



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

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

VIA EMAIL ONLY

December 9, 2021

Catharine Cummer  
[Catharine.cummer@duke.edu](mailto:Catharine.cummer@duke.edu)

**Exempt from Review – Replacement Equipment**

**Record #:** 3725  
**Date of Request:** November 4, 2021  
**Facility Name:** Duke Regional Hospital  
**FID #:** 923142  
**Business Name:** Duke University Health System, Inc.  
**Business #:** 640  
**Project Description:** Replace existing cardiac catheterization equipment  
**County:** Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion FlexArm to replace the Philips Allura FD20. 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.

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.

Sincerely,

Kim Meymandi  
Project Analyst

Micheala Mitchell  
Chief

cc: Construction Section, DHSR  
Acute & Home Care Licensure & Certification Section, DHSR

**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  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning

November 4, 2021

Via Electronic Mail

Ms. Micheala Mitchell, Chief  
Ms. Lisa Pittman, Assistant Chief  
Ms. Kimberly Meymandi, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Regional Hospital

Dear Ms. Mitchell, Ms. Pittman, and Ms. Meymandi:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project and to request the Section's written confirmation that the project is exempt from certificate of need review. The project involves the replacement of cardiac catheterization equipment originally installed pursuant to a CON (and subsequently replaced) at Duke Regional Hospital.

The current equipment is at end-of-life and needs replacement to ensure ongoing patient care without increasing downtime for maintenance and service. This equipment replacement project satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection."

### Main campus

The existing and replacement catheterization equipment are/will be located in the main Duke Regional Hospital building. This is on the “main campus” of the facility, as defined in 131E-176(14n), as “[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building” and “[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

Duke Regional Hospital is a licensed health service facility (license available upon request), and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all Duke Regional Hospital services is located at 3643 North Roxboro Road in Durham. (As it happens, Duke Regional Hospital’s chief executive office and chief financial officer also have their offices within this same building, in the Watts annex.) Floor plans showing the location of the project are enclosed.

### Certificate of Need

Duke Regional Hospital operates two cardiac catheterization machines, both acquired originally pursuant to certificates of need. After this replacement, the inventory will remain at two. The existing catheterization equipment was originally acquired as Project J-2774-86, and replaced pursuant to replacement exemptions.

### Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment are cardiac catheterization laboratories. The existing machine is currently in service and will remain so until the replacement equipment is operational, at which time it will be removed from service within the state unless the Certificate of Need Section otherwise approves its continued use in the state.

A copy of the equipment quotation is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

Ms. Kimberly Meymandi  
November 4, 2021  
Page 3

If you have questions or need any further information, please let me know. We would appreciate your confirmation that this project is exempt from CON review. Thank you for your attention to this request.

Very truly yours,

*Catharine W. Cummer*

Catharine W. Cummer

Enclosures

**EQUIPMENT COMPARISON**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Type of Equipment	Cardiac Cath/Angio	Cardiac Cath/Angio
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	N/A	N/A
Model Number	Allura FD20	Azurion FlexArm
Serial Number	1783	TBD
Provider's Method of Identifying Equipment	FDA 2579	FDA 2579
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date Acquired	May 2009	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own	Capital purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$5.9M
Total Cost of Equipment	NA	\$1.3M
Fair Market Value of Equipment	NA	\$1.3M
Net Purchase Price of Equipment	NA	\$1.3M
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
Number of Times Existing Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	>10 Equipment used daily during normal business hours and available for use 24/7.	N/A
Type of Procedures Currently Performed on Existing Equipment	Cath/PV/EP	NA
Type of Procedures New Equipment is Capable of Performing	NA	Cath/PV/EP

