



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

April 25, 2022

Tim Ludwig
tludwig@carolinaeasthealth.com

Exempt from Review – Replacement Equipment
Record #: 3873

Date of Request: April 8, 2022
Facility Name: CarolinaEast Medical Center
FID #: 923126
Business Name: CarolinaEast Health System
Business #: 2722
Project Description: Replace and relocate existing electrophysiology laboratory on main campus
County: Craven

Dear Mr. Ludwig:

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 Philips Azurion 7M12 electrophysiology laboratory to replace the Philips Allura Xper FD10F electrophysiology laboratory. 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 Gregory F. Yakaboski]

Gregory F. Yakaboski
Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: 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

From: [Timothy Ludwig](#)
To: [Yakaboski, Greg](#)
Subject: RE: [External] CON report
Date: Wednesday, April 13, 2022 2:31:16 PM
Attachments: [image001.jpg](#)

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

As part of the purchase of the new equipment, the current EP equipment will be traded in to Philips and removed from our property.

Tim Ludwig
Vice President, Ancillary Services
2000 Neuse Boulevard
New Bern, NC 28561
(252) 633-8999 Phone
(252) 633-8144 Fax
tludwig@carolinaeasthealth.com

CarolinaEast_HealthSystem_Logo2 (3)



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From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Wednesday, April 13, 2022 1:51 PM
To: Timothy Ludwig <TLudwig@carolinaeasthealth.com>
Subject: RE: [External] CON report

Hey Tim,

Your email did address the question I was asking. Thank you.

*******One additional request. We just need a statement that says:

“the existing unit of EP Equipment being replaced 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.”

This statement can be an email.

Thanks,

Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski

Project Analyst

[Division of Health Service Regulation](#), Certificate of Need

[NC Department of Health and Human Services](#)

Help protect your family and neighbors from COVID-19.

[Know the 3 Ws. Wear. Wait. Wash.](#)

#StayStrongNC and get the latest at nc.gov/covid19

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, NC 27699-2704

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From: Timothy Ludwig <TLudwig@carolinaeasthealth.com>

Sent: Wednesday, April 13, 2022 1:39 PM

To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Subject: [External] CON report

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Good afternoon Mr. Yakaboski. I am sorry that I have been hard to connect with, it's been a crazy day.....and an even crazier 2 years.

I hope below is what you need from me, or at least that is my interpretation of what my assistance replayed.

We want to replace our original EP equipment and move it down the hall a few yards. The Current EP Lab system is a Philips Allura Xper FD10F that was installed in Jan of 2007. It was preowned at the time of our purchase and reached End of Life 12/2015 and will be End of Service on 12/2022.

The new systems that we want to install is a Philips Azurion 7M12 .

The new system will have a 12" detector where the current system only has a 10" detector.

New functions that the new system is equipped with include:

DoseWise and Clarity – provides better image quality with reduced x-ray dose

Dose Reporting - Reports sent to PACS post procedure to be a part of the patient medical record

Dose information can we sent directly to NexaDose, which is our hospital wide patient radiation dose archive.

1 Large 58" LCD screen which can allow full control of external sources (hemodynamics, ultrasound, pacemaker programmers) Currently, we have 6 small screens that can only show one source coming into that screen.

Separate UPS so if there is a power failure, we are still able to image to continue the procedure until the generator comes on.

If this is not what you needed please let me know and I will provide whatever you need. Again please accept my apologies for being unavailable earlier today.

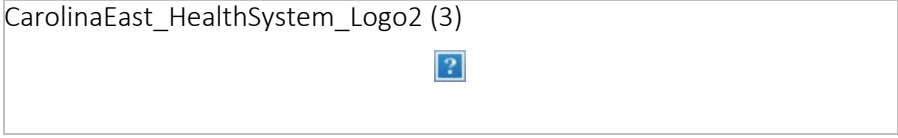
Respectfully, Tim

Tim Ludwig

Vice President, Ancillary Services

2000 Neuse Boulevard

New Bern, NC 28561
(252) 633-8999 Phone
(252) 633-8144 Fax
tludwig@carolinaeasthealth.com



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To: [Yakaboski, Greg](#)
Subject: [External] CON report
Date: Wednesday, April 13, 2022 1:39:00 PM
Attachments: [image001.jpg](#)

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Respectfully, Tim

Tim Ludwig

Vice President, Ancillary Services

2000 Neuse Boulevard

New Bern, NC 28561

(252) 633-8999 Phone

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CarolinaEast
Medical Center

SECU
Comprehensive
Cancer Center
at CarolinaEast
Medical Center

John & Reba Aylward
Diagnostic Center

CarolinaEast
Surgery Center

CarolinaEast
Rehabilitation
Hospital

CarolinaEast
Physicians

CarolinaEast
Foundation

CarolinaEast
Home Care

CarolinaEast
Wound Healing &
Hyperbaric Services

Crossroads
Mental Health

April 7, 2022

**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: Request for Exemption from Review to Replace and Relocate Existing Electrophysiology Laboratory
Facility Name: CarolinaEast Medical Center
FID #: 923126
Business Name: CarolinaEast Health System
Business #: 2722
County: Craven

