



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

July 10, 2018

Catharine W. Cummer
3100 Tower Blvd. Suite 1300
Durham, NC 27707

Exempt from Review – Replacement Equipment

Record #: 2639
Facility Name: Duke Regional Hospital
FID #: 923142
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 based on your letter of June 28, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Truebeam/Vitalbeam linear accelerator to replace the Clinac 2100 IX linear accelerator. 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.

Moreover, you need to contact the Agency's Construction, Radiation Protection and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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,

Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and 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: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning



June 28, 2018

Via Electronic Mail

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Ms. Bernetta Thorne-Williams
Project Analyst
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Regional Hospital

Dear Ms. Frisone and Ms. Thorne-Williams:


On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project for a linear accelerator at Duke Regional Hospital and to request the Section's written confirmation that the project is exempt from certificate of need review.

This 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 linear accelerator 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



Ms. Martha Frisone and Ms. Bernetta Thorne-Williams
June 28, 2018

"[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, and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all hospital is located at 3643 North Roxboro Road in Durham. Floor plans for the replacement project and the hospital's license are enclosed.

Previous Certificate of Need

The existing linear accelerator was originally developed at Duke Regional Hospital pursuant to a certificate of need issued for Project J-7797-07, pursuant to which Duke University Hospital received permission to replace an existing linear accelerator and to relocate the existing linear accelerator at Duke Regional Hospital. The Certificate of Need is enclosed.

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 linear accelerators capable of performing radiation oncology procedures. 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 for the proposed new equipment 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).

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

Very truly yours,



Catharine W. Cummer

Enclosures

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

*Effective January 01, 2018, this license is issued to
Duke University Health System, Inc.*

*to operate a hospital known as
Duke Regional Hospital
located in Durham, North Carolina, Durham County.*

*This license is issued subject to the statutes of the
State of North Carolina, is not transferable and shall remain
in effect until amended by the issuing agency.*

Facility ID: 923142

License Number: H0233

Bed Capacity: 369

General Acute 316, Rehabilitation 30, Psych 23,

Dedicated Inpatient Surgical Operating Rooms: 2

Dedicated Ambulatory Surgical Operating Rooms: 0

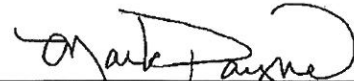
Shared Surgical Operating Rooms: 13

Dedicated Endoscopy Rooms: 4

Authorized by:



Secretary, N.C. Department of Health and
Human Services



Director, Division of Health Service Regulation

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

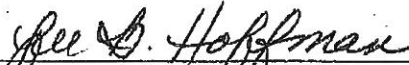
PHYSICAL LOCATION: Duke University Hospital
3000 Erwin Road
Durham, NC 27710

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

EQUIPMENT COMPARISON – Duke Regional Hospital Linear Accelerator

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Therapeutic Linear Accelerator	Therapeutic Linear Accelerator
Manufacturer of Equipment	Varian Medical Systems, Inc.	Varian Medical Systems, Inc.
Tesla Rating for MRIs	NA	NA
Model Number	Clinac 2100 IX	Truebeam/Vitalbeam
Serial Number	2346	
Provider's Method of Identifying Equipment	H272346 (Prod. Code+Ser. No.)	H19xxxx (Prod. Code+Ser. No.)
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	August 2008	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds title	
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>		\$4,743,400
Total Cost of Equipment		\$3,521,625
Fair Market Value of Equipment		\$3,521,625
Net Purchase Price of Equipment	NA (transferred from Duke University Hospital)	
Locations Where Operated	Duke Regional Hospital	
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 therapy treatments	NA
Type of Procedures New Equipment is Capable of Performing	NA	Radiation therapy treatments

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: Duke Regional Hospital – Linear Accelerator Replacement

