



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

February 21, 2019

Jeffrey Shovelin
Vidant Health
PO Box 6028
Greenville, NC 27835-6028

Exempt from Review – Replacement Equipment

Record #: 2887
Facility Name: The Outer Banks Hospital Cancer Center
FID #: 170277
Business Name: The Outer Banks Hospital, Inc.
Business #: 1822
Project Description: Replace existing CT simulator with the existing CT scanner currently located in the hospital and relocate it to the new cancer center where it will become a CT simulator and back-up CT scanner as needed
County: Dare

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of & (Date, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need a new GE Revolution EVO diagnostic CT scanner to replace the GE 64-Slice LightSpeed VCT CT. 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 Section, Radiation Protection, Construction Section and Acute and Home Care Licensure and Certification Section 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,

Handwritten signature of Jane Rhoe-Jones
Jane Rhoe-Jones
Project Analyst

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

cc: Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, 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
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

rhoe-jones, jane e

From: Shovelin, Jeffrey <JShoveli@vidanthealth.com>
Sent: Tuesday, January 29, 2019 11:25 AM
To: rhoe-jones, jane e
Subject: RE: [External] Heads Up on Letters Sent Today

Follow Up Flag: Follow up
Due By: Monday, February 04, 2019 1:00 PM
Flag Status: Flagged

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Thank you!!!!

From: rhoe-jones, jane e [mailto:jane.rhoe-jones@dhhs.nc.gov]
Sent: Tuesday, January 29, 2019 11:25 AM
To: Shovelin, Jeffrey <JShoveli@vidanthealth.com>
Subject: RE: [External] Heads Up on Letters Sent Today

CAUTION: This email message originated from outside of Vidant Health.

Hi Jeff,
I will get to the letters as soon as possible (hopefully by the end of next week).

Jane

From: Shovelin, Jeffrey [mailto:JShoveli@vidanthealth.com]
Sent: Wednesday, January 23, 2019 10:48 AM
To: rhoe-jones, jane e <jane.rhoe-jones@dhhs.nc.gov>
Subject: [External] Heads Up on Letters Sent Today

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to fedoffspam@nc.gov

Jane,

I hope all is going well with you.

I just want to give you a heads up on two letters that are being FedExed today and should arrive tomorrow. Even though there are two separate letters, they are somewhat connected. The Outer Banks Hospital has run into an issue while trying to relocate their existing CT simulator to complete their linear accelerator replacement project. The machine is essentially a paper weight because there was a major hardware and disk drive failure experienced just prior to relocation. The unit is so old, they no longer make or support these parts. To address this issue, I am sending you two letters. The first is a material compliance letter to relocate the hospital's existing CT from the hospital to the radiation treatment center. This letter probably needs to be reviewed/approved first before the second, an exempt from CON letter for adding a new CT scanner to the hospital, can be reviewed/approved. Since we can't seem to anything the easy

way, I am just giving you a heads up. The letters should be self-explanatory, but feel free to contact me if you have questions, concerns or need additional information.

If possible, could these letters be reviewed at pretty quickly? They system failure of the CT simulator was unexpected and leaves OBH using the hospital's CT scanner for simulation services. Not the ideal location. The quicker they can solve the issue, the better it will be for their cancer patients. Anything you could do would be very much appreciated, but I understand if your current workload prevents it.

Thank you!

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January 22, 2019

Ms. Jane Rhoe-Jones
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Request for Material Compliance / Project I.D. # ^BQ-11358-17 / The Outer Banks Hospital Cancer Center / Replace existing linear accelerator and relocate it to a new building across the street from the existing hospital / Dare County / FID #170277 *jrj 2/11/2019*

Dear Ms. Rhoe-Jones:

The Other Banks Hospital, Inc. d/b/a Outer Banks Hospital Cancer Center (hereinafter OBH) was awarded a Certificate of Need (CON) on September 27, 2017 to replace an existing linear accelerator and relocate it to a new building across the street from the existing hospital (certificate attached). The project was originally proposed to also include “the relocation of certain pieces of existing minor equipment, including a CT simulator” (page 27 of the CON). However, prior to the relocation process, the CT simulator (GE Hi-Speed CT) located at the former radiation therapy center had a hardware and disk drive malfunction, rendering the equipment inoperable. The CT simulator was produced in 1997 and has been adequately maintained, with major components replaced as needed throughout the service life of the unit. However, given the age of the unit, the defective computer hardware and disk drive components are no longer being produced. GE service representatives were unsuccessful in locating the needed components during repair efforts, and as such, has recommended the existing unit not be relocated to the new radiation therapy center.