Dear Ms. Mitchell:

CarolinaEast Medical Center (CEMC) hereby provides this prior written notice of a project that is exempt from Certificate of Need (CON) review. As detailed below, CEMC intends to replace and relocate its existing electrophysiology laboratory (EP lab) located on its main campus. CEMC requests written confirmation that this project, as described in detail below, is exempt from CON review.

The exemption for this replacement equipment project is pursuant to N.C. Gen. Stat. § 131E-184(f), which is referred to as the main campus replacement equipment exemption. The main campus replacement equipment exemption states that “[t]he Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.¹
- (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.”

¹ The “main campus” for purposes of N.C. Gen. Stat. § 131E-184(f) means “[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.” See N.C. Gen. Stat. § 131E-176(14n).

As outlined below, the proposed replacement satisfies the requirements for the main campus replacement equipment exemption set forth under N.C. Gen. Stat. § 131E-184(f) and is therefore exempt from CON review.

Main Campus – N.C. Gen. Stat. § 131E-184(f)(1)

As noted above, the “main campus” of the facility is defined in N.C. Gen. Stat. § 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.” The existing equipment is currently housed on Level 01 of CEMC’s main hospital building located at 2000 Neuse Boulevard, New Bern, North Carolina. This is the site from which CEMC – a licensed health service facility – provides clinical patient services and exercises financial and administrative control over the entire facility. Please see Attachment 1 for line drawings of the first floor of the medical center, which show the location of administration in the lower right corner of the drawings.

As part of this project, CEMC plans not only to replace the existing EP lab equipment, but also to relocate the lab to existing space adjacent to the medical center’s surgical and cardiac catheterization services. As such, this project includes renovations necessary to accommodate the proposed replacement equipment in the existing space. Please see Attachment 1 for line drawings of the first floor of the medical center, which illustrate the current location of the existing equipment and the planned location for the proposed replacement equipment and relocated lab.

Previous CON (If Applicable) – N.C. Gen. Stat. § 131E-184(f)(2)

Relative to specialized cardiac services, CEMC currently operates two units of fixed cardiac catheterization equipment and one unit of dedicated EP equipment. See CEMC’s 2022 Hospital License Renewal Application. CEMC has been approved to acquire a third unit of cardiac catheterization equipment and that project is currently under development. Please note that at the time the existing EP equipment was acquired, a CON was not required. As such, N.C. Gen. Stat. § 131E-184(f)(2) is not applicable in this instance.

Replacement Equipment – N.C. Gen. Stat. § 131E-184(f)(3)

Finally, CEMC, the licensed health service facility that proposes to replace its existing EP lab, provides this correspondence as prior written notice that the acquisition of replacement equipment meets the criteria for exemption outlined in N.C. Gen. Stat. § 131E-184(f). The total project cost exceeds \$2,000,000 reflecting replacement equipment and installation expenses as well as the cost associated with relocating the replacement equipment to space adjacent to the medical center’s surgical and cardiac catheterization services. A copy of the vendor quote for the proposed replacement equipment is available upon request. Please note that CEMC will not acquire any other major medical equipment or develop any other new institutional health services other than those described in N.C. Gen. Stat. § 131E-176(16)(b).

Given the facts outlined above, CEMC maintains that this project is exempt from CON review and requests written confirmation that the proposed replacement of its EP lab (and related renovation/relocation costs as described herein), are exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(f).

