



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

November 24, 2021

Catharine Cummer
Catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3747
Date of Request: November 17, 2021
Facility Name: Duke University Hospital
FID #: 943138
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 7 M20 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,

Handwritten signature of Kim Meymandi

Kim Meymandi
Project Analyst

Handwritten signature of Micheala Mitchell

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



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

November 17, 2021

Via Electronic Mail

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

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Mitchell:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of a cardiac catheterization lab at Duke University Hospital 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.

As set forth below, we believe that Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace an existing cardiac catheterization located on the 7th floor of Duke North, which is part of the main building of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[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."

In this case, Duke University Hospital is a licensed health service facility, and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children's Hospital, the Duke Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building.

(2) Previous Certificate of Need

Duke University Hospital currently operates seven cardiac catheterization labs including the two labs that will be replaced (excluding hybrid OR equipment). The CON for Project J-5327-86 documents that Duke was previously approved to operate eight cardiac catheterization labs. In 2004, DUH was approved to replace a cardiac lab with a bi-plane vascular system, leaving the number of cath labs at seven (see August 2, 2004 correspondence). While there have been replacements of the approved cath labs over time, Duke University Hospital has continued to operate a total of seven cath labs.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide cardiac catheterization procedures. The total project cost exceeds \$2,000,000 reflecting equipment and installation expenses. Copies of the equipment quotations are 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). Upon installation of the replacement equipment, the existing equipment will be taken out of service in the state.

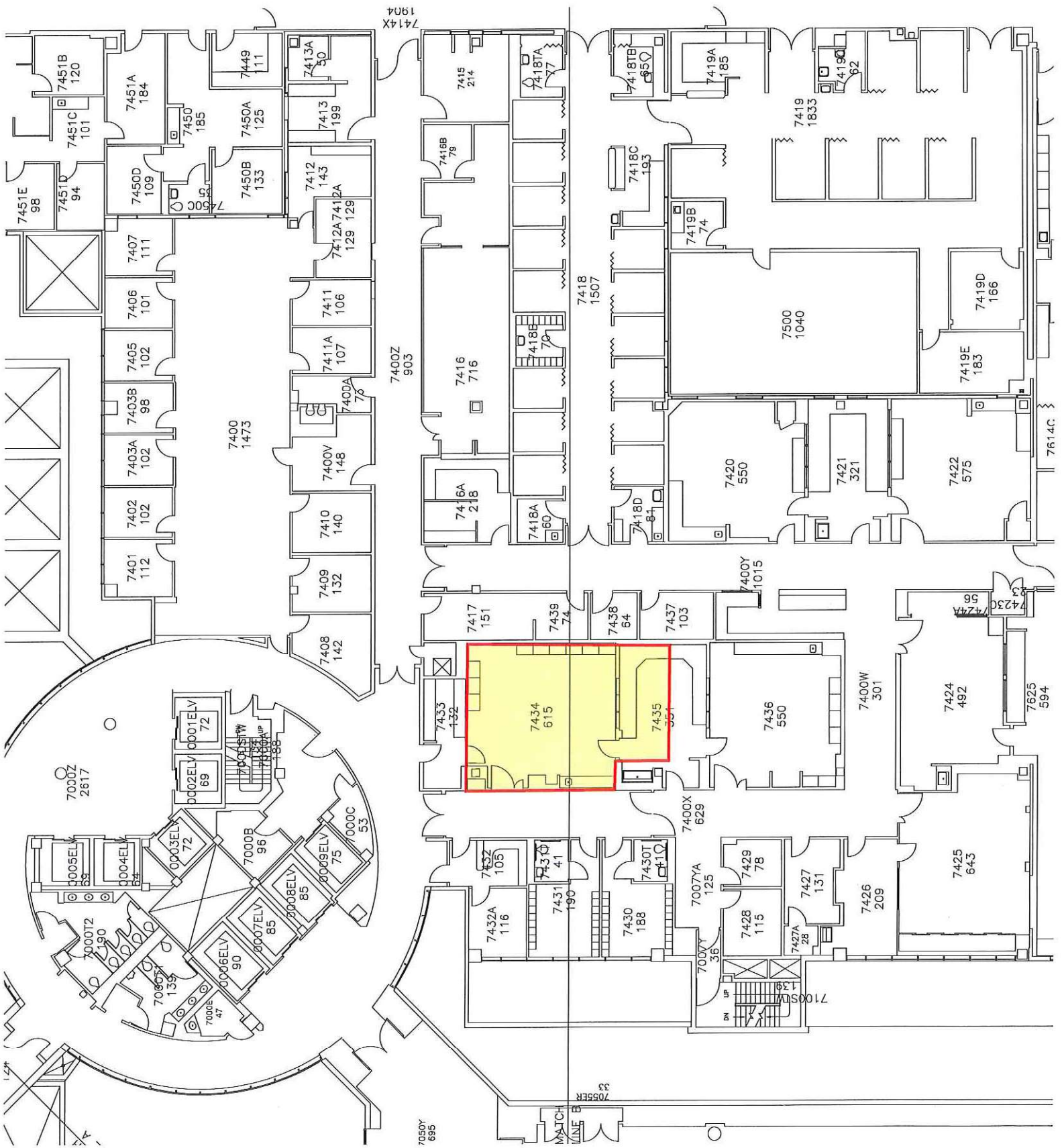
Thank you for your attention to this request. If you have questions about this information, please let me know.