To address this issue and remain materially compliant with the representations made in the CON, OBH is now planning to relocate an existing diagnostic GE 64-Slice LightSpeed VCT CT unit (serial number 1428208) from the main hospital and place it in the new radiation therapy building located across the street from the hospital. The CT unit was originally installed in 2009 through a replacement exemption filed in January 2009 (approval letters attached). OBH intends to operate the CT unit as both a diagnostic CT for non-radiation therapy patients as it currently is today, as well as provide the needed CT simulator functions to support radiation oncology services.

As stated on page 27 of the original CON application, the new center across the street from the hospital will be operated as a hospital based service under OBH's acute care hospital license, but doing business as The Outer Banks Hospital Cancer Center. OBH will **not** separately operate it as a freestanding radiation oncology center. Therefore, at the end of the project, OBH will still have 1 CT simulator and 1 diagnostic CT scanner under its hospital license, even though the two functions will be performed on the same physical unit (see attached site and floor plans).

OBH does not believe that this change represents a material change to the original CON application. At the completion of the proposed project, OBH will still:

1. Replace and relocate an existing linear accelerator.
2. Relocate an existing CT to function as a CT simulator
3. Maintain 1 CON approved diagnostic CT scanner for the hospital
4. Will not have acquired any medical equipment not identified in the original application

The proposed change will have no impact on project time line, utilization, services offered, financials, capital costs, equipment inventory, or staffing as proposed in the original application. Therefore, OBH is requesting a determination of material compliance for the changes noted above. If there are any questions or if you need additional information, please contact me at (252) 847-3631.

Sincerely,



Jeffrey Shovelin
Administrator, Corporate Planning
Vidant Health
PO Box 6028
Greenville, NC 27835-6028
252-847-3631
jshoveli@vidanthhealth.com



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 27, 2017

Jeffrey Shovelin
P.O. Box 6028
Greenville, NC 27835

Transmittal of Certificate of Need

Project ID #: R-11358-17
Facility: The Outer Banks Hospital Cancer Center
Project Description: Replace existing linear accelerator and relocate it to a new building across the street from the existing hospital
County: Dare
FID #: 170277

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) is happy to transmit your certificate of need for the above referenced project. At this time, you should contact the Agency's Acute and Home Care Licensure and Certification Section, the Construction Section and the Radiation Protection Section regarding their procedures and requirements for the development of this project. This office will notify the appropriate Sections that the certificate of need has been issued. However, please note that it is the responsibility of the holder of the certificate of need to contact these Sections concerning the next steps to follow in the development of the approved project.

Please be aware that pursuant to N.C. Gen. Stat. §131E-181(b), you are required to materially comply with the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need. **If you subsequently propose to develop the project on a site different from that named on this certificate, you must first seek and obtain approval from the Agency.** If you operate a service which materially differs from the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need, including any increase in per diem reimbursement rates/charges, the Agency may bring remedial action against the holder of the certificate of need pursuant to N.C. Gen. Stat. §131E-189 and 131E-190.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE: 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



The holder of a certificate of need is obligated to submit progress reports to this office as required by 10A NCAC 14C .0209. The applicant shall notify this office of any variations from the schedule or the projected capital cost of the project. During the development of the project, this office may request any additional information pertinent to the project, including additional progress reports, to determine:

- 1) If the timetable specified on the certificate is being met;
- 2) If the amount of the capital expenditure for the development of the project is expected to exceed the maximum amount under the certificate;
- 3) If the terms and conditions of the approval are being met; and
- 4) If the project is progressing as proposed in the application.

The first progress report on this project is due March 1, 2018. Forms for the submittal of these reports are enclosed. Failure to submit any scheduled or requested progress report in a timely manner may result in the Agency withdrawing the certificate pursuant to N.C. Gen. Stat. §131E-189. If after reviewing the status of the project, the Agency determines that the holder of the certificate is not meeting the timetable and is not making a good faith effort to meet it, the Agency may withdraw the certificate in accordance with N.C. Gen. Stat. §131E-189.