Provider/Company: Duke University Health System

<i>CON Budget Categories</i>			
A – Site Costs			
1. Full purchase price of land		N/A	
2. Closing Costs		N/A	
3. Site Inspection & Survey		\$-	
4. Legal Fees and Subsoil Investigation		\$-	
5. Site Preparation Costs		\$-	
6. Other (Specify)		\$26,554	
7. Sub-Total Site Costs			\$26,554
B – Construction Contract			
8. Cost of Materials		\$307,061	
9. Cost of Labor		\$460,600	
10. Other (Specify)		\$-	
11. Sub-Total Construction Cost			\$767,661
C – Miscellaneous Project Costs			
12. Building Purchase		N/A	
13. Fixed Equipment Purchase / Lease		\$3,521,625	
14. Moveable Equipment Purchase / Lease		\$29,000	
15. Furniture		\$35,000	
16. Landscaping		\$-	
17. Consultant Fees			
Architect / Engineering Fees	\$204,133		
Administrative & Legal Fees	\$-		
Market Analysis	\$-		
Other (Specify)	\$-		
Sub-Total Consultant Fees		\$204,133	
18. Financing Costs		\$-	
19. Interest During Construction		\$-	
20. Project Contingency		\$159,427	
21. Sub-Total Miscellaneous Project Costs			\$3,949,185
22. Total Capital Cost of Project (Sum A-C above)			\$ 4,743,400

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

 (Signature of Licensed Architect / Engineer)

 Date

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

 (Signature and Title of Officer Authorized to Represent Provider / Company)

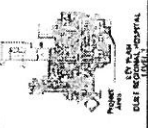
 Date

NOT FOR CONSTRUCTION
 PRELIMINARY



**Duke Regional
 Hospital Linac
 Replacement**

PROJECT NO. 137
 SHEET NO. A101
 DATE: 03.11.2010



NO. DATE DESCRIPTION

137
 03.11.2010
 DEMOLITION PLAN - LEVEL 2

A101

DEMOLITION LEGEND

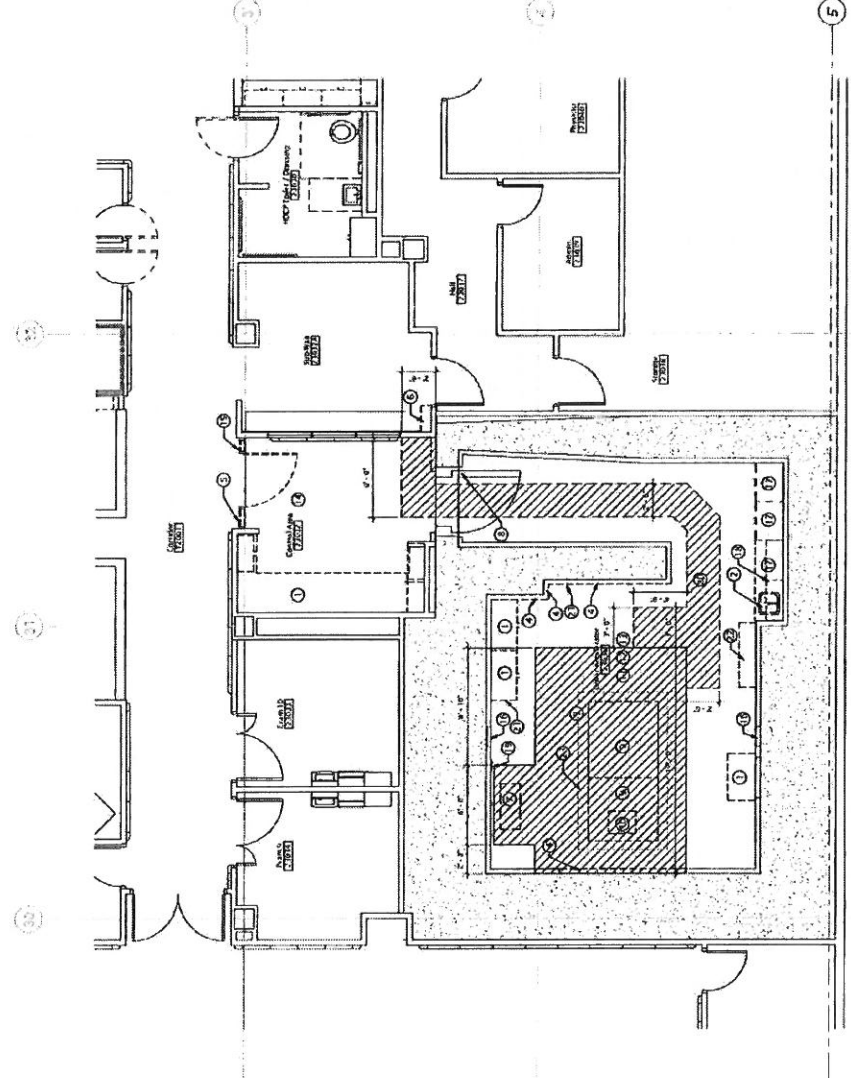
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GENERAL DEMOLITION NOTES

