



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 18, 2024

Catherine Cummer

[catharine.cummer@duke.edu](mailto:catharine.cummer@duke.edu)

**Exempt from Review – Replacement Equipment**

**Record #:** 4611  
**Date of Request:** October 9, 2024  
**Facility Name:** Duke University Hospital  
**FID #:** 943138  
**Business Name:** Duke University Health System, Inc.  
**Business #:** 640  
**Project Description:** Replacement of interventional radiology 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 Siemens Artis Icono interventional radiology equipment to replace the Phillips Allura Xper FD20 interventional radiology equipment. 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,

Cynthia Bradford  
Project Analyst

Micheala Mitchell  
Chief

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

October 9, 2024

Via Electronic Mail

Ms. Micheala Mitchell  
Chief  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Exempt Interventional Radiology 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 replacement interventional radiology equipment 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 interventional radiology equipment currently in service in 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. The hospital’s license and campus map have been previously provided to the CON Section. The construction plans showing the location of the project within the Duke North Tower are enclosed.

(2) Previous Certificate of Need/Exemption

The existing equipment was acquired and put into service in 2009 and did not require a certificate of need at that time. Duke University Hospital submitted a notice of exempt acquisition of this equipment in 2008 as evidenced by the email correspondence included with this request.

(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 interventional radiology procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. The equipment quotation is available upon request. This replacement will not affect the gross charges or governmental or contractual reimbursement rates for the services provided on this equipment. 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). The existing equipment will be removed from service in the state upon its replacement.

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

Very truly yours,

*Catharine W. Cummer*

Catharine W. Cummer

Enclosures

### EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	IR Lab	IR Lab
Manufacturer	Philips	Siemens
Model number	K4) Allura XPER FD20	K4) Artis Icono
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	1548 K4	1548 K4
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	K4) 2009	2025
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$3.295M
Total cost of the equipment	K4) \$1.3M	K4) \$1.31M
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Duke University Hospital	Duke University Hospital
Document that the existing equipment is currently in use	In use	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	IR procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	IR procedures

3100 Tower Blvd., Box 80  
University Tower, 10th Floor  
Durham, NC 27707  
(919)419-5011 - (office)  
(919) 419-5015 - (direct #)  
(919)812-3562 (mobile)  
(919) 419-5001 (fax)

----- Forwarded by Duncan Yaggy/MCAdmin/mc/Duke on 07/14/2008 10:21 AM -----



Duncan  
Yaggy/MCAdmin/mc/Duke  
07/14/2008 10:20 AM

To Mike.McKillip@ncmail.net  
cc lee.hoffman@ncmail.net, ccummer@nc.rr.com  
Subject Fw: Request for Letter of No Review for Replacement of  
Vascular Radiology Laboratory in Room 1548K4 in Duke  
Hospital

Mr. McKillip

On June 20, 2008 I delivered to you the following letter providing notice of our intent to replace the vascular radiology laboratory in Room 1548K4 at Duke Hospital and requesting a letter of no review for the project.

Inasmuch as the total project cost is estimated at \$1,642,717 and the renovations required to install the replacement equipment are minor, we see no chance that the total cost of the project will approach \$2 million. On that account, and to take advantage of an early delivery opportunity, we are proceeding with the project.

But we would still like a letter of no review, so please let me know if you have any questions about the information provided with our request . Thanks,

Duncan Yaggy

Duncan Yaggy  
Chief Planning Officer, DUHS  
3100 Tower Blvd., Box 80  
University Tower, 10th Floor  
Durham, NC 27707  
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(919) 419-5001 (fax)

----- Forwarded by Duncan Yaggy/MCAdmin/mc/Duke on 07/14/2008 10:09 AM -----



Duncan  
Yaggy/MCAdmin/mc/Duke  
06/13/2008 09:01 AM

To mike.mckillip@ncmail.net, lee.hoffman@ncmail.net  
cc  
Subject Request for Letter of No Review for Replacement of Vascular  
Radiology Laboratory in Room 1548K4 in Duke Hospital

Mr. McKillip and Ms. Hoffman:

The purpose of this letter is to provide notice that Duke University Health System d/b/a Duke University Hospital [Duke] proposes to acquire replacement equipment for the vascular radiology laboratory located in Room 1548K4 in Duke Hospital at a total capital cost of \$1,642,717 and to request a letter of no review for the project.