Moreover, please be advised that this Agency may assess a civil penalty not to exceed \$20,000 against any person who violates the terms of a certificate of need which has been issued each time the service provided is in violation of this provision (N.C. Gen. Stat. §131E-190(f)). If for some reason, the holder of a certificate of need determines it necessary to request an increase in a per diem charge or reimbursement rate over that which was stated in the application for the certificate of need, then the holder must first contact the Agency to obtain proper instructions for initiating such a request. The request for the increase will be considered by the Agency pursuant to N.C. Gen. Stat. §131E-181(b).

Please keep us informed of the progress in the development of this project. In the future, address your Progress Reports to Jane Rhoe-Jones, the Project Analyst for your county. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,



Gloria C. Hale
Project Analyst



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

GCH:MJF:mt

Enclosures

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant Healthcare Planning, DHSR
Bennifer Pate, Radiation Protection Section

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

**Project ID #: R-11358-17
FID #: 170277**

**ISSUED TO: The Outer Banks Hospital, Inc.
P.O. Box 6028
Greenville, NC 27835**

Pursuant to N.C. Gen. Stat. §131E-175, 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, as documented by the periodic progress reports required by 10A NCAC 14C .0209. 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: Replace existing linear accelerator and relocate it to a new building across the street from the existing hospital/ Dare County

CONDITIONS: See Reverse Side

**PHYSICAL LOCATION: The Outer Banks Hospital Cancer Center
4923 S. Croatan Highway
Nag's Head, NC 27959**

MAXIMUM CAPITAL EXPENDITURE: \$6,000,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: March 1, 2018

This certificate is effective as of the 23rd day of September, 2017


Martha J. Frisone, Chief

CONDITIONS:

1. The Outer Banks Hospital, Inc. shall materially comply with all representations made in the certificate of need application.
2. The Outer Banks Hospital, Inc. shall acquire no more than one linear accelerator to replace one existing linear accelerator being relocated to a new site for The Outer Banks Hospital Cancer Center. The applicant shall dispose of the existing linear accelerator being replaced by removing it from North Carolina.
3. The Outer Banks Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
4. The Outer Banks Hospital, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
5. The Outer Banks Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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 stated in the conditional approval letter was received by the Agency on September 21, 2017.

TIMETABLE:

- | | |
|--|-------------------|
| 1. Construction/Renovation Contract(s) Executed | July 1, 2018 |
| 2. 25% of Construction/Renovation Completed
(25% of the cost is in place) | September 1, 2018 |
| 3. 50% of Construction/Renovation Completed | November 1, 2018 |
| 4. 75% of Construction/Renovation Completed | January 1, 2019 |
| 5. Construction/Renovation Completed | March 1, 2019 |
| 6. Equipment Operational | May 1, 2019 |
| 7. Services Offered | May 1, 2019 |



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North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

January 30, 2009

Sue Collier, RN, MSN
Vice President, UHS Planning & Strategic Development
University Health Systems of Eastern Carolina
P.O. Box 6028
Greenville, NC 27835-6028

RE: No Review / The Outer Banks Hospital / Replace one Toshiba Asteion MultiSlice CT Scanner model # TSX-021A with one GE 64-Slice LightSpeed VCT CT Scanner / Dare County
FID #980550

Dear Sue Collier:

The Certificate of Need (CON) Section received your letter dated December 8, 2008 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Construction Section and Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

Bernetta Thorne-Williams
Bernetta Thorne-Williams, Project Analyst

Lee B. Hoffman
Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR



December 8, 2008

Mr. Gene DePorter, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Request for "No Review" for Replacement CT Scanner at The Outer Banks Hospital

Dear Mr. DePorter:

The Outer Banks Hospital (TOBH) plans to replace the one existing CT Scanner with a new unit. TOBH believes that the proposed equipment replacement is not subject to review under North Carolina's Certificate of Need (CON) laws.

The proposed project includes the replacement of one (1) Toshiba Asteion MultiSlice CT Scanner with one (1) GE 64-Slice LightSpeed VCT CT Scanner. The equipment will be secured through a capital purchase (see Appendix A for vendor quotes and Appendix D for equipment comparison table and brochure). The hospital must complete minor renovations (i.e. shielding and electrical work) to accommodate the new CT scanner in the existing CT room. The hospital plans to use a mobile CT scanner during the four months needed to complete renovations and install the new scanner so that the hospital has access at all times to one CT scanner. The total capital costs for the proposed replacement equal \$ 1,536,685 (see Appendix B for the Capital Cost Sheet). These costs include all expenses associated with equipment and options purchase, construction, and mobile CT coverage. The mobile CT unit will be removed once the replacement is complete. Appendix C contains a site plan showing the location of the existing equipment location and construction work area. After the new CT scanner is operational, the existing equipment will be permanently removed from TOBH and will no longer be exempt from CON law (see Appendix E for required documentation of equipment removal).

