



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

April 28, 2021

Catharine Cummer
catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3546
Date of Request: April 21, 2021
Project ID#: J-7797-07
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing linear accelerator
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(a)(f). Therefore, you may proceed to acquire without a certificate of need the Varian True Beam Linear Accelerator to replace the Varian Novalis TX Linear Accelerator (serial# 293691). 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 Lisa Pittman for

Lisa Pittman
Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Construction 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

April 21, 2021

Via Electronic Mail

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

Re: Exempt Linear Accelerator Replacement Project at Duke University Hospital

Dear Ms. Pittman:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement linear accelerator 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 Morris Clinic are enclosed.

(2) Previous Certificate of Need

The existing equipment was acquired pursuant to Project J-7797-07 (see enclosed CON).

(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 radiation oncology procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. A copy of the equipment quotation is available upon request. The total operating costs per procedure will increase by less than 1%, as the result of the cost of the services agreement for the replacement 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 about this information, please let me know.

Very truly yours,

Catharine W. Cumber

Catharine W. Cumber

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Tesla Rating for MRIs	NA	NA
Model Number	Novalis TX	TrueBeam
Serial Number	293691	NA
Provider's Method of Identifying Equipment	SN	SN
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	September 2007	May 2021
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>	4,430,774	4,603,895
Total Cost of Equipment	3,153,138	2,705,783
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Morris Bldg Rm 005133	Morris Bldg Rm 005133
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	Radiation treatment /IMRT	NA
Type of Procedures New Equipment is Capable of Performing	NA	Radiation treatment /IMRT



Prepared for Duke Health Facility
Planning, Design and Construction



Architect: IHR Architecture
Durham, North Carolina

MEP Engineers: Edmondson Engineers
Durham, North Carolina

Structural Engineers: Gardner & McDaniel
Durham, North Carolina



Duke Health FPDC # 4195

Blue Vault Linac Replacement

Duke Cancer Center, Sub-Basement, Morris Building
30 Duke Medicine Circle, Durham NC 27710



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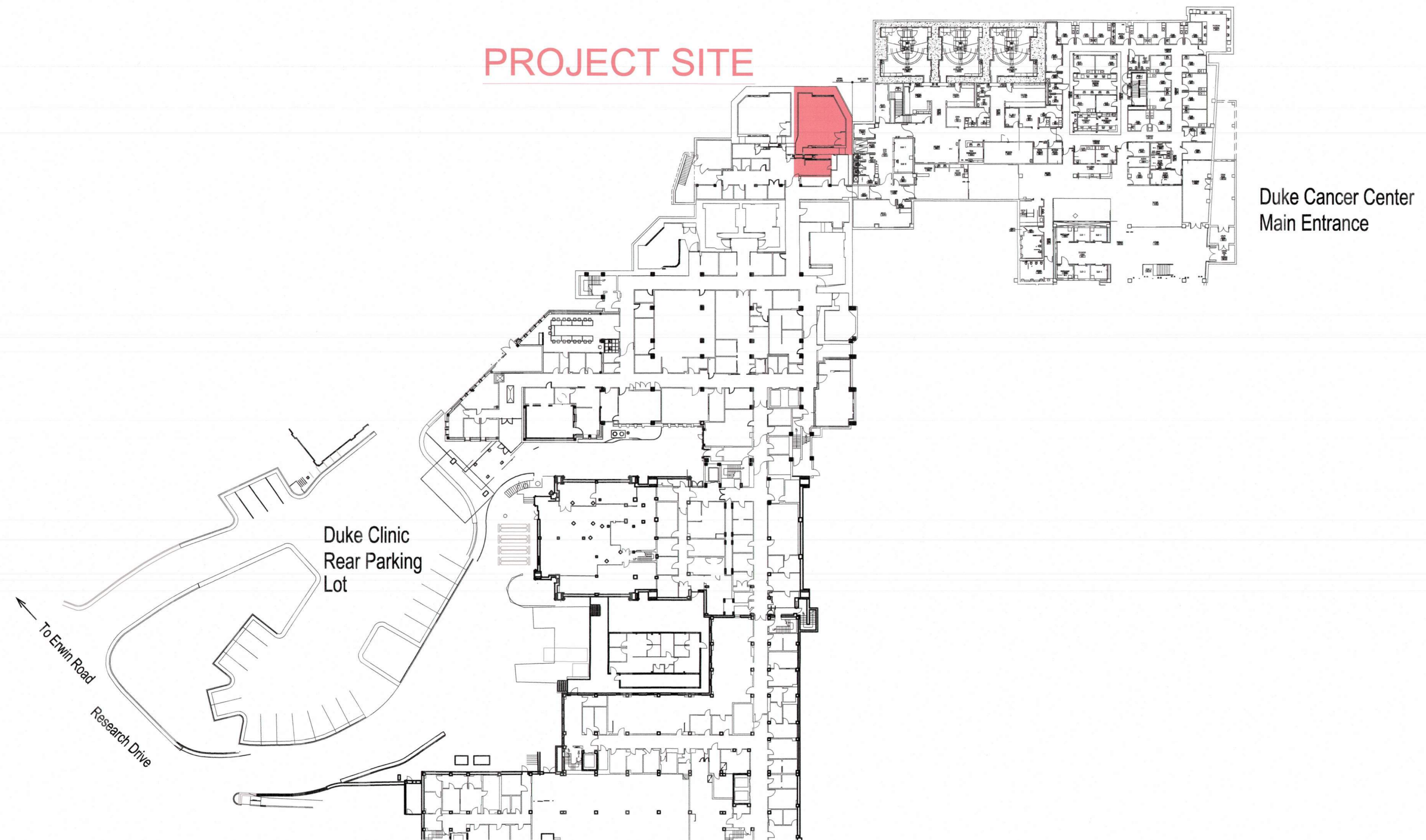