As the proposed project closely resembles one that we implemented several years ago, I enclose in Exhibit 1 a copy of the letter we sent you on June 7, 2004 requesting a letter of no review for the acquisition of replacement equipment for the vascular radiology laboratory located in the room next to Room 1548K4 (Room 1548K5) and a copy of your letter of no review dated June 14, 2004.

To facilitate your consideration of this request, we have responded below and in the enclosed exhibits to the questions that the Section asks of applicants requesting letters of no review for the replacement of equipment. The numbering of the paragraphs below follows the numbering employed in the Section's letter requesting additional information:

- 1) A table comparing the existing equipment and replacement equipment using the standard format is enclosed as Exhibit 2.
- 2) The basic functions and technology of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is being used or is capable of being used, are described in the brochures enclosed as Exhibit 3 and Exhibit 4.
- 3) A brochure describing the existing equipment is enclosed as Exhibit 3. A brochure describing the replacement equipment is enclosed as Exhibit 4.
- 4) A copy of the purchase order for the existing equipment, including all components and the purchase price, is enclosed as Exhibit 5.
- 5) The existing equipment is owned, and the replacement equipment will be owned, not leased. We do not have formal title to the existing equipment, and we do not expect to receive a formal title for the replacement equipment.
- 6) Not applicable. The replacement equipment will not be leased.
- 7) A copy of the vendor's quotation for the replacement equipment is enclosed as Exhibit 6. (Please note that the total paid to Philips will be \$1,367,717, which includes both the cost of the unit as listed on pages 2 and 20 and the cost of the options listed on pages 21 and 22.) As noted below, the vendor will remove the existing equipment, but no trade-in allowance will be provided.
- 8) A letter from the person taking possession of the existing equipment that acknowledges that the existing equipment will be removed from clinical service and not reutilized in the state of North Carolina without CON review and approval is enclosed as Exhibit 7.
- 9) A letter documenting that the existing equipment is currently in use and has not been taken out of service is enclosed as Exhibit 8.

Also enclosed are a completed Proposed Total Capital Cost of Project form (Exhibit 9) and an executed attestation statement (Exhibit 10).

Thank you for your consideration of this request. If you have questions or need further information, please let me know.

Sincerely

Duncan Yaggy

Duncan Yaggy  
Chief Planning Officer, DUHS  
3100 Tower Blvd., Box 80  
University Tower, 10th Floor  
Durham, NC 27707  
(919)419-5011 - (office)  
(919) 419-5015 - (direct #)  
(919)812-3562 (mobile)  
(919) 419-5001 (fax)

**DOOR HARDWARE SCHEDULE**

NOTE: All hardware to be approved by Duke University Key Shop. Provide "Building Standards".

