



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 19, 2022

Catharine Cummer

Catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3880

Date of Request: April 13, 2022

Facility Name: Duke University Hospital

FID #: 943138

Business Name: Duke University Health System, Inc.

Business #: 640

Project Description: Temporarily replace a clinical CT scanner undergoing maintenance and repair with a CT scanner taken out of service and currently in storage until the clinical CT scanner is repaired

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)(7). Therefore, you may proceed to temporarily replace a clinical CT scanner undergoing maintenance and repair with the Siemens Somatom Definition Flash CT scanner taken out of service pursuant to Exemption #3552 until the clinical CT scanner is repaired. This determination is based on your representations that once the clinical CT scanner is repaired, the Siemens Somatom Definition Flash CT scanner 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,

Kim Meymandi, Project Analyst

Micheala Mitchell, Chief

cc: 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

From: [Waller, Martha K](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Duke University Hospital Temporary Utilization of CT Scanner
Date: Thursday, April 14, 2022 10:38:21 AM
Attachments: [3552 Durham DUH 943138 Exemption \(Updated\).pdf](#)
[LONR 3552 DUH Replace Existing CT Scanner 05.05.21.pdf](#)
Importance: High

From: Catharine Cummer <catharine.cummer@duke.edu>
Sent: Wednesday, April 13, 2022 9:29 AM
To: Meymandi, Kimberly <kim.meymandi@dhhs.nc.gov>; Mckillip, Mike <mike.mckillip@dhhs.nc.gov>
Subject: [External] Duke University Hospital Temporary Utilization of CT Scanner
Importance: High

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Kim and Mike,

I am writing to request confirmation that we can make a temporary replacement of a clinical CT scanner as follows:

As set forth in the attached exemption, as updated, DUH replaced a CT scanner last year. The existing equipment was decommissioned and taken out of service, but remains at Duke University Hospital, essentially in storage. We now face a situation where we have 3 CT scanners out of service and in need of maintenance, including one used for emergency department patients. We would like to put the old equipment back into service as a temporary replacement scanner to ensure our ability to provide uninterrupted patient care. We would take this equipment out of service again upon the completion of repairs on the 3 scanners. At no time will we increase the total number of scanners used for clinical procedures. This will obviate the need to consider a contract for mobile CT services, which would be much more expensive and operationally efficient than the plan we propose.

I believe this is consistent with how we have been permitted to proceed with temporary replacements in the past to address emergency maintenance needs. If you need any further information please let me know. I would appreciate your response at your earliest convenience so we can minimize the disruption of patient care. Thank you very much.

Yours,
Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning, Duke University Health System
(919) 668-0857 (office) | (919) 423-6928 (cell)

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VIA EMAIL ONLY

January 14, 2022

Catharine Cummer

Catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment (UPDATED)

Record #: 3552
Date of Request: April 30, 2021
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing CT scanner
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 Siemens Somatom Force MDCT scanner to replace the Siemens Somatom Definition Flash CT scanner. The replacement equipment will be used exclusively for research purposes initially and will then transition to clinical use upon FDA approval. 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,

Kim Meymandi, Project Analyst

Micheala Mitchell, Chief

cc: Radiation Protection Section, DHSR
Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

From: [Catharine Cumber](#)
To: [Meymandi, Kimberly](#)
Subject: [External] RE: CT replacement
Date: Monday, January 10, 2022 12:06:04 PM
Attachments: [image001.jpg](#)

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Kim,

A little more follow up about the provenance of the existing CT scanner to be taken out of service: DUHS had 5 incremental CT scanners approved in Project ID #J-8030-07 (Major Hospital Addition), and 3 incremental and one replacement scanner approved in the Project ID #J-8275-08 (Cancer Center). To the best of my understanding, the equipment to be replaced is one of the scanners subject to the Cancer Center project. Please let me know if you need a copy of that CON or any other information. Thanks again.

Catharine

Catharine Cumber

Regulatory Counsel, Strategic Planning, Duke University Health System
(919) 668-0857 (office) | (919) 423-6928 (cell)

From: Catharine Cumber <catharine.cumber@duke.edu>

Sent: Monday, January 10, 2022 11:12 AM

To: Kimberly Meymandi <Kim.Meymandi@dhhs.nc.gov>

Subject: Re: CT replacement

Kim,

Thanks very much for your call today. Here are the answers to the questions you raised:

1) The existing equipment to be taken out of service is currently located in the Duke North tower of Duke University Hospital (on the hospital main campus). The new equipment will be implemented as proposed in the original exemption notice, including its specified location on the hospital mail campus. Consistent with the original exemption notice, the existing equipment to be replaced will not be used in North Carolina without further CON approval.
2) I will seek the specific CON number attached to this existing equipment. As I mentioned, Duke has 15 CT scanners on the main hospital campus used for diagnostic imaging (and well as 5 fixed or mobile intraoperative or AIRO scanners). I can attest that all of them, including the existing equipment to be replaced, were acquired either with a CON, pursuant to a replacement exemption, or as equipment that did not meet the cost threshold for major medical equipment, and this project will not change the total inventory, but I will provide you what confirming documentation specific to this scanner I can identify.

Thanks again for your expedited review of this information, and please let me know if you need anything further.

Catharine

Catharine Cumber

Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)

On Jan 7, 2022, at 3:25 PM, Catharine Cummer <catharine.cummer@duke.edu> wrote:
<3552 Durham Duke University Hospital 943138 Exemption(3).pdf>

Kim,

I hope you're doing well. I have learned that in connection with the project described in the attached exemption notice, we have determined that we have a more compelling need to replace the following equipment, rather than the equipment identified in the original notice:

Siemens Somatom Definition Flash CT scanner

Serial Number: 4681

Asset Number: 162455

Install Date: March 2012

Location: DN 1402 C3 DUH- North

Address: 2301 Erwin Rd, Durham, NC 27710

All other aspects of the project remain the same, and the resulting inventory of CT scanners will remain consistent. We therefore believe that the plan continues to meet the requirements of the applicable exemption provision, and would appreciate your confirmation of this. It turns out that this change in plan is somewhat time sensitive so I would really appreciate it if you could let me know as soon as possible if you have any concerns. Thanks very much!

Yours,

Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
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