Construction Documents 01-06-2021

Duke Health FPDC # 4195
Blue Vault Linac Replacement
Morris Building, Duke Cancer Center
30 Duke Medicine Circle, Durham NC 27710

Cover Sheet

#4195
Duke Blue Vault Linac
IHR #19 0028
DATE: 1-6-2021
ISSUE: Construction Documents
APPROVED:
SHEET NO. **A0.1**



INDEX OF DRAWINGS

ARCHITECTURAL DRAWINGS	
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A0.2	Building Code Summary
A0.3	Life Safety Plan
A0.4	Infection Control and Construction Risk Assessment, Contractor Access Route
A0.5	UL Details
A0.6	UL Details
A1.1	Floor Plans: Concrete Slab Demolition and Replacement
A1.2	Floor Plans: Demolition
A1.3	Floor Plans: Renovation, Schedules
A1.4	Floor Plans: Interior Design Finishes
A2.1	Reflected Ceiling Plans: Demolition
A2.2	Reflected Ceiling Plans: Renovation
A3.1	Interior Elevations and Casework
A3.2	Interior Elevations and Casework
A4.1	Wall Types and Construction Details
A5.1	Reference Structural and Utility Maze Shielding
V1.1	Vendor Drawings - Varian

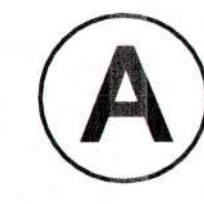
ENGINEERING DRAWINGS	
S1.1	Foundation Plan, Sections and Details
P0.1	Plumbing Legends, Notes and Schedules
P1.1	Plumbing Demolition Plan - Medical Gas - Sub-Basement
P2.1	Plumbing Renovation Plan - Medical Gas - Sub-Basement
M0.1	Mechanical Legends, Notes and Abbreviations
M0.2	Mechanical Specifications
M1.1	Mechanical Demolition Plans
M2.1	Mechanical Renovation Plans
M3.1	Mechanical Details
FP0.1	Fire Protection Schedules, Legends and Details
FP1.1	Fire Protection Demolition Plans
FP2.1	Fire Protection Renovation Plans
E1.1	Electrical Demolition Plan
E2.1	Power and Lighting Plans
E2.2	Varian Equipment Raceway Plans
E2.3	Electrical Schedules and Details
E2.4	Electrical Specifications
FA1.1	Fire Alarm Plans

INFECTION CONTROL

PROJECT: #4195 Blue Vault Linac Replacement
 PROJECT MANAGER: GLENN MASTY - FPDC
 PROJECT START DATE: TBD
 PROJECT COMPLETION DATE: TBD
 OTHER:

CONSTRUCTION ACTIVITY

CONSTRUCTION ACTIVITY
 NO YES TYPE A: INSPECTION, NONINVASIVE ACTIVITY
 NO YES TYPE B: SMALL SCALE, SHORT DURATION, MODERATE TO HIGH LEVELS.
 NO YES TYPE C: ACTIVITY GENERATES MODERATE TO HIGH LEVELS OF DUST, REQUIRES GREATER THAN 1 WORK SHIFT TO COMPLETE.
 NO YES TYPE D: MAJOR DURATION AND CONSTRUCTION ACTIVITIES, REQUIRING CONSECUTIVE WORK SHIFTS.