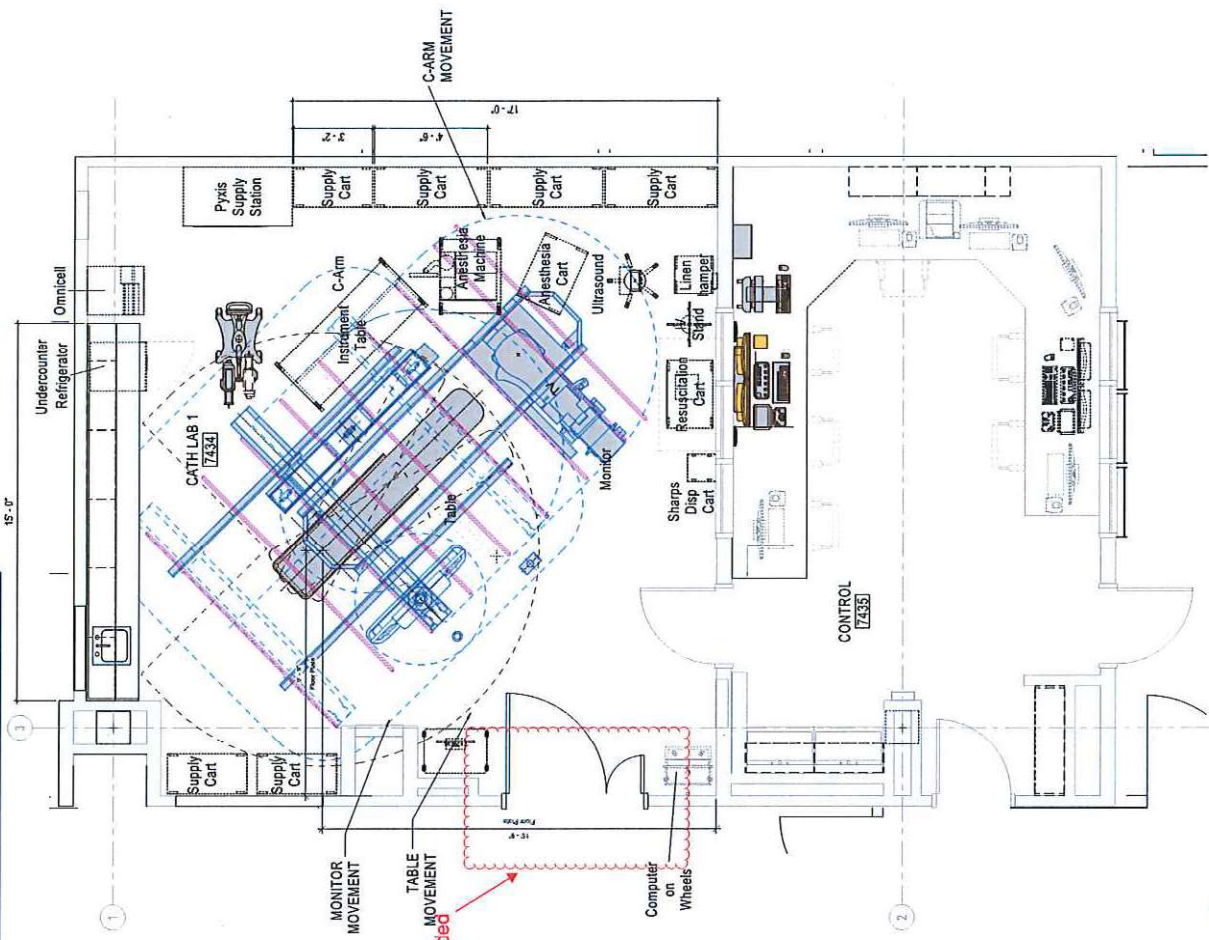
Very truly yours,

Catharine W. Cummer

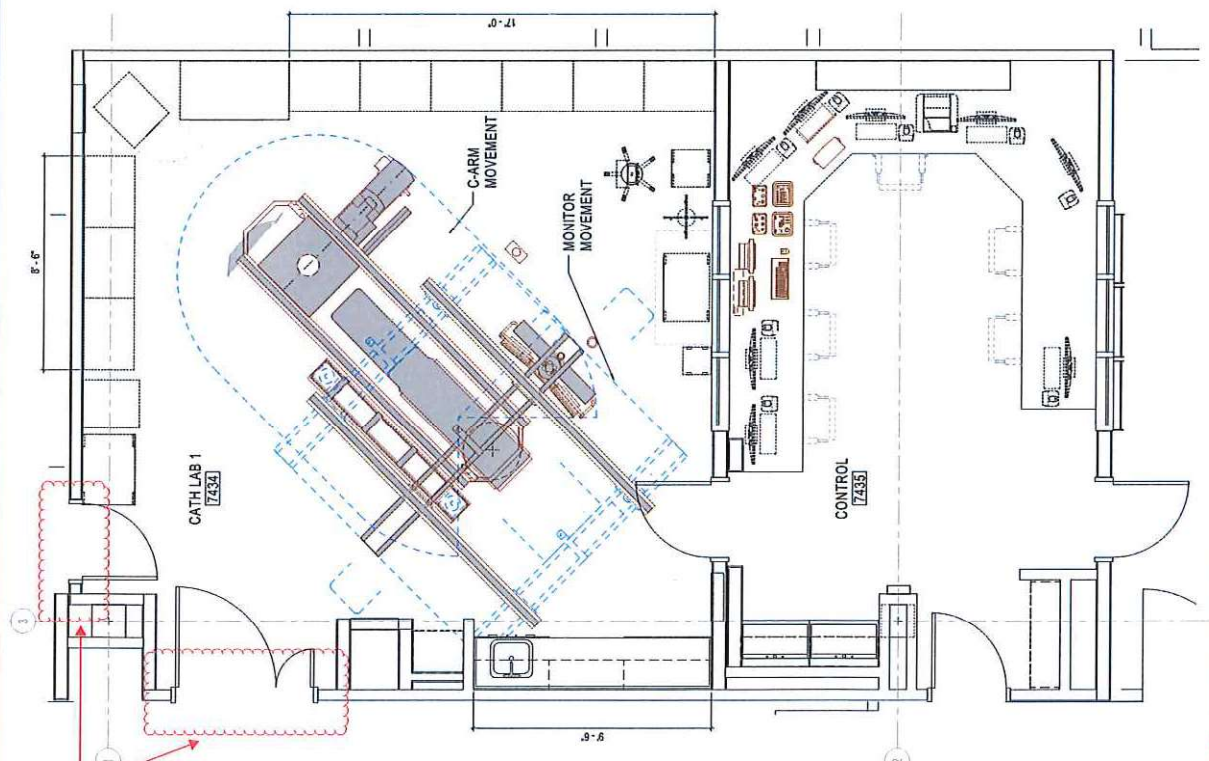
Catharine W. Cummer

Enclosures



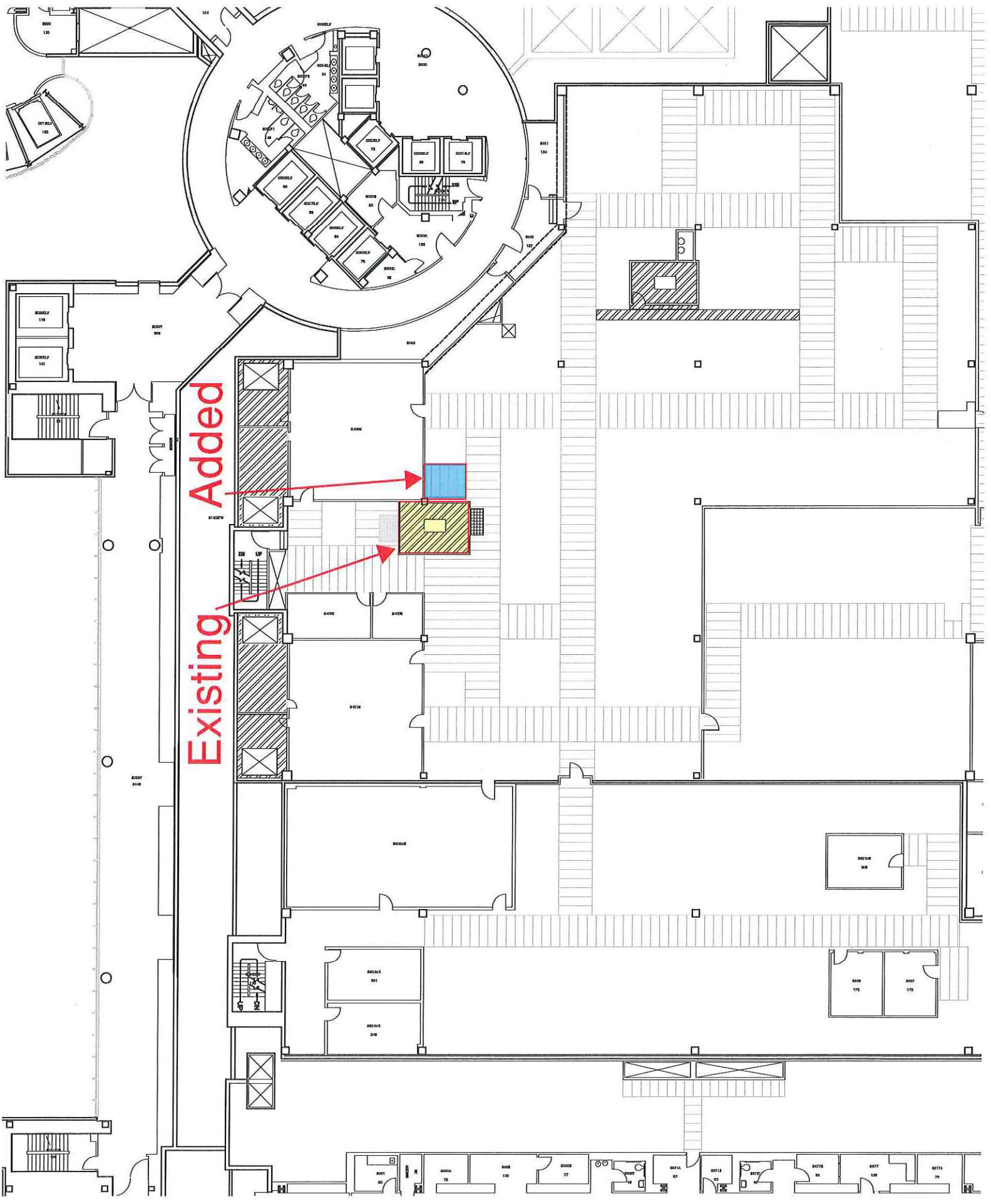


2 CATH LAB 7434 - NEW
1/2" = 1'-0"



1 CATH LAB 7434 - EXISTING
1/2" = 1'-0"

Doors removed and new lead-lined drywall added



Added

Existing

PARTIAL EIGHTH FLOOR PLANS – EP & CATH LABS

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	Cath Lab	Cath Lab
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	NA	NA
Model Number	Allura FD 20	Azurion 7 M20
Serial Number	591	NA
Provider's Method of Identifying Equipment	Cath I	Cath I
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date Acquired	Feb 8, 2008	NA
Does Provider Hold Title to Equipment or Have a Capital Lease?	Owned	Owned