1. ALL EXISTING COMPONENTS ARE TO BE DEMOLISHED AND REMOVED FROM THE PROJECT SITE. THE CONTRACTOR SHALL BE RESPONSIBLE FOR THE PROPER DISPOSAL OF ALL DEMOLISHED MATERIALS IN ACCORDANCE WITH ALL APPLICABLE REGULATIONS AND PERMITS.
2. THE CONTRACTOR SHALL BE RESPONSIBLE FOR THE PROTECTION OF ALL EXISTING UTILITIES AND SERVICES. ALL UTILITIES AND SERVICES TO BE PROTECTED SHALL BE IDENTIFIED AND MARKED PRIOR TO THE START OF DEMOLITION WORK. THE CONTRACTOR SHALL BE RESPONSIBLE FOR THE PROTECTION OF ALL EXISTING UTILITIES AND SERVICES THROUGHOUT THE DEMOLITION PROCESS.
3. ALL EXISTING WALLS TO BE DEMOLISHED SHALL BE DEMOLISHED TO THE FINISH SURFACE. ALL EXISTING WALLS TO REMAIN SHALL BE DEMOLISHED TO THE FINISH SURFACE AND RECONSTRUCTED TO THE FINISH SURFACE.
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KEYED DEMOLITION NOTES

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DEMOLITION PLAN - LEVEL 2
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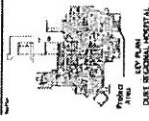
1000 Lakeside Dr.
Durham, NC 27701
704.286.1000
www.rnd.com

NOT FOR CONSTRUCTION
PRELIMINARY



**Duke Regional
Hospital Linac
Replacement**

3000 South Research Road, Durham, NC
27704



Project: LINAC REPLACEMENT
Date: 05/11/2009

Project Number: 1217
Date: 05/11/2009
Author: [Name]
Revision: [Number]
Drawing Title: RENOVATION REFLECTED CEILING PLAN - LEVEL 2