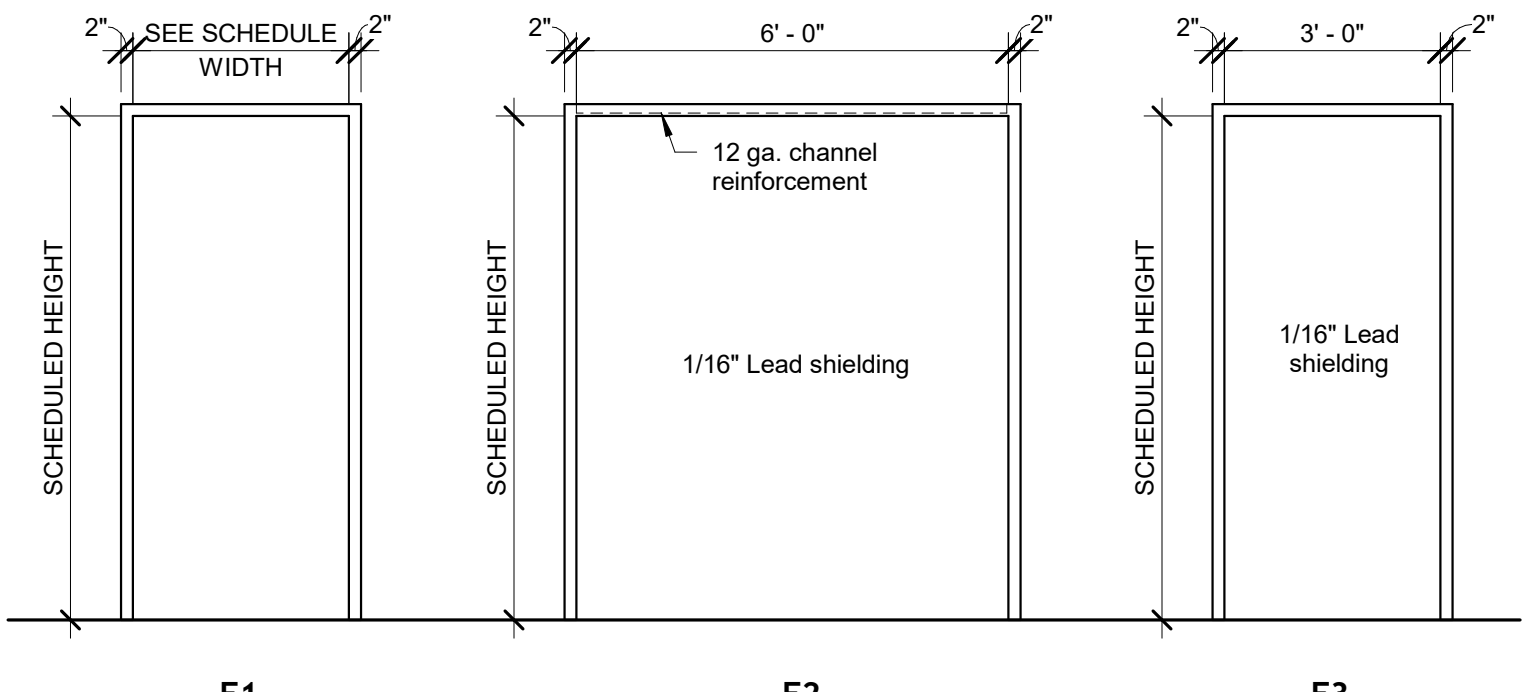
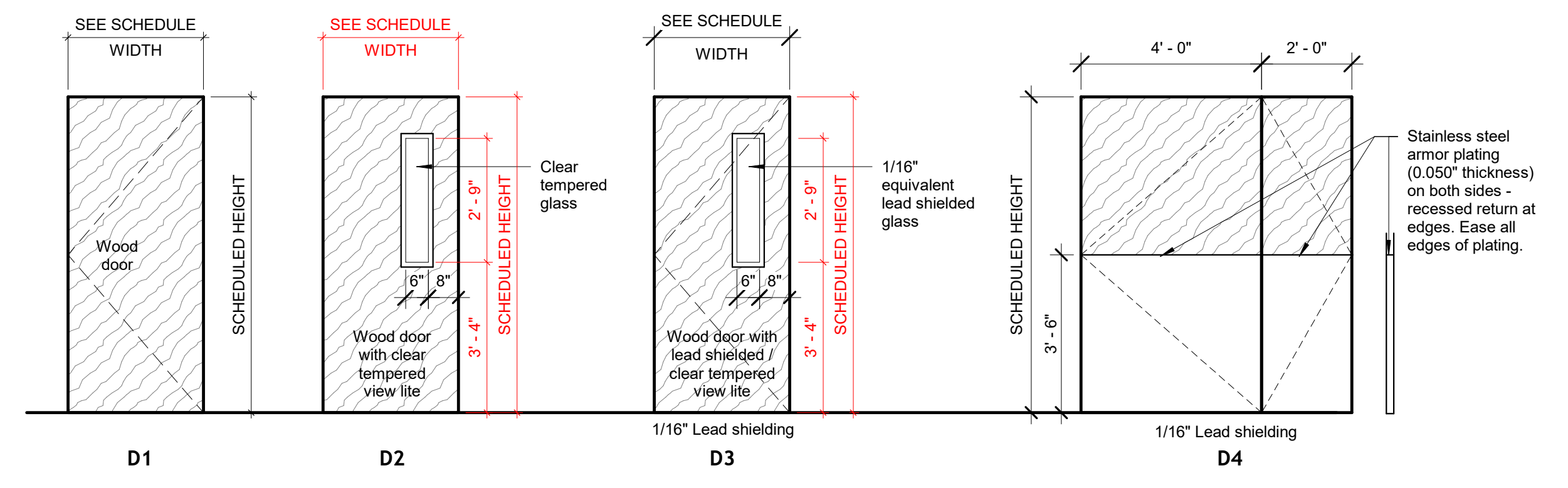
Qty.	Description	Qty.	Description	Qty.	Description	Qty.	Description
2 Each	Continuous Hinge	1 Each	Continuous Hinge	3 Each	4-12" x 4-1/2" Hinges	3 Each	4-12" x 4-1/2" Hinges
1 Each	Lockset	1 Each	Lockset	1 Each	Lockset	1 Each	Lockset
1 Each	Electric Strike	1 Each	Closer w/ Hold Open - Connect to Fire Alarm	1 Each	Closer	1 Each	Closer
1 Each	Automatic Door Operator	3 Each	Silencers	2 Each	Hand Wave	3 Each	Silencers
1 Each	Hand Wave						
1 Each	Card Reader						
2 Each	Armor Plate						
3 Each	Silencers						
1 Each	Head Flush Bolt						

