



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

December 19, 2023

Catherine Cummer
Catherine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 4336
Date of Request: December 11, 2023
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace 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 GE K3) GE Allia IGS interventional radiology (IR) equipment to replace the Phillips K3) Allura XPER FD20 IR 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

December 11, 2023

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 linear accelerator currently in service in the Morris Clinic, 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

The existing equipment was acquired and put into service in 2007. Correspondence documenting that the existing equipment was the subject of an exempt acquisition is enclosed.

(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 | GE |
| Model number | K3) Allura XPER FD20 | K3) GE Allia IGS |
| Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #) | 1548 K3 | 1548 K3 |
| Is the equipment mobile or fixed? | Fixed | Fixed |
| Date of acquisition | K3) 2007 | 2024 |
| 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 | \$3.971M |
| Total cost of the equipment | \$1.1M | \$1.476M |
| 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 average charge per procedure ? | 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 average operating expense per procedure ? | 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 |



FPDC Budget Summary
Project Name: DN Radiology K3 Renovation
FPDC Project Number: 4146

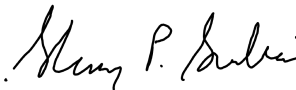
Project Manager: **Name: Tony Rinaldi**

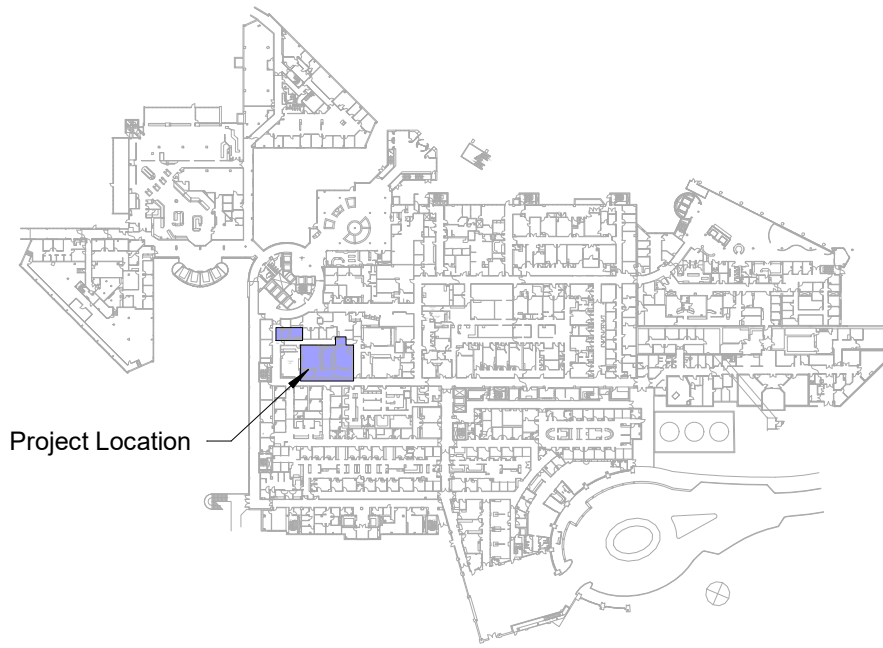
September 15, 2023

Budget Estimate No: 1

Total gsf 2,800

| Description | Totals | Remarks |
|---|--------------------|----------------|
| Total Building Construction | \$1,820,110 | |
| Total Utilities, Permits, Inspections | \$50,000 | |
| Total Furniture, Equipment & Technology | \$1,555,000 | |
| Total Design & Management | \$321,100 | |
| Subtotal | \$3,746,210 | |
| Project Contingency | \$224,790 | |
| Total Project Cost | \$3,971,000 | |