INFECTION CONTROL GENERAL NOTES

- DUKE UNIVERSITY MEDICAL CENTER IS COMMITTED TO PROVIDING A SAFE ENVIRONMENT FOR THEIR PATIENTS, VISITORS, AND EMPLOYEES. SINCE CONSTRUCTION AND DEMOLITION CAN GENERATE A LARGE AMOUNT OF DUST THAT CAN HARBOR ASPERGILLUS FUNGUS SPORES, THE FOLLOWING GUIDELINES HAVE BEEN ADOPTED IN CONJUNCTION WITH THE INFECTION CONTROL AND EPIDEMIOLOGY DEPARTMENT. THESE SPORES CAN CAUSE SERIOUS INFECTIONS IN CERTAIN PATIENTS WHOSE IMMUNE SYSTEMS ARE QUITE FRAIL AS A RESULT OF THEIR DISEASES AND TREATMENTS. THE GENERAL CONTRACTOR AND ALL SUBCONTRACTORS SHALL FOLLOW THESE GUIDELINES FOR INFECTION CONTROL DURING ALL CONSTRUCTION ACTIVITY.
- 1- THE PROJECT SITE MUST BE CONTAINED COMPLETELY WITHIN CONSTRUCTION BARRIERS. THE BARRIERS MUST CONSIST OF SOLID WALL CONSTRUCTION (I.E. DRY WALL) IN SITUATIONS WHERE HEAVY DEMOLITION WILL BE INVOLVED. PLASTIC DRAPES THAT ARE TAPED TO THE CEILING AND TAPED TOGETHER TO PREVENT DUST FROM PENETRATING, CAN BE USED FOR AREAS NOT INVOLVING DEMOLITION.
- 2- REFER TO LIFE SAFETY PLAN FOR LOCATION OF TEMPORARY PARTITIONS AND TEMPORARY EXITING REQUIREMENTS.
- 3- THE NUMBER OF DOORS IN CONSTRUCTION BARRIERS SHOULD BE MINIMIZED. THE CONSTRUCTION BARRIERS ENTRANCES ARE TO BE COVERED AT ALL TIMES. IN DEMOLITION AREAS THE ENTRANCES ARE TO HAVE SOLID DOORS. IF THE PROJECT IS ON A SMALLER SCALE, THE ENTRANCE MAY BE FRAMED OUT WITH AN IMPENETRABLE PLASTIC BARRIER. WHEN SECURITY ISSUES ARE OF CONCERN, A SOLID WOOD DOOR WITH A WINDOW IS AN ACCEPTABLE ALTERNATIVE.
- 4- CEILING TILE REMOVAL RELEASES ENORMOUS AMOUNTS OF ASPERGILLUS INTO THE AIR. ANY WORK DONE ABOVE THE CEILING IN PATIENT CARE OR PATIENT TRANSPORT AREAS IS TO BE DONE QUICKLY AND THE CEILING TILES ARE TO BE REPLACED UPON COMPLETION OF THE WORK THAT DAY, EVEN IF MORE WORK IS ANTICIPATED. AT NO TIME ARE THE CEILING TILES TO REMAIN OUT OF POSITION AFTER THE CONSTRUCTION CREW HAS FINISHED FOR THE DAY. SEE SPECIFICATIONS FOR INFORMATION REGARDING "3-TILE" RULE.
- 5- CONSTRUCTION TRAFFIC AND PATIENT TRAFFIC MUST REMAIN SEPARATED WHEN FEASIBLE FOR SAFETY OF THE PATIENTS.