Door Number	Size		Door		Frame		Details					Comments
	Width	Height	Material	Type	Material	Type	Head	Jamb	Salvage	Hardware	Rating	
1548	3'-0"	7'-0"	Wood	D1	HM	F1	4/A101	5/A101			Set 4	
1548K4	6'-0"	7'-0"										

**WALL LEGEND**

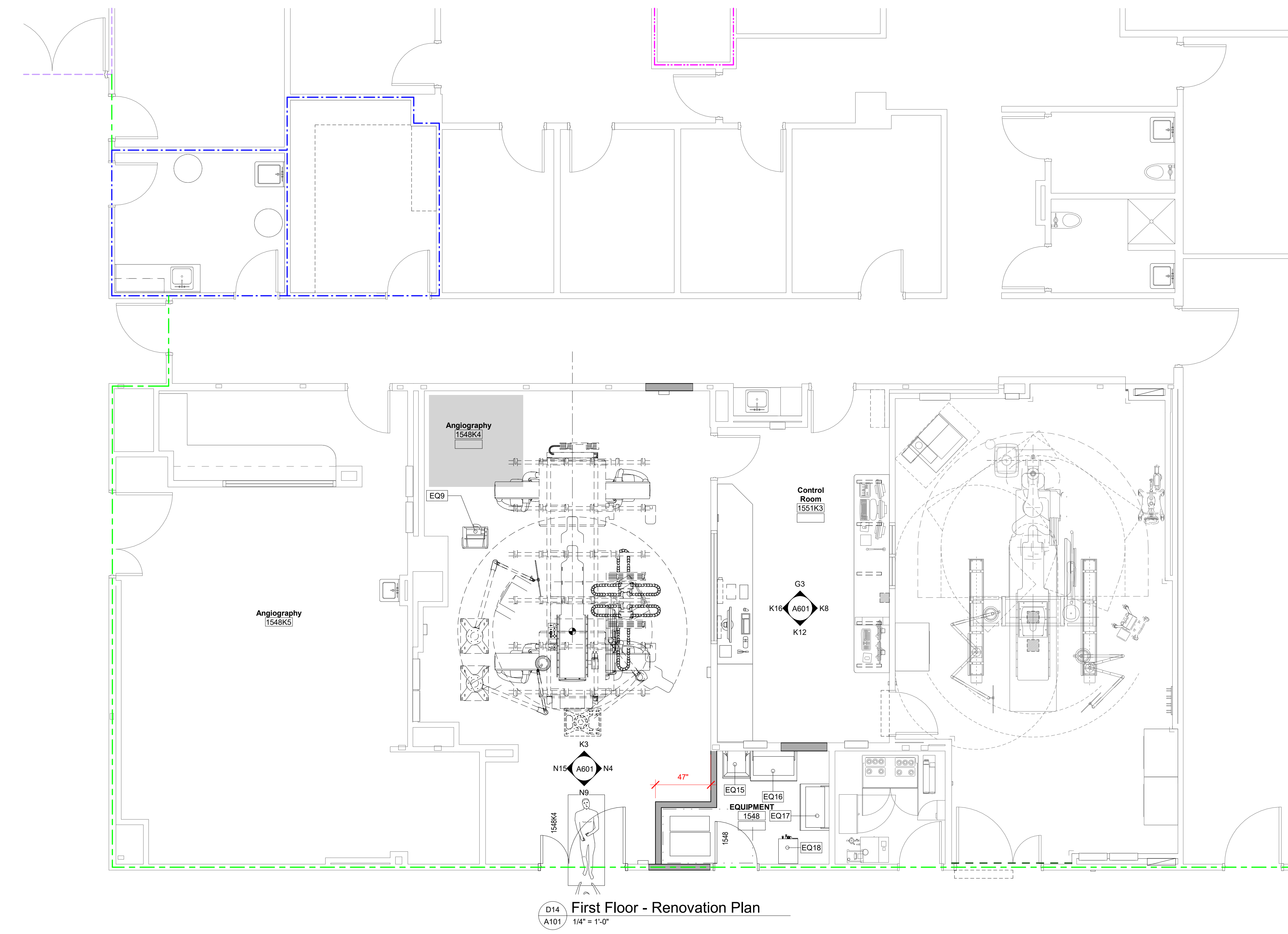
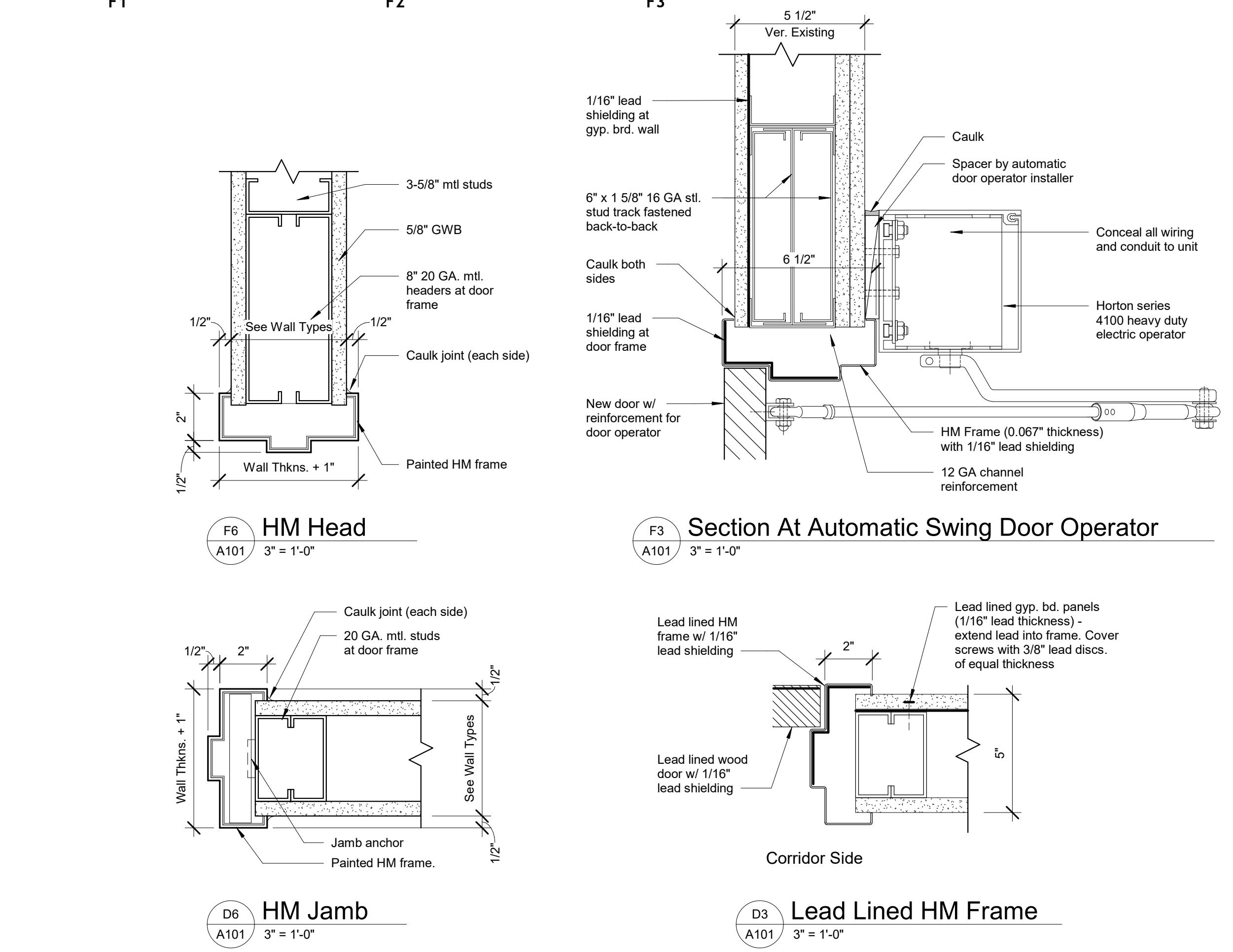
- EXISTING CONSTRUCTION
- DEMOLISHED CONSTRUCTION
- TEMPORARY CONSTRUCTION
- NEW CONSTRUCTION
- SMOKE TIGHT WALL
- 1HR FIRE BARRIER
- 2HR FIRE BARRIER
- 2HR FIRE/SMOKE