TOBH's proposed project meets the definition of replacement equipment found in G.S. 131-E-176(22a). The total capital expenditure for the equipment is less than \$2,000,000 and the equipment being purchased is for the sole purpose of replacing comparable medical equipment. We believe that TOBH's proposal meets the definition of "replacement equipment" and thereby eliminates this project from the requirements for "major medical equipment" or a "new institutional health service." TOBH requests approval of a no review status for the proposed project as soon as possible. The hospital must have the replacement scanner operational no later than May 2009 to accommodate the anticipated increase in demand during the summer months.

If you require additional information or clarification, please contact me at 252.847.2222 or scollier@pcmh.com.

Sincerely,



Sue Collier, RN, MSN
Vice President, UHS Planning & Strategic Development

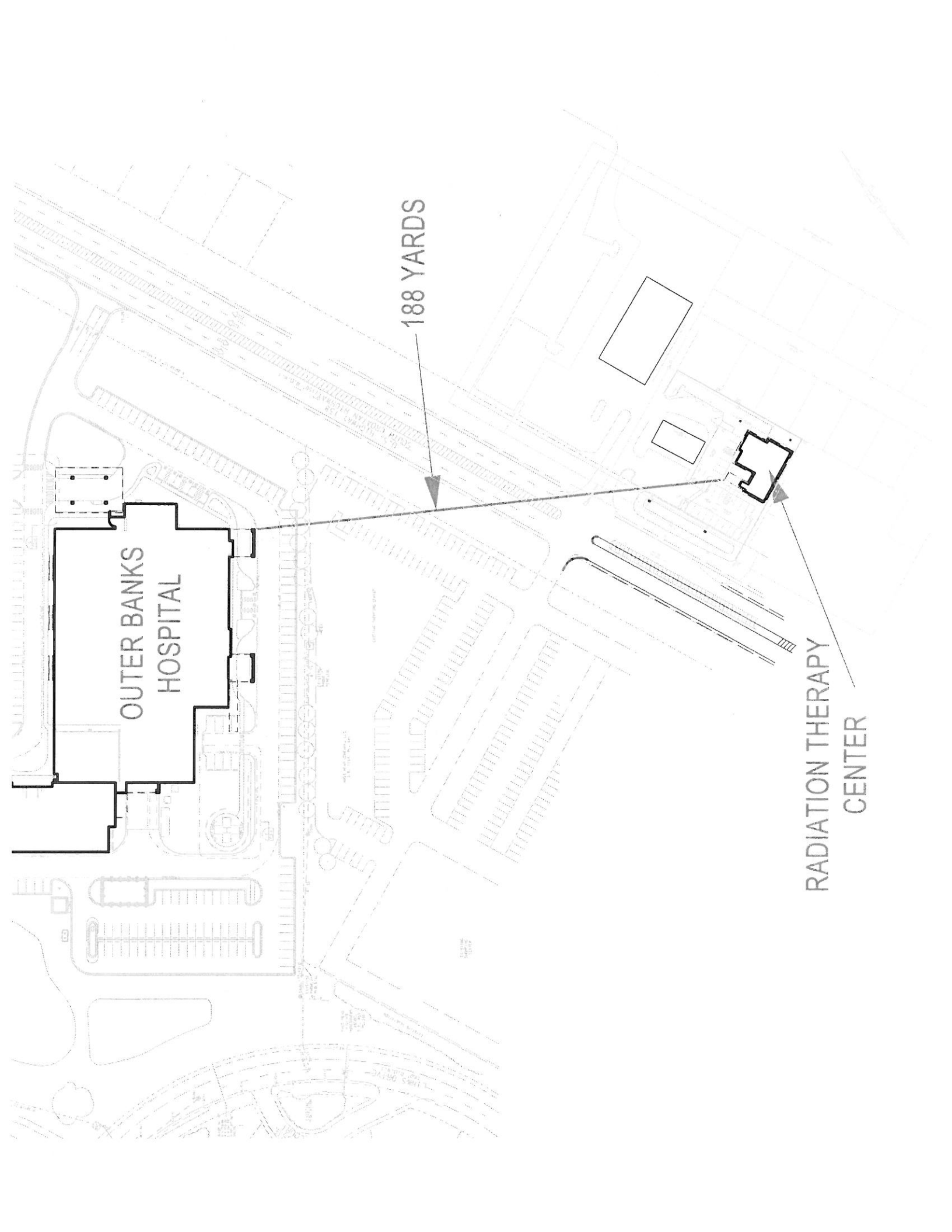
cc: Van Smith, President, TOBH
Belita Rock, Radiology Manager, TOBH
Sandra Sackrison, Administrator, Radiology, UHS
Tim McDonnell, Chief Design & Construction Officer, UHS