approved:  9.18.23
Shawn Subasic, Assoc. VP Duke Health Facilities Date



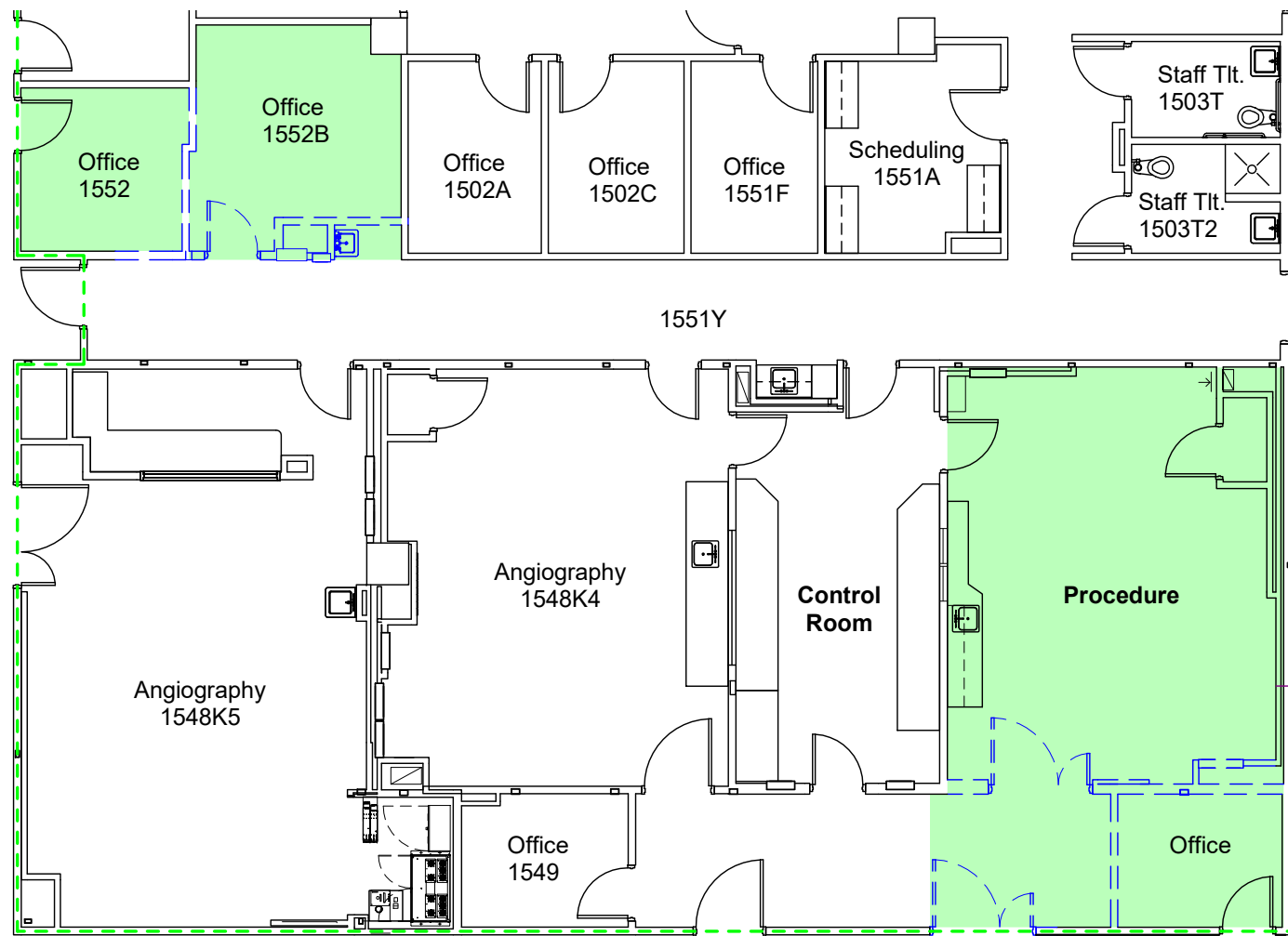
Project Location

Key Plan - Duke North Level 1

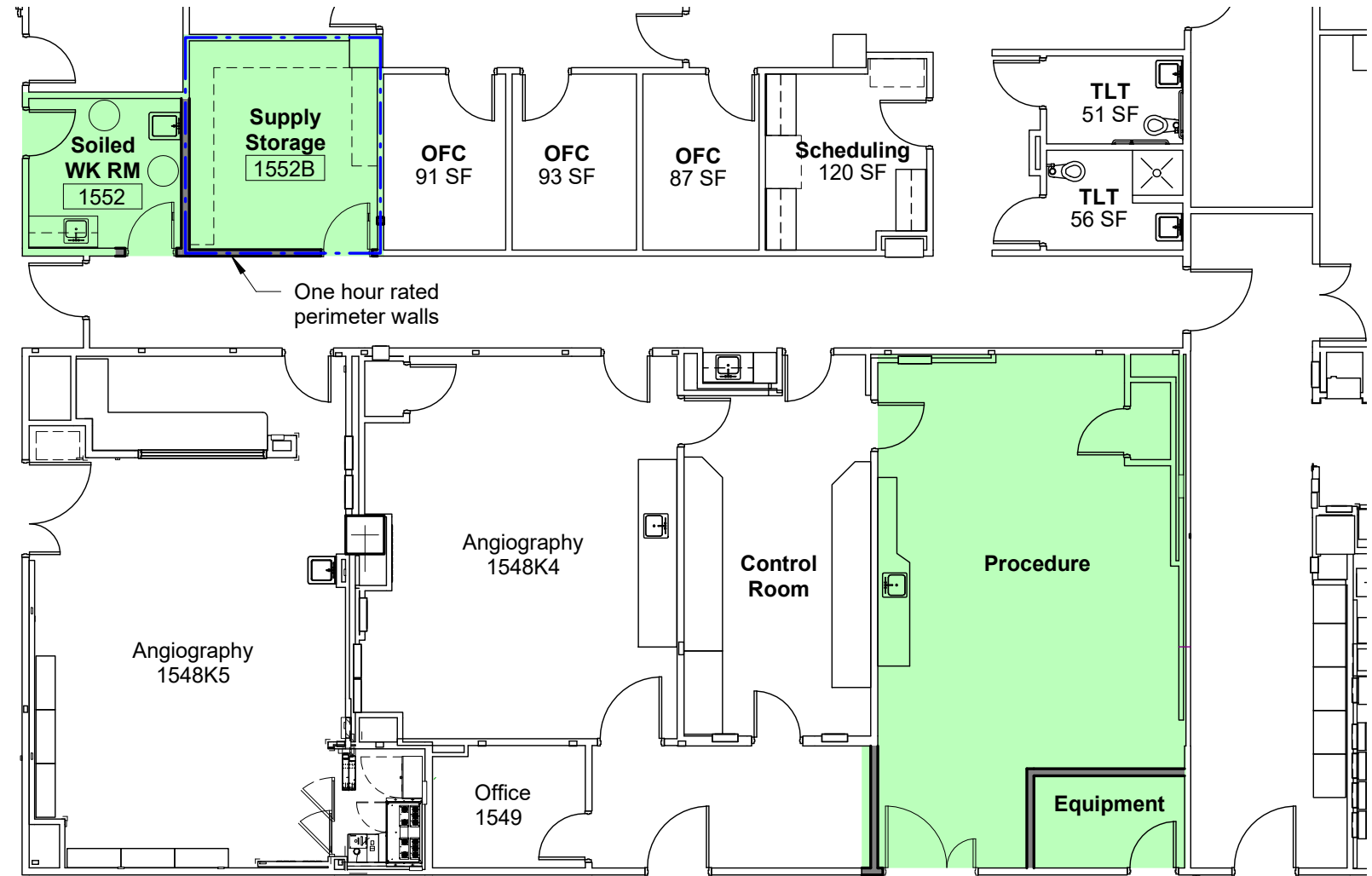
No Scale

Option 2:

Prepare design documents for installing new GE equipment in existing K3 procedure room. Reuse existing control room and create new equipment room from existing adjacent office space. Existing steel columns and frame to remain as is. Modify existing ceiling-mounted uni-strut as needed. New soiled work room and supply room are created on service corridor.