**DOOR & FRAME TYPES**



**Door and Frame Notes:**

**Doors and Lead-Lined door**  
 Manufacturer: VT Industries or equal  
 Type: 5 ply engineered composite lumber core WDMA/AWS extra heavy duty SCL-5 w/ matching edges ME  
 Grade: Premium with "AA" face veneers  
 -Book match and centered  
 -Door pairs to match  
 Species/Finish: Oak to match adjacent doors as close as possible  
 Doors to have factory finish  
 Color: Match existing first floor Duke North  
 Notes: Provide reinforcement for swing door operators



**ROOM TAG FINISH KEY**

Waiting: Room Name, Room Number, Wall, Ceiling.

**FLOOR**

**BASE**

**1 Homogenous Sheet Vinyl**  
 Mfr.: Mohawk Group  
 Style: Medella Hues C2062  
 Color (SV1): Natural H5312  
 Color (SV2): Grayed H5532

**2 Static Dissipative Tile**  
 Mfr.: Flexco / Delane Collection DISS  
 Color: White / Gray 40, Size: 36" x 36"

**3 Rubber Base**  
 Mfr.: Roppe  
 Size: 4"  
 Color: Dolphin 129

**CEILING**

**1 ACT 1**  
 Mfr.: Armstrong Clean Room VL - Unperforated  
 868 - Square Edged, 24x24x5/8, Color: White  
 Grid: Clean Room - Steel (Gas-ketted)  
 15/16" Exposed Tee - Heavy Duty, Color: White

**2 ACT 2**  
 Mfr.: Armstrong Health Zone Ultima  
 1835 - Square Edged, 24x24x3/4, Color: White  
 Grid: Prelude XL Fire Guard 15/16" Exposed Tee - Heavy Duty, Color: White

**PROJECT FINISHES**

**Homogenous Sheet Vinyl**  
 - Mohawk Group  
 - Medella Hues C2062  
 - Color (SV1): Natural H5312  
 - Color (SV2): Grayed H5532

**Static Dissipative Tile**  
 - Flexco  
 - Delane Collection DISS (Static Dissipative)  
 - Color: White/Gray 40  
 - Size: 36" x 36"

**Rubber Base**  
 - Roppe  
 - Pinnacle Standard  
 - Dolphin 129  
 - Note: 4"H Standard Toe Cont. Rolls

**Transition Strip**  
 - Whenever possible feather to align flooring materials.  
 - If transition is required, slim profile metal from KUBERTUSA - Finish A1

**Wall Paint (Field Color)**  
 - Benjamin Moore  
 - Color: "Building Standard"

**Wall Paint (Accent Color Paint / AP)**  
 - Benjamin Moore  
 - Color: Elmira White HC-84

**Epoxy Wall Paint (Field Color)**  
 - Benjamin Moore  
 - Color: Elmira White HC-84

**Door Frame Paint**  
 - Match adjacent wall finish w/ Semi-Gloss Finish

**Corner Guards (all outside corners)**  
 - Acroyn by Design  
 - Organic Collection / Pattern Linen  
 - Color: Nantucket 10130  
 - Thickness: 0.06 butt seams

**Wall Protection Sheets (Wainscot in 1548K3)**  
 - Acroyn by Design  
 - Organic Collection / Pattern Linen  
 - Color: Nantucket 10130  
 - Thickness: 0.06 butt seams

**RENOVATION SHEET KEYNOTES**

101 Corner Guard - See Project Finishes; mount above base. Mount with heavy duty construction adhesive according to mfg. guidelines. All fasteners required to be provided by manufacturer.