Date of last revision: 12/4/2020

### GENERAL DEMOLITION NOTES

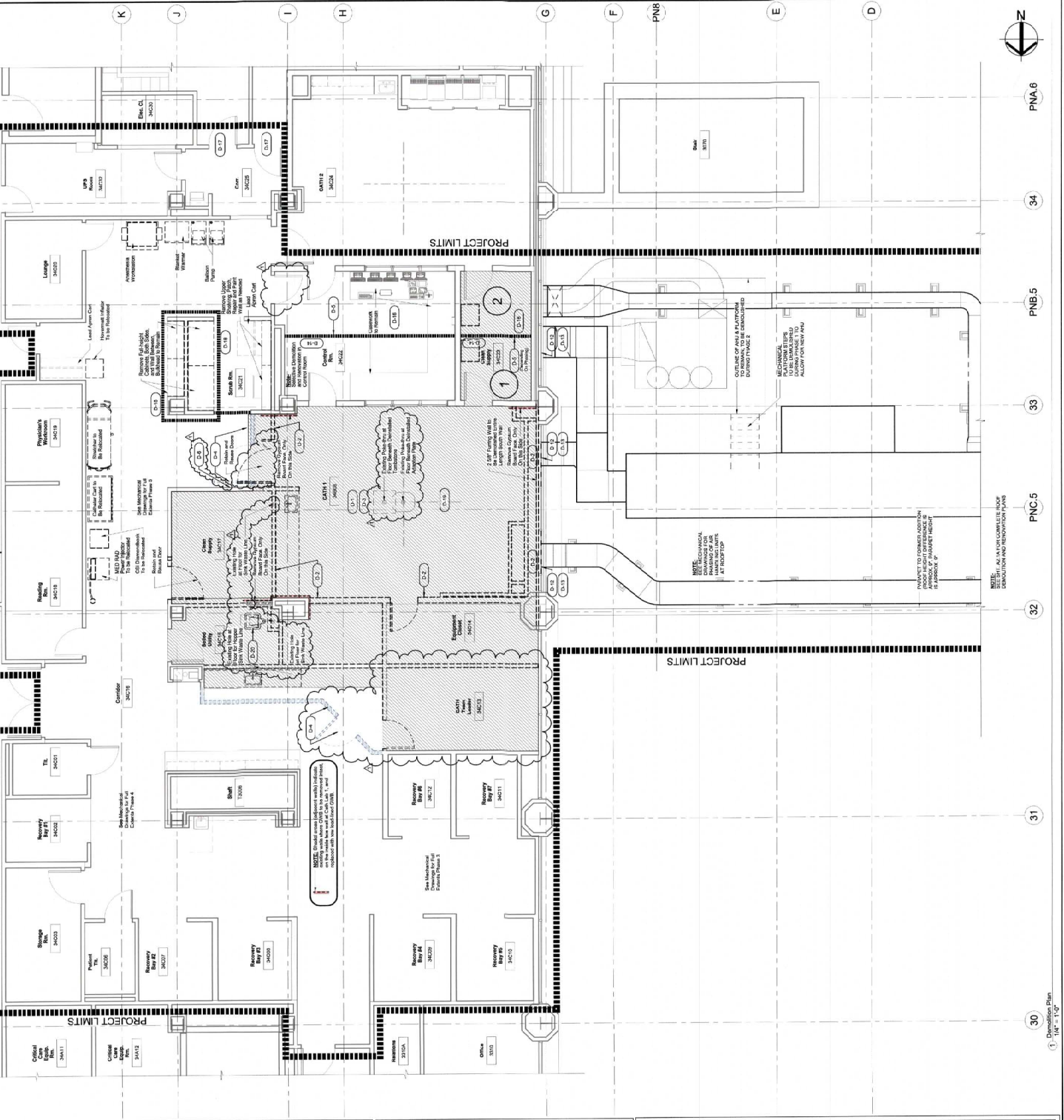
1. Confirm to test flooring and masonry for asbestos presence prior to start of construction. Contractor to take required steps to remove or to protect against asbestos. Asbestos testing and removal to be performed by a specialist under a separate contract.
2. Do not demolish any fire or smoke barriers until the new fire or smoke barrier has been constructed.
3. Erect dust partitions where shown prior to demolition. Maintain existing wall with dust partition construction.
4. Connect all new raised walls prior to the demolition of the existing raised walls.
5. Verify location of structure below prior to cutting for new glazing and mechanical ductwork, vendor plates, etc.
6. Refer to life safety plan for additional wall construction information.
7. General contractor shall list every dimensions and report all discrepancies to the architect.
8. The owner shall remove all items from demolition spaces that they intend to salvage. All other items remaining shall be removed by contractor unless otherwise noted. Not all items to be salvaged are necessary for completion of construction activity. Certain items may extend beyond these limits as noted on other drawings.
9. Comply with NFPA 101 sections 4.6.11.1, 7.1.1, NFPA 241 8.5.2, and 2020 IBC Fire Code section 1027 for protective construction particulate barrier during demolition.
10. Refer to risk assessment and contractor access plans for required precautions during construction.
11. Existing conditions shown in this document are for information only. Patch as necessary to meet building code requirements.
12. Phase 1 demolition includes Phillips mechanical (all 6.5 weeks) inspections and owner accommodations. Allow 6-7 weeks prior to starting phase 11 activities.
13. The general contractor shall visit the site at one-at-a-time walk through. Not all existing features to be protected are delineated on these drawings.
14. Prepare floor at Cath. Lab. 1 for subemployment topping required for fitness, shall be installed first for dimensional accuracy.