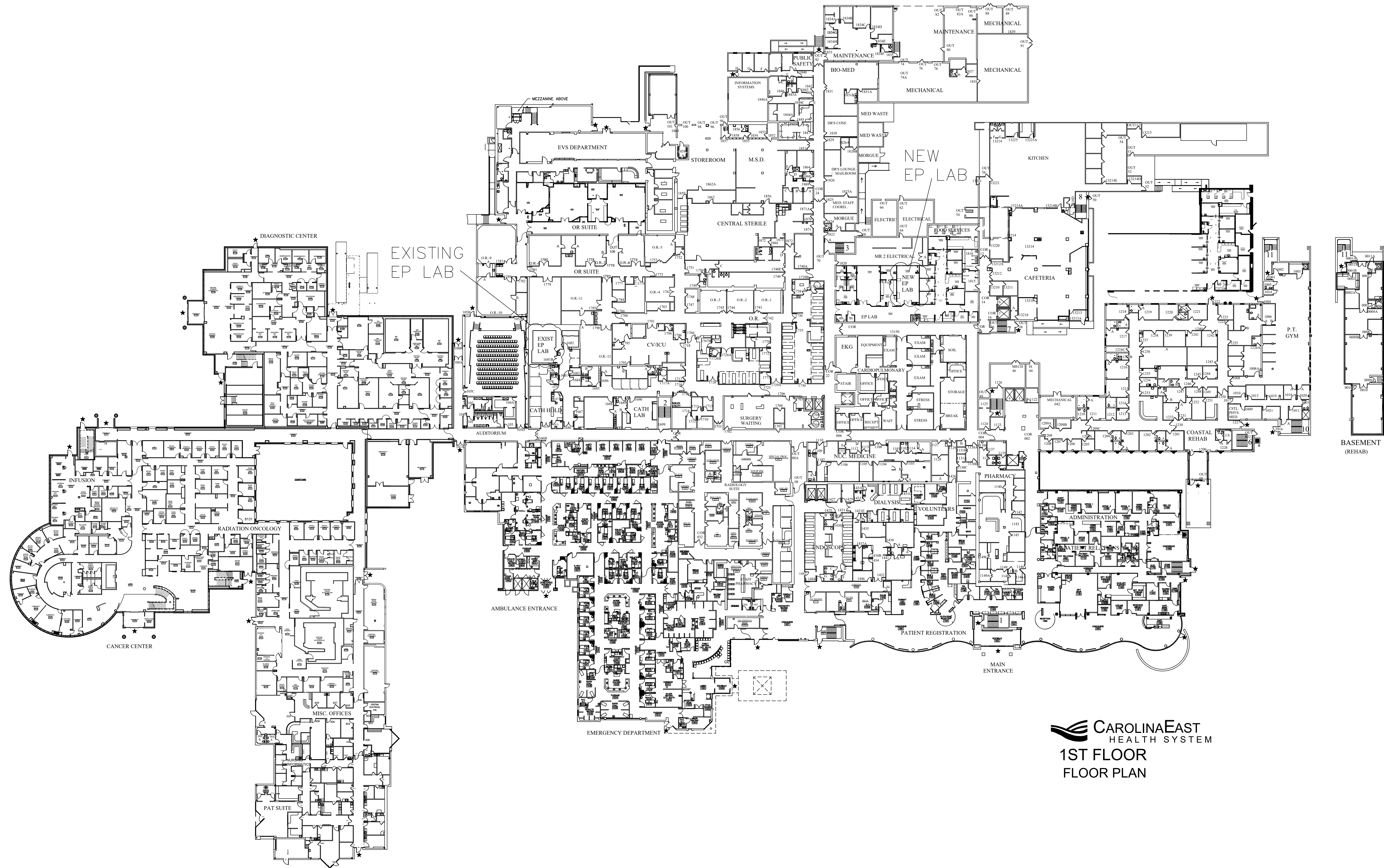
Thank you in advance for your consideration of this request. If you have any additional questions, please do not hesitate to contact me. CEMC hopes to commence work on this project in the near future, so please let me know if I can provide any additional information to expedite our request.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Tim Ludwig', with a long horizontal stroke extending to the right.

Tim Ludwig
Vice President, Ancillary Services
CarolinaEast Health System

Attachment 1



CAROLINA EAST
HEALTH SYSTEM
1ST FLOOR
FLOOR PLAN

REV	DATE	DESCRIPTION	BY	CHK
REV1	REV/DATE1	DESCRIPTION1	BY1	CHK1
REV2	REV/DATE2	DESCRIPTION2	BY2	CHK2
REV3	REV/DATE3	DESCRIPTION3	BY3	CHK3
REV4	REV/DATE4	DESCRIPTION4	BY4	CHK4
REV5	REV/DATE5	DESCRIPTION5	BY5	CHK5
REV6	REV/DATE6	DESCRIPTION6	BY6	CHK6
REV7	REV/DATE7	DESCRIPTION7	BY7	CHK7
REV8	REV/DATE8	DESCRIPTION8	BY8	CHK8
REV9	REV/DATE9	DESCRIPTION9	BY9	CHK9
REV10	REV/DATE10	DESCRIPTION10	BY10	CHK10
REV11	REV/DATE11	DESCRIPTION11	BY11	CHK11

SEA

SEA



CAROLINA EAST
HEALTH SYSTEM

2000 Neuse Boulevard
PO Box 12157
New Bern, NC 28561
252-633-8111

PROJECT NO.	DRAWN BY
PROJECT_NO	DRAWN_BY
PROJECT TITLE	—
	—
	FLOOR PLAN
DRAWING TITLE	—
	—
	FIRST FLOOR PLAN

DRAWING NO.
A-101