veenpluis 6      Mathijn.ungerer@philips.com  
5684 PC Best  
The Netherlands

Ref: MB019026      Date: 14-Mar-2019

Subject: Refurbished Systems Best declaration for Medical Device North Carolina.  
RE: Allura FD 10 Serial Number 000428

To whom it may concern,

Herewith we, Refurbished Systems Best part of Philips Medical Systems Nederland B.V, declare that we will not, under any circumstances, replace the respective used medical devices back into the market of North Carolina.




Reviewed and approved 14 March, 2019

  
14<sup>th</sup> March 2019

Mathijn Ungerer

Quality & Regulatory Officer, Q&R  
Philips, Refurbished Systems Best

  
14<sup>th</sup> March 2019.

Sreedar Handeth

Head Q&R  
Philips, Refurbished Systems Best