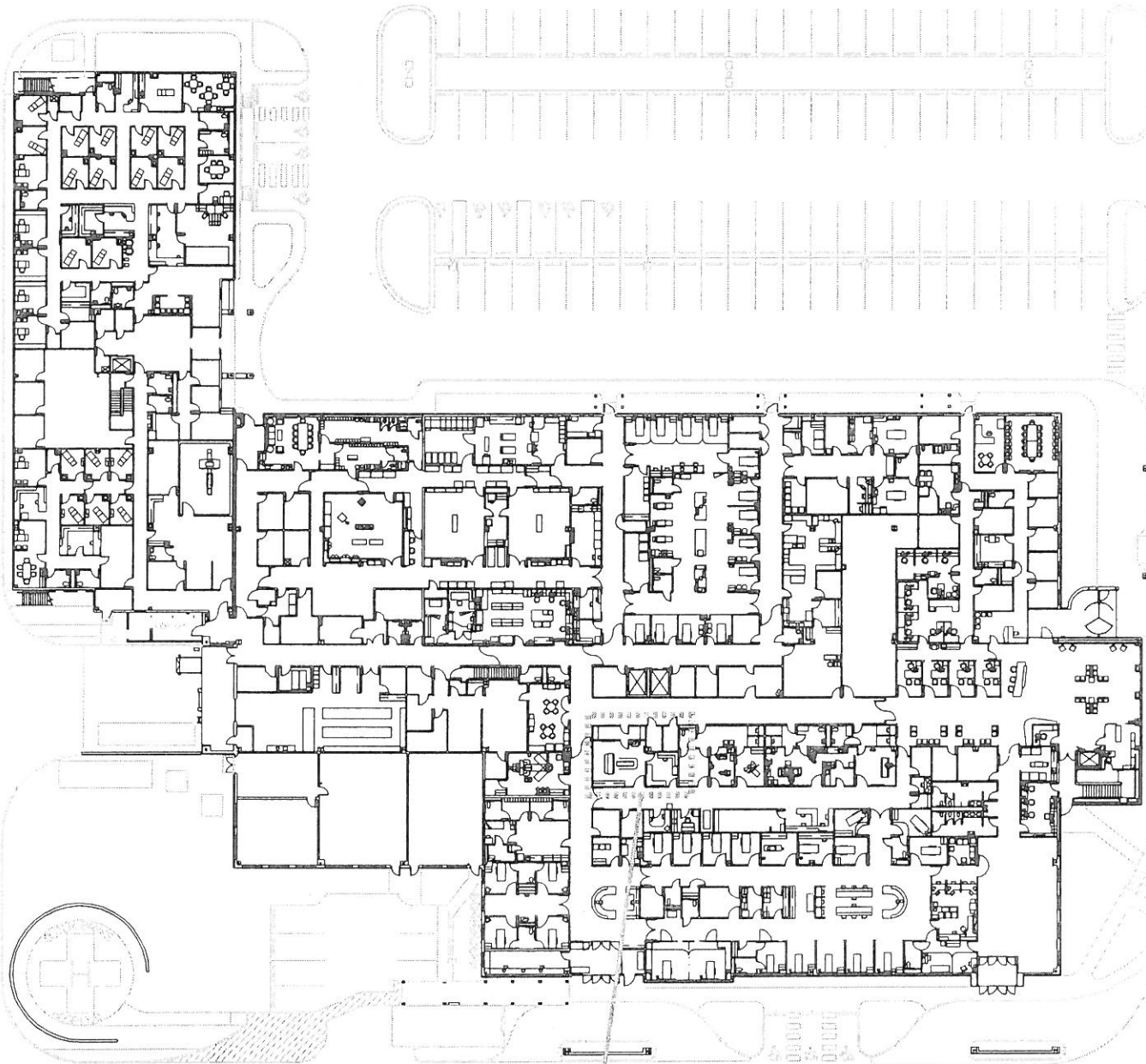
TOBH Request for No Review
Replacement CT Scanner
December 8, 2008