- 6- CONSTRUCTION DEBRIS MUST BE REMOVED IN LARGE BINS WITH APPROPRIATE COVERS. WHEN THE BINS DO NOT HAVE COVERS, THE TOP LAYER OF THE DEBRIS SHOULD REMAIN MOIST TO PREVENT AEROSOLIZING OF PARTICULATE MATTER FROM THE DEBRIS AND HAVE A LOOSE FABRIC OR POLYETHYLENE COVER. IF THE REMOVAL OF DEBRIS HAS TO PASS THROUGH PATIENT WARDS, THE PATIENT DOORS MUST BE CLOSED DURING TRANSPORT OF THE DEBRIS TO THE ELEVATORS.
- 7- AIR HANDLING DUCTS ARE TO BE COVERED DURING ALL DEMOLITION ACTIVITIES AND CONSTRUCTION ACTIVITIES THAT CREATE LARGE AMOUNTS OF DUST. (THIS PREVENTS AN INCREASE OF ASPERGILLUS SPORES CIRCULATING WITHIN THE VENTILATION SYSTEM) DURING PROJECTS IN AREAS THAT ARE NOT CONTAINED BEHIND BARRIERS, THE WORK AREA SHOULD BE VACUUMED AND DUSTED COMPLETELY AT THE END OF EACH DAY.
- 8- PROTECT ALL SPACES FROM EXPOSURE TO MOISTURE. THOROUGHLY DRY ALL COMPONENTS THAT GET WET TO ELIMINATE POTENTIAL GROWTH OF MOLD AND MILDEW.

CONTRACTOR RESPONSIBILITIES

- 1- REFER TO COVER SHEET FOR ADDITIONAL REQUIREMENTS.
- 2- REFER TO INFECTION CONTROL PRECAUTIONS BY CLASS REQUIRED FOR PROJECT AREA.
- 3- REFER TO RISK ASSESSMENT CHART. COORDINATE WITH DUKE PERSONNEL DESIGNATED WHEN WORK INVOLVES ITEMS NOTED AND RESTRICTIONS INDICATED.
- 4- REFER TO RISK ASSESSMENT FOR APPLICABLE CONTRACTOR ACTIONS REQUIRED.

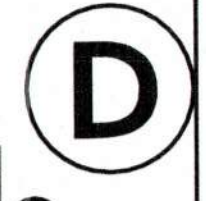
PATIENT OCCUPANCY RISK LEVEL

PATIENT GROUP BY RISK	
RISK	AREAS
LEVEL 1	OFFICE AREAS
LEVEL 2	CARDIOLOGY, ECHOCARDIOGRAPHY, ENDOSCOPY, NUCLEAR MEDICINE, PHYSICAL THERAPY, RADIOLOGY, RESPIRATORY THERAPY
LEVEL 3	CPU, EMERGENCY ROOM, LABOR & DELIVERY, LABORATORIES, NEWBORN NURSERY, OUTPATIENT SURGERY, PEDIATRICS, PHARMACY, POST ANESTHESIA CARE UNIT, SURGICAL UNITS
LEVEL 4	AREAS OF IMMUNOCOMPROMISED PATIENTS, BURN UNIT, CARDIAC CATH LAB, CENTRAL STERILE SUPPLY, INTENSIVE CARE UNITS, MEDICAL UNIT, NEGATIVE PRESSURE ISOLATION ROOMS, ONCOLOGY, OPERATING ROOMS INCLUDING C-SECTION ROOMS



CLASS OF PRECAUTIONS

RISK GROUP	CONSTRUCTION PROJECT TYPE			
	TYPE A	TYPE B	TYPE C	TYPE D
LEVEL 1	I	II	II	III/IV
LEVEL 2	I	II	III	IV
LEVEL 3	I	II	III/IV	IV
LEVEL 4	II	III/IV	III/IV	IV