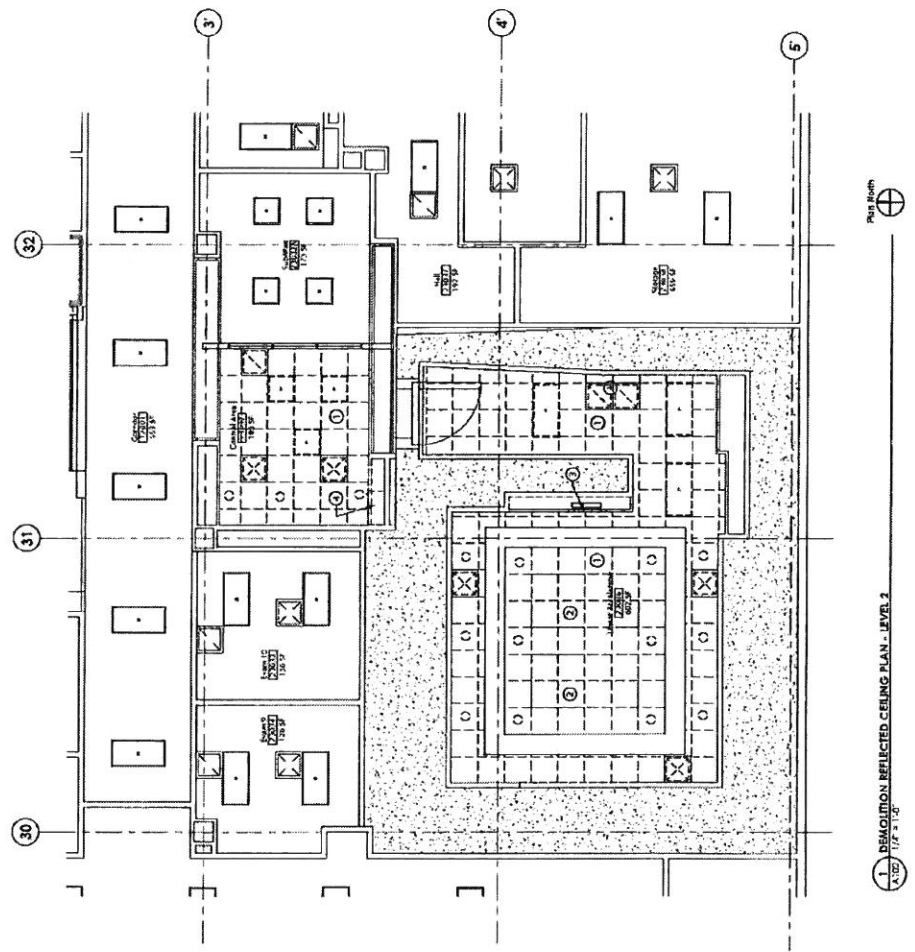
A102

CEILING LEGEND

SYMBOL	DESCRIPTION
[Symbol]	CEILING HEIGHT - A.E.C.
[Symbol]	RECESSED LIGHT FIXTURE
[Symbol]	FLUORESCENT STRIP FIXTURE
[Symbol]	2X2 FLUORESCENT FIXTURE
[Symbol]	2X4 FLUORESCENT FIXTURE
[Symbol]	SUPPLY AIR DIFFUSER
[Symbol]	RETURN AIR DIFFUSER
[Symbol]	EXIT LIGHT
[Symbol]	EMERGENCY LIGHT
[Symbol]	SMOKE DETECTOR
[Symbol]	CONTROL POINT FOR BALANCE
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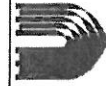


RENOVATION REFLECTED CEILING PLAN - LEVEL 2



REGISTRATION NO. 1379
 PROFESSIONAL ENGINEER
 MECHANICAL, ELECTRICAL, PLUMBING
 2700 W. HARRIS BLVD., SUITE 200
 DURHAM, NC 27709
 (919) 486-7200
 WWW.RNDENGINEERS.COM

PRELIMINARY
 NOT FOR CONSTRUCTION



Duke Regional Hospital Linac Replacement

340 South Holden Road Durham, NC 27709
 PROJECT NO. 1379
 DATE: 05.13.19



PROJECT AREA: RCP PLAN - HOSPITAL
 SHEET NO.: RCP-01
 REVISION: 1

DATE: 05.13.19
 DRAWN BY: [Name]
 CHECKED BY: [Name]
 PROJECT: RCP PLAN - HOSPITAL
 SHEET NO.: RCP-01
 REVISION: 1

A202

CEILING LEGEND

SYMBOL	DESCRIPTION
[Symbol]	CEILING HEIGHT - A.G.
[Symbol]	RECESSED LIGHT FIXTURE
[Symbol]	ACROBATIC STEP
[Symbol]	2x4 FLUORESCENT FIXTURE
[Symbol]	2x4 FLUORESCENT FIXTURE
[Symbol]	SUPPLY AIR DIFFUSER
[Symbol]	RETURN AIR DIFFUSER
[Symbol]	EXIT LIGHT
[Symbol]	EXIT SIGN LIGHT
[Symbol]	SMOKE DETECTOR
[Symbol]	CEILING SPEAKER
[Symbol]	COMPUTER MONITOR
[Symbol]	RECEPTACLE
[Symbol]	A/C CEILING
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NOTE: COORDINATE WITH M.P.S. 1.0
 FOR ALL CEILING DEMONSTRATIONS. FOR
 DEMONSTRATIONS, SEE M.P.S. 1.0 FOR
 DEMONSTRATION SYMBOLS AND CEILING PLAN
 DEMONSTRATIONS FOR LOCATION ONLY - FINAL.