102 Automatic swing operator: Horton 4100LE operator - full frame width housing. 7220-1 electric strike interface - Proximity card readers wall switch in corridor and "hand wave" inside room.

103 Proximity card reader (CR) / Hand Wave (HW)

104 New millwork

105 Wall Protection - See Project Finishes. Install corner to corner - with beveled top edge. Height Installation 4' - 4" A.F.F. for Procedure Room. Height Installation 5' - 4" A.F.F. for Soiled Wk. Room and Supply Storage

106 Salvaged wall racks for lead-shielded aprons - G.C. to provide in-wall blocking (18 ga.) for attachment, and install racks.

107 New acoustical ceiling system

108 New sink - See Plumbing drawings

109 Provide 1/16" lead shielding and one layer of 5/8" type "X" gypsum board on existing wall of Procedure Room

110 Conduit Risers core drill floor - See Structural drawings

**GENERAL ARCHITECTURAL NOTES**

1. Coordinate all work with building owner that may impact other building tenants. This includes possible utility interruptions, noise or personnel activity in the building.

2. Patch and paint all wall locations where demolition creates an interruption in wall finish.

**EQUIPMENT SHEET KEYNOTES**

EQ01 GE Equipment - See GE Drawings

EQ02 Anesthesia Machine\*

EQ03 Inner Space Carts\*

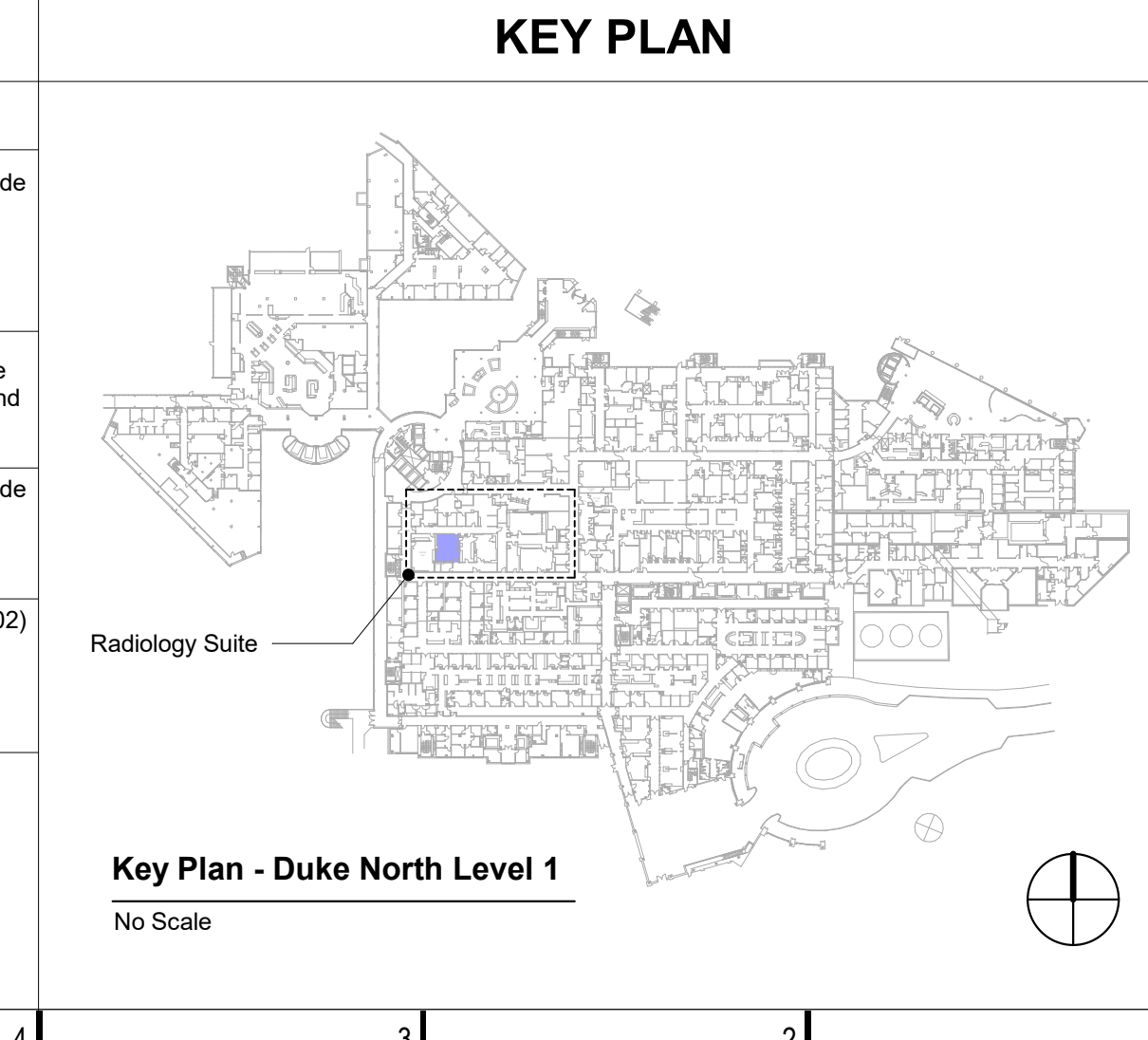
EQ04 Catheter Cabinets\*

\* Equipment by Owner

**WALL TYPES LEGEND**

Type Mark	Construction Detail	Description
A	5"	- Gypsum board: 5/8" type "X" gypsum board on each side - Steel studs: 3-5/8" 20ga. steel studs at 16" on center - 3" mineral wool batt insulation - Floor to braced structure above - 1/16" lead shielding on procedure side
B	4 1/4"	- Gypsum board: 5/8" type "X" gypsum board on one side - Steel studs: 3-5/8" 20ga. steel studs at 16" on center and 1/16" lead shielding on procedure side