DUKE CONSTRUCTION RISK ASSESSMENT

CRITERIA	AFFECTED	NOT AFFECTED	COMMENTS
UTILITIES / COMMUNICATIONS / BUILDING SYSTEMS			
ELECTRICAL	YES		
HVAC	YES		
PLUMBING	YES		
MEDICAL GAS	YES		
STEAM		NO	
NURSE CALL	YES		
PLTIS		NO	
PNEUMATIC TUBE SYSTEM		NO	
ELEVATOR		NO	
WATER / SEWER	YES		
TELEPHONE SYSTEM	YES		
PAGING SYSTEM		NO	
DATA SYSTEM	YES		
SECURITY			
WORK IMPAIRS BUILDING SECURITY SYSTEM, LOCKING SYSTEMS OR ALARMS		NO	
WORK IS IN PEDIATRIC AREA		NO	
WORK IS IN PSYCHIATRIC AREA		NO	
WORK IS IN EMERGENCY DEPARTMENT		NO	
WORK IS IN OTHER HIGH SECURITY LOCATION		NO	
WORKERS HAVE PROPER I.D. AND CLEARANCE	YES		
FIRE SAFETY			
WORK ALTERS OR COMPROMISES EXIT ACCESS, EXITING, OR EXIT DISCHARGE	YES		TEMPORARY / ABOVE CEILING WORK / OFF HOURS
WORK COMPROMISES BLDG. FIRE/SMOKE COMPARTMENTS AND/OR SEPARATIONS, OR OTHER DEFEND-IN-PLACE ELEMENTS	NO		
WORK IMPAIRS BLDG. FIRE ALARMS, SPRINKLER OR FIRE SUPPRESSION SYSTEMS	YES		
WORK INCL. IGNITION SOURCES-WELDING, CUTTING OR FLAME/SPARK GENERATION	YES		BOLTING PREFERRED, POSSIBLE MINOR WELDING
GENERAL SAFETY			
WORK INCLUDES LARGE QUANTITIES OF COMBUSTIBLE OR FLAMMABLE MATERIALS		NO	
WORK GENERATES LARGE QUANTITIES OF DUST AND DEBRIS	YES		
WORK REQUIRES RELOCATING EQUIPMENT TO CORRIDOR		NO	
ASBESTOS			
ODORS WILL BE PRESENT	YES		
CONFINED SPACE ENTRY REQUIRED		NO	
PATIENTS, VISITORS, STAFF WILL HAVE ACCESS TO CONSTRUCTION AREA		NO	
SIGNIFICANT NOISE WILL BE GENERATED	YES		
SIGNIFICANT VIBRATION WILL BE GENERATED	YES		LIMITED DURATIONS
OTHER RISKS			



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NOTES:

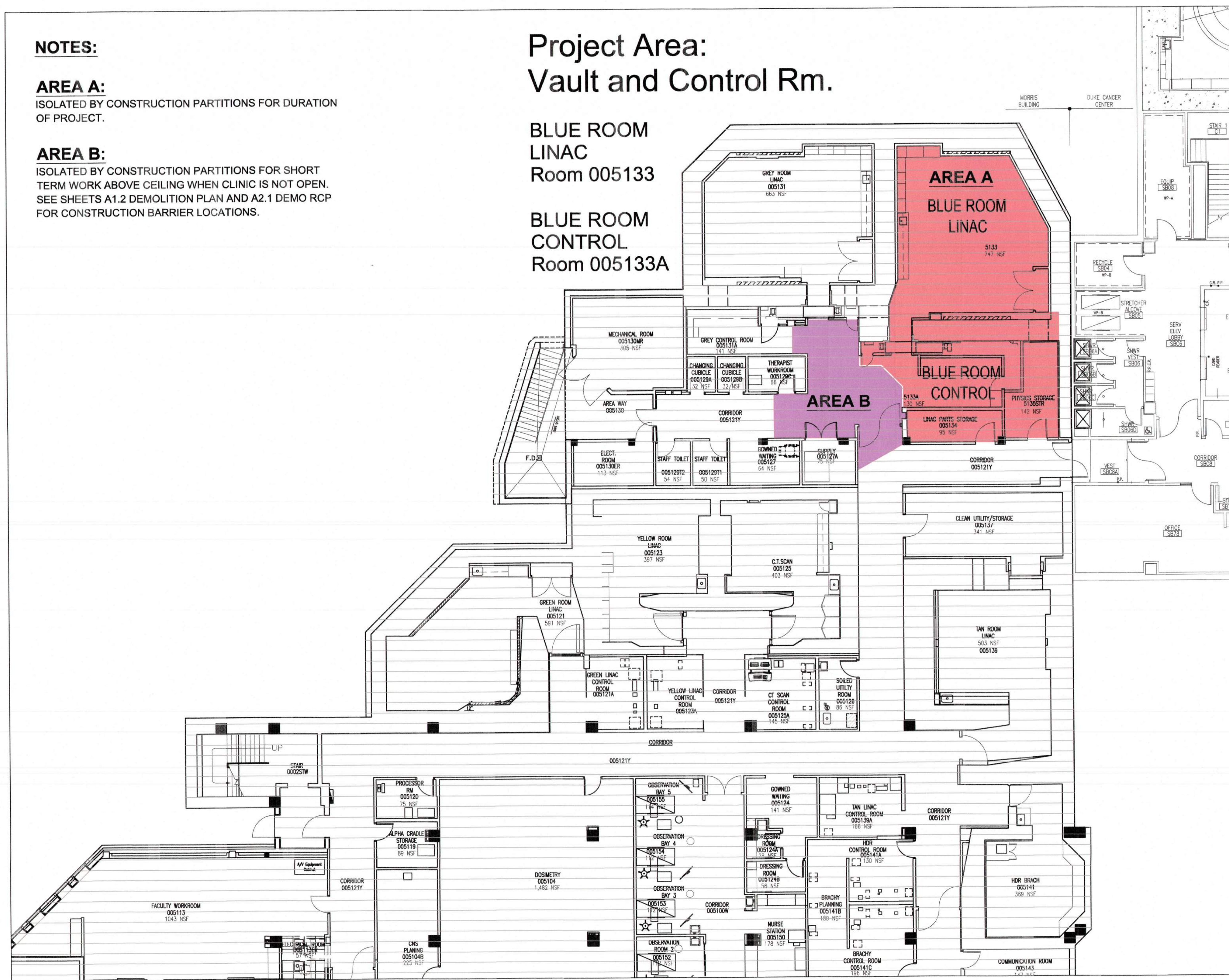
AREA A:
ISOLATED BY CONSTRUCTION PARTITIONS FOR DURATION OF PROJECT.