RCP KEYED RENO NOTES

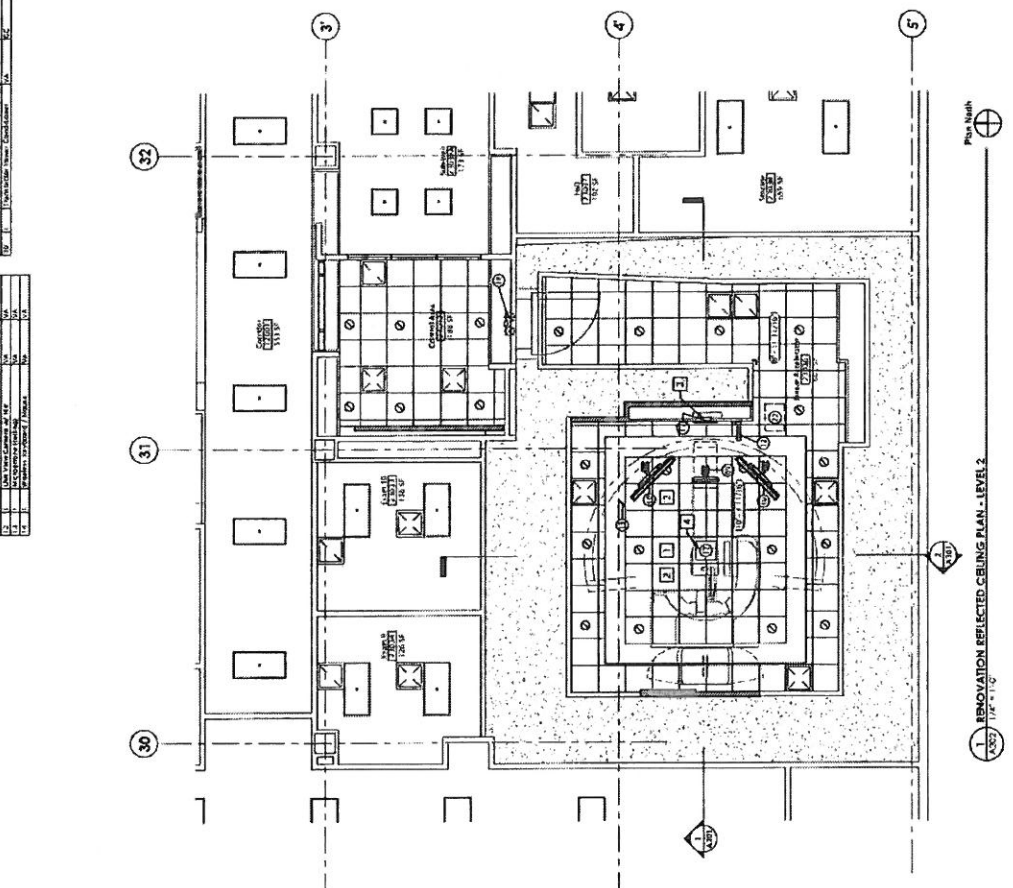
NO.	NOTE
1	SEE KEYED RENO PLAN FOR DEMONSTRATIONS.
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VARIAN COMPONENTS

Item	Description	Quantity	Installed by
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VARIAN COMPONENTS

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1 RENOVATION REFLECTED CEILING PLAN - LEVEL 2
 (REV. 05.13.19)