### DEMOLITION LEGEND

- DEMOLISHED WALLS
- DEMOLISHED DOORS, SOME ARE REPLACED
- ROOMS SHOWN IN PARTITION & SOAK, TEMPORARY WALLS
- DOORS TO SEPARATE CONSTRUCTION PROJECT AREAS
- FROM PATIENT STAFF AREAS
- FIRE RETARDANT PLASTIC SHEET DUST BARRIER
- ALLOWING ACCESS TO CRITICAL AREAS
- COMPLETE DEMOLITION AREA - DEMOLISH ARCHITECTURAL ELEMENTS AND FIRE PROTECTION OF THOSE ELEMENTS UNLESS OTHERWISE NOTED IN THIS DOCUMENT SET. ALL STRUCTURAL ELEMENTS TO REMAIN, THEY SHALL BE REPLACED WITH LEAD-LINED GYPSUM BOARD. (SEE NOTES ON PLAN)
- DEMOLISH FLOORING ONLY (BY PHASE)
- DEMOLISH CEILING ONLY

### DEMOLITION PLAN KEY NOTES

- D-1 Equipment de-installation by Phillips. Refer to vendor drawings for new equipment.
- D-2 Remove existing lead-lined drywall as required for new services throughout the space.
- D-3 Remove Phillips equipment base plates and patch floor with similar construction. Coordinate with interior drawings.
- D-4 Rigid Dust Partition and Door.
- D-5 Dust Barrier
- D-6 Remove existing "bush" and patch wall to match existing.
- D-7 Not Used.
- D-8 Not Used.
- D-9 Not Used.
- D-10 Not Used.
- D-11 Not Used.
- D-12 Coordinate access with Owner for construction access to make mechanical/electrical components through portion of exterior glazing into ceiling cavity to serve CATH.1 & CATH.2.
- D-13 Minimize penetrations of exterior skin for mechanical/electrical components from minimum 4".
- D-14 Install dust partition to separate phase 1 & 2. Provide rigid partition with sound barrier. Maintain staff access to lounge area for Cath. 2.
- D-15 Not Used.
- D-16 Maintain staff access to the men's and women's locker room for the duration of the entire project.
- D-17 Not Used.
- D-18 Coordinate with Owner moving equipment to this side of the space which is to be D-12 occurs. Transport equipment to the other side of the temporary partition and work area occupancy at Phase 1.
- D-19 Maintain staff access to the men's and women's locker room for the duration of the entire project.
- D-20 Remove hyper-alk and piping. Patch where needed with similar materials.



**NOTES:**

- REMOVE AND REINSTALL CEILING GRID, TILE IS REQUIRED TO COMPLETE INSTALLATION OF MECHANICAL, ELECTRICAL OR PLUMBING EQUIPMENT AND COMPONENTS. SEE SCHEDULE FOR EQUIPMENT AND COMPONENTS. SEE SCHEDULE FOR EQUIPMENT AND COMPONENTS.
- REPAIR OR REMOVE NEW ANY CEILING GRID TILE DAMAGED. SEE ARCHITECTURAL AND MEP DRAWINGS FOR FINISHES TO MAINTAIN FIRE RATING AS REQUIRED.
- PATCH AND REPAIR ALL VERTICAL AND HORIZONTAL CHASES TO MAINTAIN FIRE RATING AS REQUIRED.