AREA B:
ISOLATED BY CONSTRUCTION PARTITIONS FOR SHORT TERM WORK ABOVE CEILING WHEN CLINIC IS NOT OPEN. SEE SHEETS A1.2 DEMOLITION PLAN AND A2.1 DEMO RCP FOR CONSTRUCTION BARRIER LOCATIONS.

**Project Area:
Vault and Control Rm.**

**BLUE ROOM
LINAC
Room 005133**

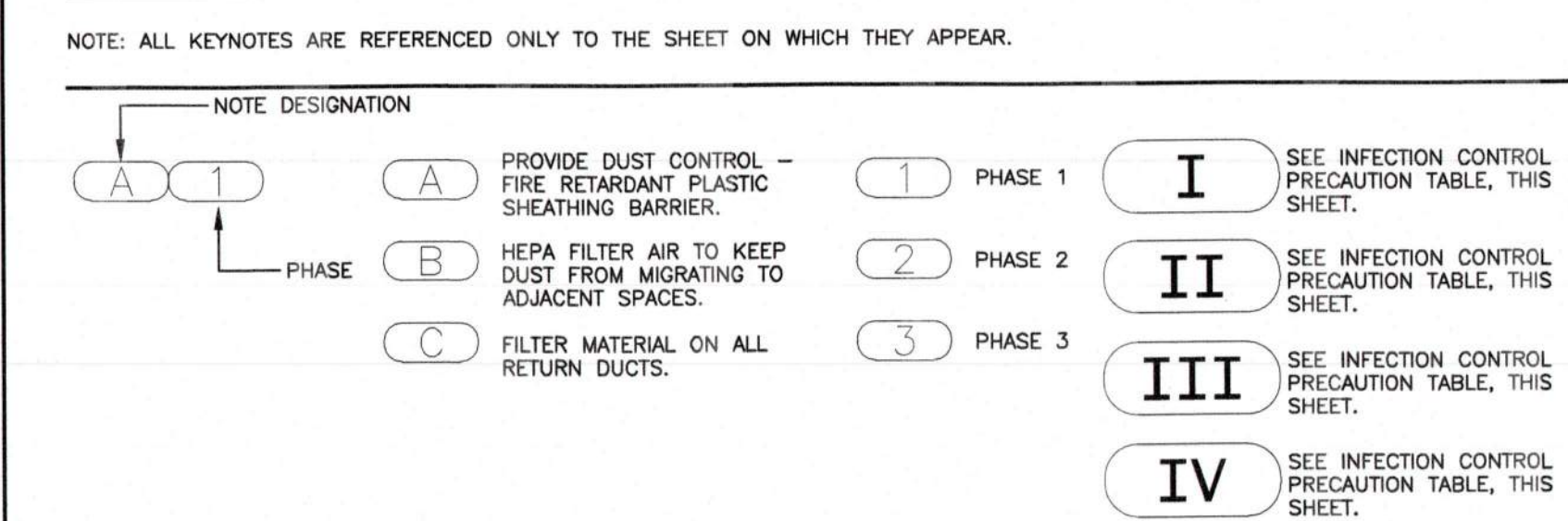
**BLUE ROOM
CONTROL
Room 005133A**



LEGEND PATIENT OCCUPANCY

- LEVEL 1: LOW RISK
- LEVEL 2: MEDIUM RISK
- LEVEL 3: HIGH RISK
- LEVEL 4: HIGHEST RISK

INFECTION CONTROL KEY NOTE SCHEDULE



INFECTION CONTROL PRECAUTIONS BY CLASS

CLASS	DURING CONSTRUCTION PROJECT	AFTER CONSTRUCTION PROJECT
CLASS I	<ol style="list-style-type: none"> EXECUTE WORK BY METHODS TO MINIMIZE RAISING DUST FROM CONSTRUCTION OPERATIONS. IMMEDIATELY REPLACE A CEILING TILE DISPLACED FOR VISUAL INSPECTION. 	
CLASS II	<ol style="list-style-type: none"> PROVIDE ACTIVE MEANS TO PREVENT AIRBORNE DUST FORM DISPERSING INTO ATMOSPHERE. WATER MIST WORK SURFACES TO CONTROL DUST WHILE CUTTING. SEAL UNUSED DOORS WITH DUCT TAPE. BLOCK OFF AND SEAL AIR VENTS. PLACE DUST MAT AT ENTRANCE AND EXIT OF WORK AREA. REMOVE OR ISOLATE HVAC SYSTEM IN AREAS WHERE WORK IS BEING PERFORMED. 	<ol style="list-style-type: none"> WIPE WORK SURFACES WITH DISINFECTANT. CONTAIN CONSTRUCTION WASTE WITH HEPA FILTERED VACUUM BEFORE LEAVING WORK AREA. WET MOP AND/OR VACUUM WITH HEPA FILTERED VACUUM BEFORE LEAVING WORK AREA. REMOVE ISOLATION OF HVAC SYSTEM IN AREAS WHERE WORK IS BEING PERFORMED.
CLASS III	<ol style="list-style-type: none"> REMOVE OR ISOLATE HVAC SYSTEM IN AREA WHERE WORK IS BEING DONE TO PREVENT CONTAMINATION OF DUCT SYSTEM. COMPLETE ALL CRITICAL BARRIERS I.E. SHEET ROCK, PLYWOOD, PLASTIC, TO SEAL AREA FROM NON-WORK AREA OR IMPLEMENT CONTROL CUBE METHOD (CART WITH PLASTIC COVERING AND SEALED CONNECTION TO WORK SITE WITH HEPA VACUUM FOR VACUUMING PRIOR TO EXIT) BEFORE CONSTRUCTION BEGINS. MAINTAIN NEGATIVE AIR PRESSURE WITHIN WORK SITE UTILIZING HEPA EQUIPPED AIR FILTRATION UNITS. CONTAIN CONSTRUCTION WASTE BEFORE TRANSPORT IN TIGHTLY COVERED CONTAINERS. COVER TRANSPORT RECEPTACLES OR CARTS. TAPE COVERING UNLESS SOLID LID. 	