**Duke Regional
 Hospital Linac
 Replacement**

PROJECT LOCATION
 400 PEARL
 DISEASE CONTROL
 SYSTEMS

No.	Date	Description
1	01.11.2011	Issue for RFI
2	02.01.2011	Issue for RFI
3	02.01.2011	Issue for RFI
4	02.01.2011	Issue for RFI
5	02.01.2011	Issue for RFI
6	02.01.2011	Issue for RFI
7	02.01.2011	Issue for RFI
8	02.01.2011	Issue for RFI
9	02.01.2011	Issue for RFI
10	02.01.2011	Issue for RFI
11	02.01.2011	Issue for RFI
12	02.01.2011	Issue for RFI
13	02.01.2011	Issue for RFI
14	02.01.2011	Issue for RFI
15	02.01.2011	Issue for RFI
16	02.01.2011	Issue for RFI
17	02.01.2011	Issue for RFI
18	02.01.2011	Issue for RFI
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25	02.01.2011	Issue for RFI
26	02.01.2011	Issue for RFI
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28	02.01.2011	Issue for RFI
29	02.01.2011	Issue for RFI
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31	02.01.2011	Issue for RFI
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47	02.01.2011	Issue for RFI
48	02.01.2011	Issue for RFI
49	02.01.2011	Issue for RFI
50	02.01.2011	Issue for RFI