OUTER BANKS
HOSPITAL

188 YARDS

RADIATION THERAPY
CENTER





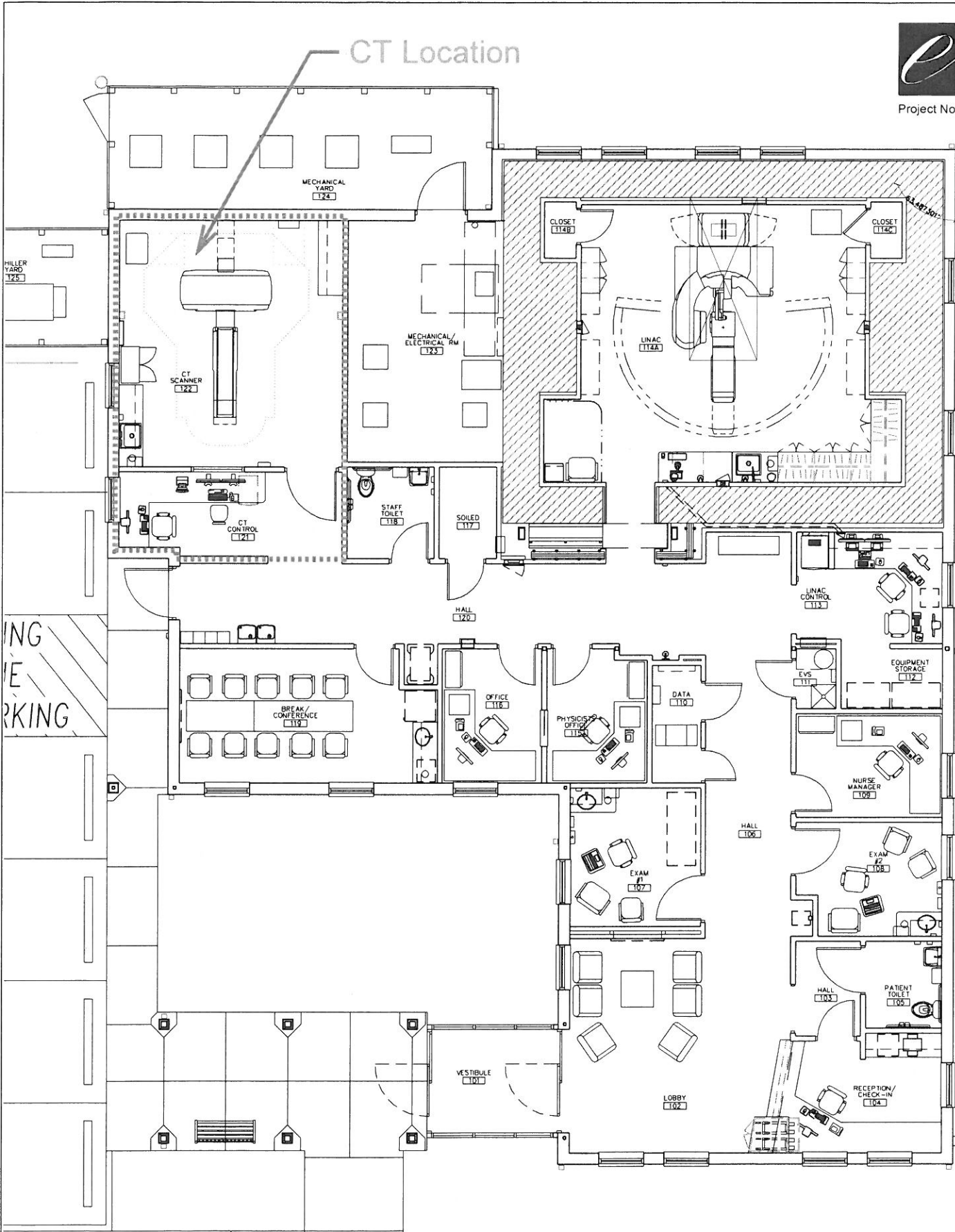
Replacement of existing
CT equipment

The Outer Banks Hospital Floor Plan

January 15, 2019



CT Location



Radiation Therapy Center
The Outer Banks Hospital

Floor Plan

January 15, 2019