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$3,083,000.00
Total Cost of Equipment	\$1,186,040.82	\$1,093,642.34
Fair Market Value of Equipment	NA	\$1,093,642.34
Net Purchase Price of Equipment	NA	\$1,093,642.34
Locations Where Operated	Duke University Hospital	Duke University 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	1,073	NA
Type of Procedures Currently Performed on Existing Equipment	R/L Heart Caths, Coronary Angiography and Stents, Biopsy, Peripheral Arteriogram, Peripheral Artery Angioplasty and Stents, IABP	NA
Type of Procedures New Equipment is Capable of Performing	NA	R/L Heart Caths, Coronary Angiography and Stents, Biopsy, Peripheral Arteriogram, Peripheral Artery Angioplasty and Stents, IABP

Date of last revision: 12/4/2020

From: [Catharine Cummer](#)
To: [Waller, Martha K](#)
Subject: [External] Equipment replacement notice -- Duke University Hospital
Date: Wednesday, November 17, 2021 3:40:04 PM
Attachments: [To State Exemption Notice DUH Cardiac Cath replacement 2021.pdf](#)
[Replacement Equipment Comparison Form -- DUH Cath Lab 1.docx](#)
[DUH Cath Lab 1 replacement plans.pdf](#)

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Martha,
I hope you're doing well! Attached please find an equipment exemption notice and accompanying exhibits. Please let me know if you have any questions. Thank you!

Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning, Duke University Health System
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In support of Duke Health's values,
I stand for Black lives and against systemic racism.