**RENOVATION PLAN LEGEND -**

NEW WALLS	3" SURFACE MOUNTED CORNER GUARD	WALL TAG (SHOWN AT A2.1)
NEW DOORS	2" SURFACE MOUNTED CORNER GUARD	DOOR TAG
SECTION	WASH RAIL & PROTECTION; SEE DTL 1004.2	WAVE TAG (SHOWN AT A2.1)
ELEVATION	CRASH RAIL; SEE DTL 1004.2	WAVE TAG (SHOWN AT A2.1)
DETAIL	FIRE EXTINGUISHER CABINET	WAVE TAG (SHOWN AT A2.1)

**RENOVATION GENERAL NOTES -**

- SKIM AND PATCH FLOORING AS REQUIRED AT CATH LAB 1 TO ENSURE FLOOR IS LEVEL.
- AT CATH LAB 1, ANY FLOOR UNDERLAYMENT TOPPING REQUIRED FOR FLATNESS SHALL BE INSTALLED FIRST FOR DIMENSIONAL ACCURACY.
- PROVIDE METAL BLOCKING FOR ALL WALL MOUNTED ACCESSORIES AND ELECTRONICS REGARDLESS OF WHO IS THE SUPPLIER.
- RADIUS ALL EXPOSED COUNTERTOP CORNERS 2".
- REPAIR ANY DISTURBED OR EXISTING FIREPROOFING DEFICIENCIES.
- SEAL ANY EXISTING AND NEW PENETRATION IN RATED ASSEMBLIES.