PROJECT NUMBER: 1177
 SHEET NO.: 011.001
 DATE: 01.11.2011

BUILDING & DETAIL SECTIONS

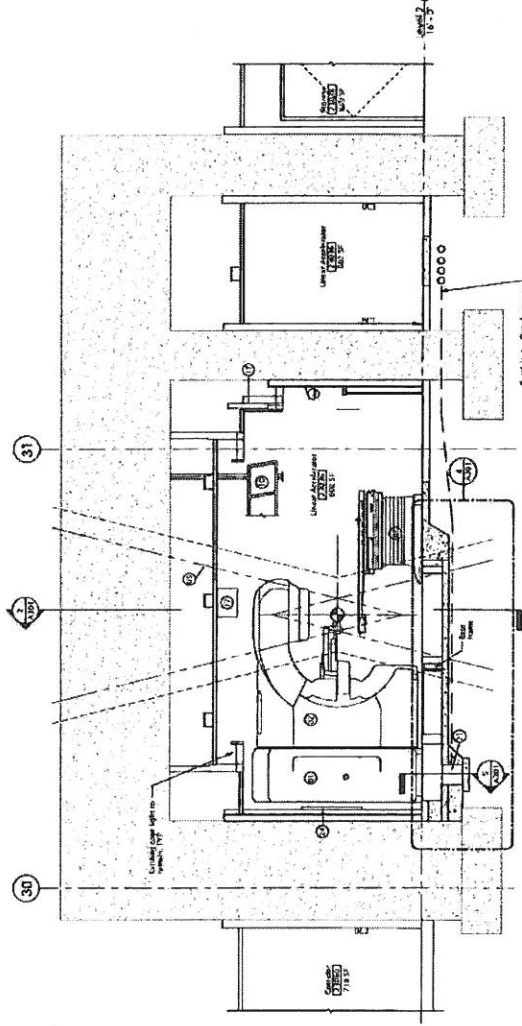
A301

① VARIAN COMPONENTS

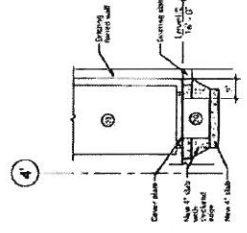
Item	Brand	Description	Quantity	Notes
1	Varian	Linear Accelerator	1	
2	Varian	Beam Stop	1	
3	Varian	Beam Flattening Filter	1	
4	Varian	Beam Defining Filter	1	
5	Varian	Beam Modulator	1	
6	Varian	Beam Transport System	1	
7	Varian	Beam Monitor	1	
8	Varian	Beam Positioning System	1	
9	Varian	Beam Collimator	1	
10	Varian	Beam Filter	1	
11	Varian	Beam Shield	1	
12	Varian	Beam Support Structure	1	
13	Varian	Beam Control System	1	
14	Varian	Beam Safety System	1	
15	Varian	Beam Interlock System	1	
16	Varian	Beam Diagnostic System	1	
17	Varian	Beam Maintenance System	1	
18	Varian	Beam Calibration System	1	
19	Varian	Beam Alignment System	1	
20	Varian	Beam Tuning System	1	
21	Varian	Beam Servicing System	1	
22	Varian	Beam Replacement System	1	
23	Varian	Beam Storage System	1	
24	Varian	Beam Transport System	1	
25	Varian	Beam Control System	1	
26	Varian	Beam Safety System	1	
27	Varian	Beam Interlock System	1	
28	Varian	Beam Diagnostic System	1	
29	Varian	Beam Maintenance System	1	
30	Varian	Beam Calibration System	1	
31	Varian	Beam Alignment System	1	
32	Varian	Beam Tuning System	1	
33	Varian	Beam Servicing System	1	
34	Varian	Beam Replacement System	1	
35	Varian	Beam Storage System	1	
36	Varian	Beam Transport System	1	
37	Varian	Beam Control System	1	
38	Varian	Beam Safety System	1	
39	Varian	Beam Interlock System	1	
40	Varian	Beam Diagnostic System	1	
41	Varian	Beam Maintenance System	1	
42	Varian	Beam Calibration System	1	
43	Varian	Beam Alignment System	1	
44	Varian	Beam Tuning System	1	
45	Varian	Beam Servicing System	1	
46	Varian	Beam Replacement System	1	
47	Varian	Beam Storage System	1	
48	Varian	Beam Transport System	1	
49	Varian	Beam Control System	1	
50	Varian	Beam Safety System	1	

② VARIAN COMPONENTS

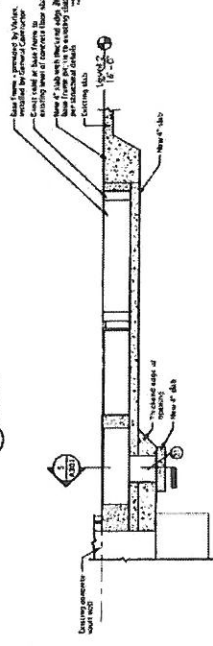
Item	Brand	Description	Quantity	Notes
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50	Varian	Beam Safety System	1	



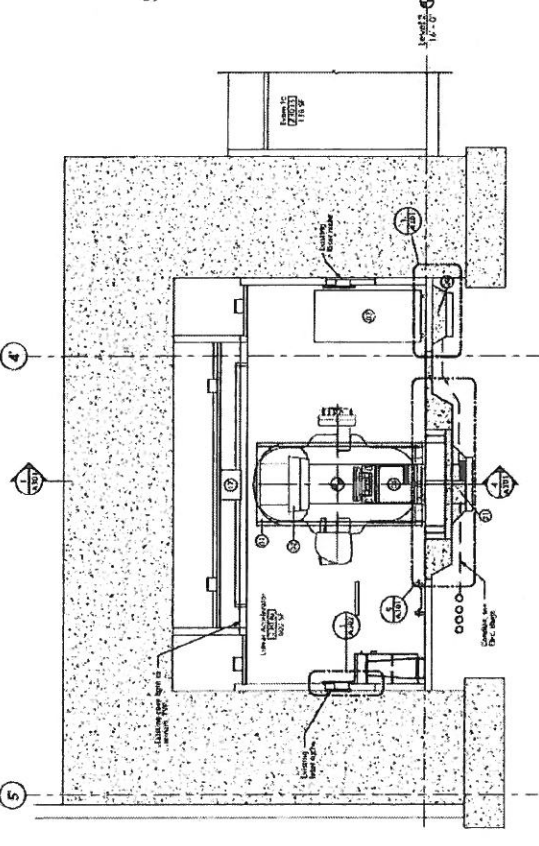
1 Building Section North
 318' x 110'



3 Moving Modulator Pull Box Section Detail
 17 1/2\" x 11\"



4 Knee Plate Section Detail North
 5' x 4'



2 Building Section West
 318' x 110'

5 Knee Plate Section Detail West
 5' x 4'