<ol style="list-style-type: none"> DO NOT REMOVE BARRIERS FROM WORK AREA UNTIL COMPLETED PROJECT IS INSPECTED BY THE OWNER'S SAFETY DEPARTMENT AND INFECTION CONTROL DEPARTMENT AND THOROUGHLY CLEANED BY THE OWNER'S ENVIRONMENTAL SERVICES DEPARTMENT. REMOVE BARRIER MATERIALS CAREFULLY TO MINIMIZE SPREADING OF DIRT AND DEBRIS ASSOCIATED WITH CONSTRUCTION. VACUUM WORK AREA WITH HEPA FILTERED VACUUMS. WET MOP AREA WITH DISINFECTANT. REMOVE ISOLATION OF HVAC SYSTEM IN AREAS WHERE WORK IS BEING PERFORMED.
CLASS IV	<ol style="list-style-type: none"> ISOLATE HVAC SYSTEM IN AREA WHERE WORK IS BEING DONE TO PREVENT CONTAMINATION OF DUCT SYSTEM. COMPLETE ALL CRITICAL BARRIERS I.E. SHEET ROCK, PLYWOOD, PLASTIC, TO SEAL AREA FROM NON-WORK AREA OR IMPLEMENT CONTROL CUBE METHOD (CART WITH PLASTIC COVERING AND SEALED CONNECTION TO WORK SITE WITH HEPA VACUUM FOR VACUUMING PRIOR TO EXIT) BEFORE CONSTRUCTION BEGINS. MAINTAIN NEGATIVE AIR PRESSURE WITHIN WORK SITE UTILIZING HEPA EQUIPPED AIR FILTRATION UNITS. SEAL HOLES, PIPES, CONDUITS, AND PUNCTURES APPROPRIATELY. CONSTRUCT ANTEROOM AND REQUIRE ALL PERSONNEL TO PASS THROUGH THIS ROOM SO THEY CAN BE VACUUMED USING A HEPA VACUUM CLEANER BEFORE LEAVING WORK SITE OR THEY CAN WEAR CLOTH OR PAPER COVERALLS THAT ARE REMOVABLE EACH TIME THEY LEAVE THE WORK SITE. ALL PERSONNEL ENTERING WORK SITE ARE REQUIRED TO WEAR SHOE COVERS. SHOE COVERS MUST BE CHANGED EACH TIME THE WORKER EXITS THE WORK AREA. DO NOT REMOVE BARRIERS FROM WORK AREA UNTIL COMPLETED PROJECT IS INSPECTED BY THE OWNER'S SAFETY DEPARTMENT AND INFECTION CONTROL DEPARTMENT AND THOROUGHLY CLEANED BY THE OWNER'S ENVIRONMENTAL SERVICES DEPARTMENT. 	<ol style="list-style-type: none"> REMOVE BARRIER MATERIAL CAREFULLY TO MINIMIZE SPREADING OF DIRT AND DEBRIS ASSOCIATED WITH CONSTRUCTION. CONTAIN CONSTRUCTION WASTE BEFORE TRANSPORT IN TIGHTLY COVERED CONTAINERS. COVER TRANSPORT RECEPTACLES OR CARTS. TAPE COVERING UNLESS SOLID LID. VACUUM WORK AREA WITH HEPA FILTERED VACUUMS. WET MOP AREA WITH DISINFECTANT. REMOVE ISOLATION OF HVAC SYSTEM IN AREAS WHERE WORK IS BEING PERFORMED.