**\* FLOOR TO FLOOR ELEVATION = '6' - 0" \***

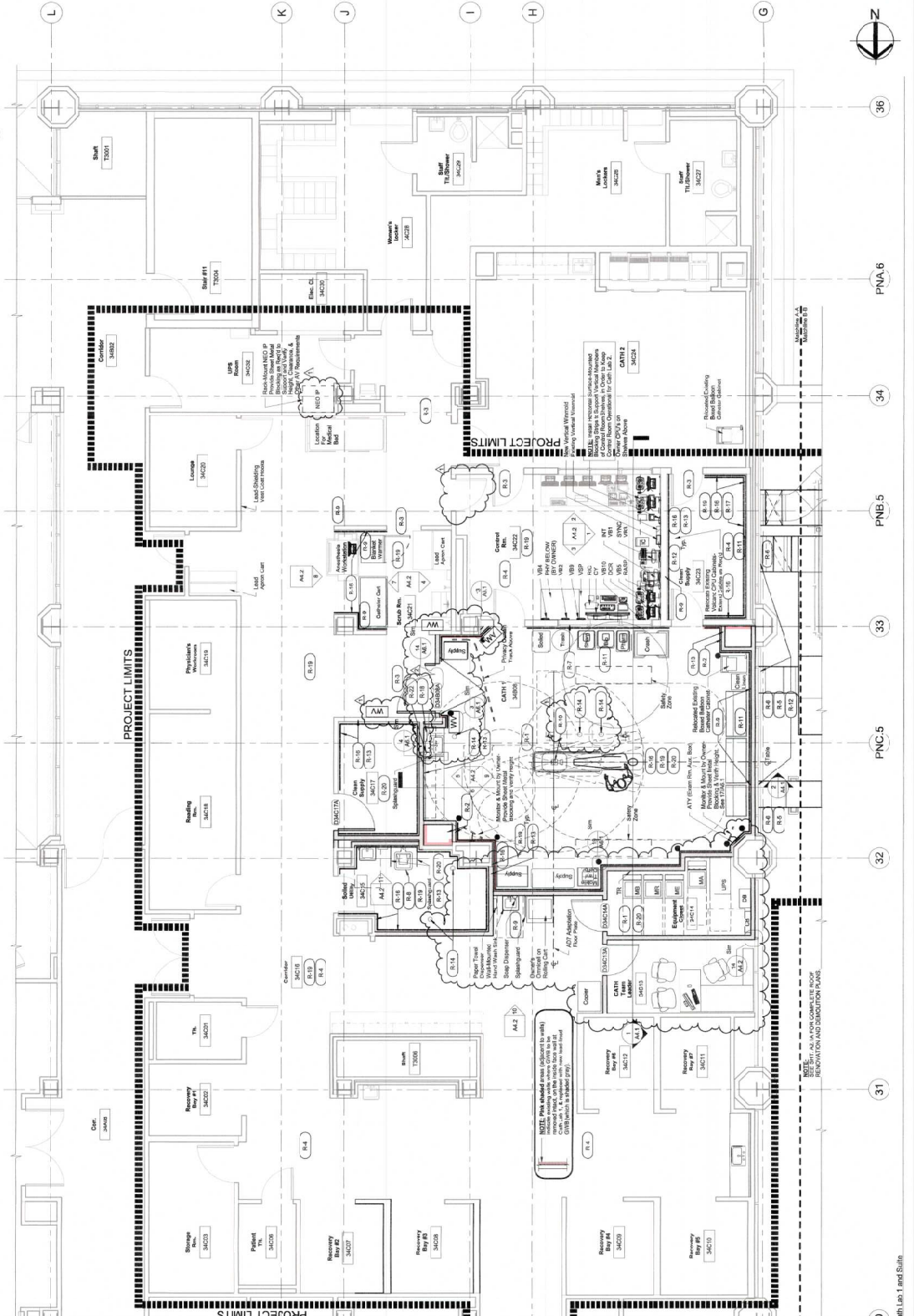
**RENOVATION PLAN KEY NOTES -**

- R.1.1 Refer to Philips Vendor Drawings for EP equipment installation. (Provided with this Set)
- R.1.2 Low-HVAC Room
- R.1.3 Maintain access to staff facilities throughout project
- R.1.4 Refer to S.H. A1.0 and Mechanical Dept. for phasing
- R.1.5 Seal all penetrations and make weather tight
- R.1.6 Provide insulated aluminum panel where duct penetrates window frame and make weather tight. Color of panel to match existing window frame.
- R.1.7 Protect existing Lead Glass and Frames
- R.1.8 Install Owner-provided flush valve hopper sink.
- R.1.9 Coordinate with engineering drawings for new services within wall.
- R.1.10 Patchwork as needed to match existing.
- R.1.11 Fit new hose for floor conduct pipe thru an AD7 adapter plate location with flashing. See Spec. Section 07 84 13 for full-responses detail.
- R.1.12 Loose & fixed equipment provided by subcontractor/vendor.
- R.1.22 Coordinate access to ceiling for mechanical life-lins. Rentable/repair ceiling to match existing.
- R.1.23 OWB on all walls at this room or area shall extend to the underside of the floor deck above. Multiple nominated walls. Fire stop all rated walls.
- R.1.24 Fill existing floor holes at removal areas (3) and both the designated AD7 and AD7 adapter plate locations with concrete deck with polymer-modified cementitious grout. Grout shall be finished with a smooth, non-slip, epoxy resin coating compound.
- R.1.25 New floor for life and associated ductwork. Coordinate with mechanical and electrical drawings.
- R.1.26 Wall protection panel around entire perimeter room. See DTL 1004.2.
- R.1.27 Repair all lengths existing. See DTL 1004.2.
- R.1.28 Repair (mud, see third party) walls that require patching.
- R.1.29 Replace flooring and paint walls.
- R.1.30 Patch & repair readings where required from demolishing existing (MH), mechanical platforms, any supports & working pads. floor to match existing & DR1 standards.
- R.1.31 Soap Dispenser: Owner-provided. Contractor-installed.



FDC# 4121 HSDF DRH  
 CATH Lab 1 Renovation  
 363 N REXFORD RD. DURHAM, NC 27704  
 3RD FLOOR, DURE REGIONAL HOSPITAL

Renovation Plan at Cath Lab 1  
 PROJECT NO. 19003  
 SHEET NO. A2.1



**From:** [Catharine Cummer](#)  
**To:** [Waller, Martha K](#)  
**Cc:** [Lara Orgain](#)  
**Subject:** [External] Exemption Notice DRH cath lab replacement 2021  
**Date:** Thursday, November 4, 2021 2:05:40 PM  
**Attachments:** [To State Exemption Notice DRH cath lab replacement 2021.pdf](#)  
[Replacement Equipment Comparison Form DRH Cath Lab 2021.docx](#)  
[DRH Cath Lab #1 New Floor Plan.pdf](#)  
[DRH Cath Lab #1 Demo Floor Plan.pdf](#)

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Martha,

I hope you're doing well. Attached for submission is an exemption notice for Duke Regional Hospital. Please let me know if you need anything further. Thank you!

Catharine

Catharine Cummer

Regulatory Counsel, Strategic Planning, Duke University Health System

3100 Tower Blvd, Suite 1300, Durham NC 27707

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In support of Duke Health's values,  
I stand for Black lives and against systemic racism.