Existing Plan



Renovation Plan

Controlled Access Corridor



Duke University Medical Center
4146 HSDC DUH Radiology - GE Discovery Installation
Option 2B - Room K3 Controlled Access Corridor

SCALE: 3/32" = 1'-0"

August 15th, 2023





DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

October 24, 2005,

Mr. Mike McKillip, Project Analyst
Ms. Lee Hoffman, Chief
Certificate of Need Section
Division of Facility Services
Department of Health & Human Services
2704 Mail Services Center
Raleigh, NC 27699-2704

Re: Replacement of Vascular Radiology Laboratory in Room 1548K-3 in Duke University Hospital

Dear Mr. McKillip and Ms. Hoffman:

The purpose of this letter is to request your written confirmation that the replacement of the vascular radiology laboratory in Room 1548K-3 in Duke Hospital at a total project cost of \$1,471,226.18 will not require certificate of need review.

To facilitate your consideration of this request, we provide below and in the exhibits enclosed with this letter our responses to the points listed in the Section's standard letter requesting additional information from those proposing equipment replacement projects. The numbering below follows the numbering in the Section's letter:

1. A comparison of the existing and replacement equipment, using the prescribed format, is enclosed as Exhibit 1.
2. A description of the basic technology and functions of the existing equipment and the replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used, is provided in the brochures for the existing equipment and the replacement equipment enclosed as Exhibits 2 and 3.
3. A brochure describing the capabilities of the existing equipment is enclosed as Exhibit 2. A brochure describing the capabilities of the replacement equipment is enclosed as Exhibit 3.
4. A copy of the purchase order for the existing equipment, including all components in the original purchase price is enclosed as Exhibit 4.

Page Two

5. Not applicable. The existing equipment was purchased by Duke University, and it is owned by Duke University Health System, but no title was issued.

6. Not applicable. The replacement equipment will not be leased.

7. A copy of the vendor's quotation for the proposed replacement equipment, including a detailed description of all the components, is enclosed as Exhibit 5. Please note that the purchase price (\$1,177,226.18) is listed on the second page of the quotation. On page 19 of the quotation, the list price (\$1,757,054) and discount (\$579,827.82) are noted. A letter explaining that the list price is not the fair market value or the real price is attached to this letter.

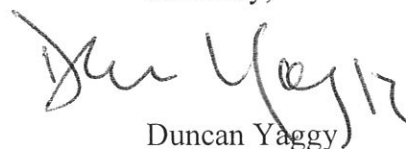
8. A letter from the vendor, which will take possession of the existing equipment, is enclosed as Exhibit 6. Please note that the letter clearly states that the existing equipment will be taken out of clinical service and "permanently removed from the State of North Carolina."

9. A letter documenting that the existing equipment is currently used and has not been taken out of service is enclosed as Exhibit 7.

Also enclosed, as Exhibits 8 and 9, are completed Proposed Total Capital Cost of Project and Attestation Forms.

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

Sincerely,



Duncan Yaggy

DY:dw

Attachments



**North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section**

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

November 4, 2005

Duncan Yaggy, Chief Planning Officer
Duke University Health System
3100 Tower Boulevard
Suite 600, Box 80
Durham, NC 27707

RE: Exempt from Review - Replacement Equipment/Duke University Health System d/b/a Duke University Hospital/Replace existing Phillips Integris V3000 vascular radiology unit with a Philips Allura Xper FD20 vascular radiology unit/Durham County
FID # 943138

Dear Mr. Yaggy:

In response to your letter of October 24, 2005, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Philips Allura Xper FD20 vascular radiology unit to replace the existing Phillips Integris V3000 vascular radiology unit [Serial # 9292.3517]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.



Mr. Yaggy
Page 2
November 4, 2005

Sincerely,



Michael J. McKillip, Project Analyst



Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS
Construction Section, DFS

From: [Catharine Cummer](#)
To: [Stancil, Tiffany C](#)
Cc: [Lara Orgain](#)
Subject: [External] Equipment replacement exemption -- DUH
Date: Monday, December 11, 2023 12:07:01 PM
Attachments: [To State Exemption Notice K3 IR equipment.docx](#)
[FPDCQuote DUHK3Replace 9.15.2023.pdf](#)
[From State LONR Vascular Radiology Lab in 1548 K-3 04 Nov 2005.pdf](#)
[To State LONR Vasc Radiology Lab 24 Oct 05.pdf](#)
[K3 equipment comparison form.docx](#)

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,

I hope you're doing well. Please see the attached exemption notice and enclosures for filing and let me know if you have any questions. Thank you very much,
Catharine

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