C	4 7/8"	- Gypsum board: 5/8" type "X" gypsum board on each side - Steel studs: 3-5/8" 20ga. steel studs at 16" on center - 3" mineral wool batt insulation - Floor to braced structure above
D	4 7/8"	- Gypsum Board Wall (UL Design U465 - See Sheet G002) - 5/8" type "X" gypsum board on each side - Steel studs: 3-5/8" 25ga. steel studs at 16" on center - Sound attenuation batts - Floor to structural deck above

Note: All fasteners and devices in lead-shielded walls to be designed and installed to maintain integrity of lead shielding.



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**DukeHealth**

**BHPD ARCHITECTURE**  
 COLUMBIAS RALEIGH CHARLOTTE  
 517 E. MAIN STREET, SUITE 1000, RALEIGH, NC 27601  
 PH: 919.972.1000 FAX: 919.972.1001  
 www.bhpd.com

**EDMONDSON ENGINEERS**  
 CONSULTING ENGINEERS  
 600 GARDNER & MCDANIEL, P.A.  
 2301 ERWIN ROAD, DURHAM, NORTH CAROLINA 27705

Project Manager: JFK  
 Drawn: MML  
 Checked: AJP  
 Issue/Revision/Date: 04/11/2024  
 Project Number: DKM01.10  
 A101

Autodesk Docs://DKM0110 K4 Renovation/DKM0110-R23-RDU-B3-Duke K4.rvt 8/27/2024 2:16:47 PM



**From:** [Catharine Cummer](#)  
**To:** [Stancil, Tiffany C](#)  
**Subject:** [External] FW: Equipment Comparison Form: DUH K4 Replacement  
**Date:** Wednesday, October 9, 2024 9:01:57 AM  
**Attachments:** [To State Exemption Notice K4 IR equipment.docx](#)  
[2024 08 27 FPDC4611 K4 Drawings 5.pdf](#)  
[LONR - DUH K4 replacement.pdf](#)

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**CAUTION:** External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Tiffany,

Enclosed for filing is a notice of exempt equipment replacement at Duke University Hospital. Please let me know if you have any questions. Thank you,  
Catharine

Catharine W. Cummer  
Regulatory Counsel, Strategic Planning, Duke University Health System  
Office 919-668-0857 | Cell 919-423-6928