CONTRACTOR SHALL OBSERVE THESE PRECAUTIONS. SEE PLAN FOR MORE INFO.

Infection Control Plan
Scale: 1/16" = 1'-0"

Duke Health FPDC # 4195
Blue Vault Linac Replacement
 Morris Building, Duke Cancer Center
 30 Duke Medicine Circle, Durham NC 27710

Infection Control Plan
Risk Assessment

#4195
 Duke Blue Vault Linac
 IHR #19 0028

DATE: 1-6-2021
 REVISIONS:
 ISSUE: Construction Documents
 APPROVED:

SHEET NO.
A0.4

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CERTIFICATE OF NEED

For

Project Identification Number #J-7797-07

FID# 943138

ISSUED TO: Duke University Health System
d/b/a Duke University Hospital
3000 Erwin Road
Durham, NC 27710

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16) e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Duke University Health System d/b/a Duke University Hospital proposes replacement and upgrade of one Varian 2100C Linear Accelerator to a Varian Trilogy Linear Accelerator. The Varian 2100C, from DUH, will be used to replace a 13 year old Linear Accelerator at Durham Regional Hospital/Durham County.

CONDITIONS: See Reverse Side

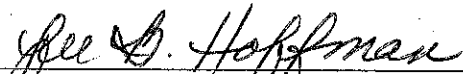
PHYSICAL LOCATION: Duke University Hospital
3000 Erwin Road
Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$ 3,173,855

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 7, 2008

This certificate is effective as of the 28th day of June, 2007.



Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

1. Duke University Health System d/b/a Duke University Hospital shall materially comply with the representations made in its certificate of need application.
2. Duke University Health System d/b/a Duke University Hospital shall not acquire as part of this project, equipment that is not included in the capital expenditure in Section VIII of the application that would otherwise require a certificate of need.
3. Duke University Health System d/b/a Duke University Hospital shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions was received by the Certificate of Need Section on May 30, 2007.

TIMETABLE:

Ordering Equipment -----	July 6, 2007
Arrival of Equipment -----	November 30, 2007
Occupancy/Operation of Equipment -----	January 2, 2008